Instructions For Use

DxU 850m Iris and DxU 840m Iris

CE IVD

PN C49320AB
January 2022

Manufactured by
Beckman Coulter Ireland Inc.
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O'Callaghan's Mills
Co. Clare, Ireland 353-65-683-1100

BECKMAN COULTER | Iris

DxU 850m Iris and DxU 840m Iris
Instructions for Use
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Find us on the World Wide Web at:
www.beckmancoulter.com

Symbols Glossary is available at **www.beckmancoulter.com/techdocs**. See Related Documents for part number.

Rx Only in the U.S.A.

Original Instructions

Revision History

This document applies to the latest software listed and higher versions. When a subsequent software version affects the information in this document, a new issue will be released to the Beckman Coulter website. For labeling updates, go to www.beckmancoulter.com and download the latest version of the manual or system help for your instrument.

Issue AA, September 2021
Software version 8.5

Issue AB, January 2022
Software version 8.5

Note: Changes that are part of the most recent revision are indicated by a change bar in the left margin of the page.

The following sections were modified:

- Added NOTE in How to Use the Operator's Manual in Introduction
- Added DxU Microscopy Series section in CHAPTER 1, System Overview
- Added NOTE in Performance and Operational Characteristics in CHAPTER 1, System Overview
- Added DxU Microscopy Series Analytical Performance Summary section in CHAPTER 1, System Overview

Safety Notice

Read all product manuals and consult with Beckman Coulter-trained personnel before attempting to operate instrument. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your Beckman Coulter Representative.

Alerts for Warning, Caution, Important, and Note

⚠ WARNING

WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.

⚠ CAUTION

CAUTION indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis.

IMPORTANT IMPORTANT is used for comments that add value to the step or procedure being performed. Following the advice in the Important adds benefit to the performance of a piece of equipment or to a process.

NOTE NOTE is used to call attention to notable information that should be followed during installation, use, or servicing of this equipment.

Summary of Warnings and Precautions

⚠ WARNING

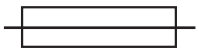
- **For continued protection against risk of fire and hazard, replace only with the same type and rating fuse.**
- **Equipment requires connection to protective earth for safety reasons.**
- **The instrument's main supply inlet is being used as the mains disconnect device.**
- **Use only Iris System Cleanser for the Wash Cycle. Other similar solutions of hypochlorite should not be used because of the risk of particulate contaminants, trace oils or releasing compounds that could cause blockage or damage to the optical window.**

⚠ CAUTION

- **Make sure the barcode labels are properly oriented in the rack. The sample tubes must be placed straight and resting in the middle of the grommets located in the base of the rack.**
- **The instrument should be allowed to warm up for 1 or 2 hours to operating temperature if it was turned off for more than 6 hours.**
- **Do not insert the cotton swab inside the Rinse/Waste Tube; cotton particles may clog the tubing connectors.**
- **Indoor Use Only.**

Symbols

The following is a list of symbols used on the product labeling consumables and the instrument with their meaning.

Symbol	Meaning
	Fuse Identifies a fuse box location and rating. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5016*
 BIOHAZARD	Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Symbol	Meaning
	Caution ISO 7000; 0434A To indicate that caution is necessary when operating the device or control to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesireable consequences.
	Caution ISO 7010: W 001 To signify a general warning.
	Disposal of Electrical Instrumentation It is very important that customer understand and follow all laws regarding the safe and proper disposal of electrical instrumentation. The symbol of a crossed-out wheeled bin on the product is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates: 1. that the device was put on the European Market after August 13, 2005 and 2. that the device is not to be disposed via the municipal waste collection system of any member state of the European Union. For products under the requirement of WEEE directive, please contact your dealer or local Beckman Coulter office for the proper decontamination information and take back program which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of device.
	RoHS Notice These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) are to meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 "Marking for Control of Pollution Caused by Electronic Information Products" requirements.
	China RoHS Caution Label This label indicates that the electronic information product contains certain toxic or hazardous substances. The center number is the Environmentally Friendly Use Period (EFUP) date, and indicates the number of calendar years the product can be in operation. Upon the expiration of the EFUP, the product must be immediately recycled. The circling arrows indicate the product is recyclable. The date code on the label or product indicates the date of manufacture.
	A "CE" mark indicates that a product has been assessed before being placed on the market, and has been found to meet European Union safety, health, and/or environmental protection requirements.

Contents

Illustrations

Tables

Introduction

How to Use the Operator's Manual

This manual is designed for use with the DxU 850m Iris and DxU 840m Iris (DxU Microscopy Series) version 8.5 software or higher version. It is intended for anyone who will operate the system and must have a thorough knowledge of it. It also specifically references information concerning system components, operation, theory, utility, and performance.

This document is the Operator's Manual for the DxU Microscopy Series. It is intended to explain the instrument operations in detail, to be a training guide for new operators and to be a troubleshooting reference resource.

NOTE The iQ200ELITE, iQ200SPRINT, DxU 850m Iris, and DxU 840m Iris are all part of the iQ200 Series. All the instruments have the same design, algorithm, performance, and safety features.

About This Manual

NOTE Screens and hardware depicted in this manual may differ slightly from the screens and hardware in your system configuration.

The information in your Instructions for Use manual is organized as follows:

CHAPTER 1, System Overview
States the instrument's intended use, the control and indicators to be used, information on performance, and information on using the system's software.

CHAPTER 2, Operation Principles
Contains a description of the derivation of parameters and descriptions of the various modules.

CHAPTER 3, Startup
Provides information on how to perform a startup.

CHAPTER 4, Quality Control
Provides information on how to run quality control material.

CHAPTER 5, Sample Analysis
Provides information on specimen collection.

CHAPTER 6, Data Review
Provides information on reviewing and interpreting sample results, including flagged results.

CHAPTER 7, Manual Orders
Provides information on manual orders.

CHAPTER 8, Shutdown
Provides information on shutting down the system.

CHAPTER 9, Setup
Provides information on setting up your system including supplies, operators and roles, flagging and rules, reporting, patient demographics, quality control, and system settings.

CHAPTER 10, Troubleshooting
Describes safety precautions, operational hazards, and troubleshooting guides.

CHAPTER 11, Quality Assurance
Provides an overview of calibration, instructions for precalibration checks, and procedures for calibration.

CHAPTER 12, Cleaning Procedures
Describes when, why, and how to perform cleaning procedures.

CHAPTER 13, Replacement/Adjustment Procedures
Describes when, why, and how to perform adjustment and replacement procedures.

CHAPTER 14, iWARE Expert System
Describes the iWARE Expert System and rule generator systems.

CHAPTER 15, iQ Body Fluids Module
Describes the iQ Body Fluids Module.

CHAPTER 16, Auto-Release (Edit-Free Release)
Describes the auto-release function.

CHAPTER 17, Consumables Traceability
Describes consumables information.

This manual also includes references, appendices, a list of abbreviations and acronyms, a glossary, and an index.

On-board Help

The **Help** button is located in the middle top of the screen and is visible virtually at all times.

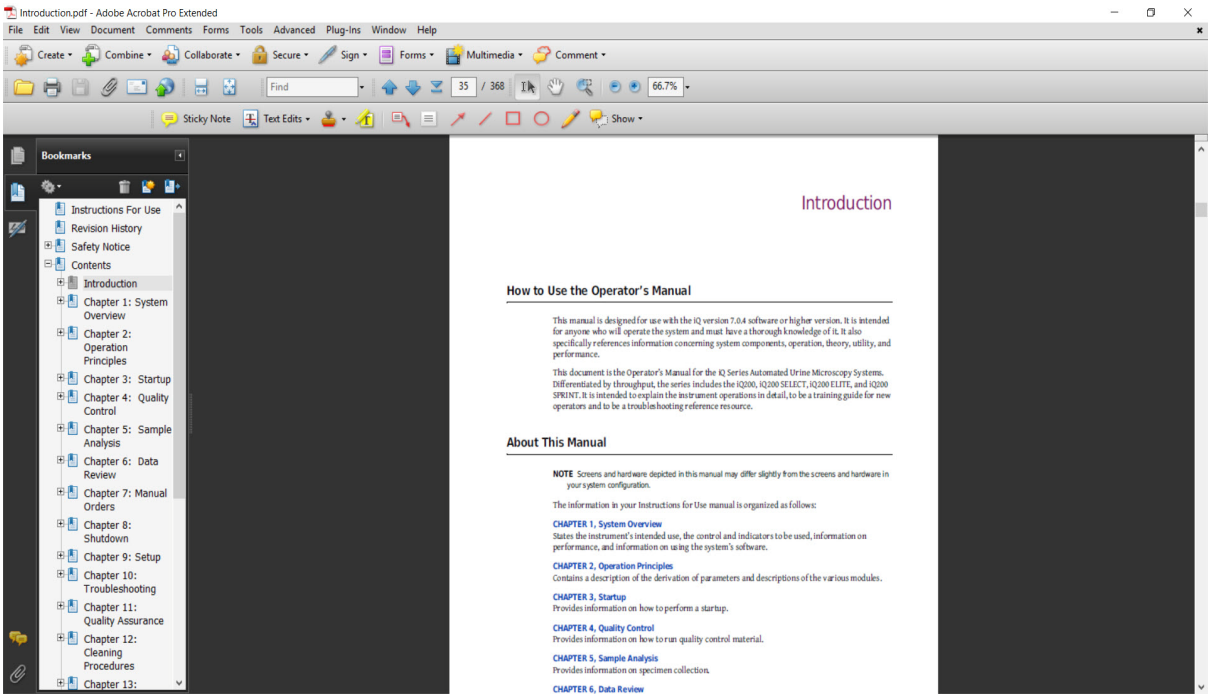
Opening the Help File

1 Select  to display the Operator's Manual. An Open Help File window is displayed.

NOTE HELP feature may also be used to access additional troubleshooting documents on the U drive.

2 Select the file to open according to the desired language.

3 Select **Open**. The selected Operator's Manual is displayed in the side panel IFU tab.



Accessing a Section Using the Bookmark Pane

The Bookmark pane, located on the left side of the screen, can be used as a *linked* table of contents.

Select a bookmark to go automatically to the starting page of the selected section.

- To expand the selection, select + located next to the bookmark.
- To collapse the selection, select - located next to the bookmark.

NOTE For Windows 10, to expand the selection, select > located next to the bookmark, and to collapse the selection, select ∨ located next to the bookmark.

Following a Link Inside the Manual

In order to avoid searching for a specific section, links have been created to jump to other locations and to give immediate access to the related information. Links are indicated by blue text. Example: See Symbols in the Safety Notice.

1 Position the pointer over the linked area on the page until the pointer changes to .

2 Select the link. The destination screen is displayed.

3 To return to the previous section, select **View** > **Go to** > **Previous View**.

NOTE For Windows 10, to return to the previous screen, right-click and select **Previous View**.

Downloading the Operator's Manual to the Instrument

1 Access the Operator's Manual from the Beckman Coulter website: www.beckmancoulter.com

2 From the *Support* tab, select **Search for Technical Documents**.

3 In the *Searched* field, enter the part number of the Operator's Manual.

4 For *Languages*, select the appropriate language.

5 For *Document Categories*, select **Instrument IFU**.

6 Download the manual.

7 Copy the manual to a CD-R.

8 Copy the manual to the desktop or another file location, as appropriate.

Conventions

This manual uses the following conventions:

- **Bold** font indicates buttons on the screen.
- *Italics* font indicates screen text displayed by the system.
- The term *Select* is used to indicate either one or both of the following actions:
  - to tap or touch with your finger
  - to click with a mouse

IMPORTANT IMPORTANT is used for comments that add value to the step or procedure being performed. Following the advice in the IMPORTANT adds benefit to the performance of a piece of equipment or to a process.

NOTE NOTE is used to call attention to notable information that should be followed during use or maintenance of this equipment.

Graphics

All graphics, including screens and printouts, are for illustration purposes only and must not be used for any other purpose.

Side Panel

The Side Panel consists of the following utilities:

- IFU
- Notepad
- Reader
- Videos
- Screen Expand and Collapse Icon

IFU Tab

Use the IFU feature to access onboard IFUs.

- If the system is configured as microscopy only under System Configuration, the microscopy IFU will appear.
- If the system is configured as microscopy and chemistry under System Configuration, the microscopy and the chemistry IFU will be displayed.

1 Select the picture of the instrument to display the associated IFU.

2 Select the IFU tab to close the IFU.

3 Select the Expansion tool to expand or minimize the IFU screen view.

Notepad Tab

Use the Notepad feature to write and save notes and paste images.

1 Select Notepad to display the following options: **New**, **Open**, **Save**, or **Print**.

2 Select **New** and save the contents when prompted.

3 Select **Open** and save the contents when prompted.

4 Select **Save** and save Notepad as a specific file name on the User (U) drive when prompted.

5 Select **Print** and you are directed to all available print utilities.

Reader Tab

Use the Reader feature to access PDFs with informational content. For example, the Image Encyclopedia.

1 Select the Reader tab and the **Open** button is displayed.

2 Select **Open** and the operator is prompted to save in a specific file name on the User (U) drive.

Video Tab

Use the video feature to access onboard videos.

1 Select the **Video** tab and a list of available videos is displayed.

2 Select a video to view.

NOTE Videos can be accessed while the system is processing samples.

Screen Expand and Collapse Icon

The Screen Expand and Collapse Icon is designated by two opposing arrows and is located directly above the Side Panel. Use this icon to expand or minimize the screen view.

Banner

The Banner is located in the lower left section of the instrument screen and consists of five shortcuts for the following applications:

- Windows Explorer
- Virtual Keyboard
- Sticky Notes
- Snipping Tool
- Microsoft Paint

Windows Explorer Shortcut

The Windows Explorer shortcut provides access to User Drive (U) contents.

Virtual Keyboard Shortcut

The Virtual Keyboard shortcut allows access to perform any function that would routinely be done using an external keyboard.

Sticky Notes Shortcut

The Sticky Notes shortcut allows an electronic note to be placed on the instrument screen, which can be seen and used by other operators.

Snipping Tool Shortcut

The Snipping Tool shortcut allows you to highlight and snip information to paste into specific locations.

Follow the steps below to use this tool:

1. Move the cursor to highlight an area or use the graphics icons located at the top of the screen.
2. After the area is highlighted, move the cursor to the Notepad.
3. Select **Paste**.
4. To delete an entry, select the area to delete and press the delete key on the keyboard.

Microsoft Paint Shortcut

Select **PAINT** to cut and paste information or to create graphics that you can place in specific locations.

CHAPTER 1

System Overview

Intended Use

The DxU Microscopy Series is an in-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis. Optionally, the DxU Microscopy Series analyzers can be used as stand-alone units, or the results from the DxU Microscopy Series analyzers can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

Workcell Connections

The DxU Microscopy Series analyzers are in-vitro diagnostic devices intended to replace manual or other urine sediment examination methods. Two different types of urine chemistry systems can be connected physically and electronically to the DxU Microscopy Series to form the Series Automated Urinalysis workcell. These urine chemistry systems include the DxU 810c Iris and the AX-4030 (available USA Only). The workcell is used to automate the complete routine urinalysis profile, including urine test strip chemistry panel, specific gravity, color, clarity, and microscopic analysis. As a workcell, the microscopy and chemistry results are combined for review. Table 1.1, DxU Microscopy Series Configurations depicts the possible workcell configurations (contact a Beckman Coulter Representative for available configurations):

Table 1.1 DxU Microscopy Series Configurations

Configurations		
	DxU 810c Iris	**AX-4030 (USA Only)**
DxU 850m Iris	X	X
DxU 840m Iris	X	X

Requirements

The system has few special environmental requirements. It uses alternating current at 100V to 240V and 50 Hz/60 Hz. (Input voltage and frequency selection are automatic within this range.) Uninterruptible power supplies are recommended for the DxU Microscopy Series and the analysis processor (and the chemistry system, if applicable) to maintain system operation during short

power outages and brownouts. This allows for an orderly shutdown of instruments without the loss of data.

⚠ CAUTION

The equipment inside fixed covered areas of the instrument is not operator-serviceable and may present electrical shock hazards.

⚠ WARNING

- **For continued protection against risk of fire and hazard, replace only with the same type and rating fuse.**
- **Equipment requires connection to protective earth for safety reasons.**
- **The instrument's main supply inlet is being used as the mains disconnect device.**

Precautions and Safety

⚠ WARNING

- **Risk of injury. Beckman Coulter urges its customers to comply with all national health and safety standards such as the use of barrier protection. This may include, but is not limited to, protective eyewear, gloves, and suitable laboratory attire.**
- **Operators collecting DxU Microscopy Series waste in discrete containers or jugs and who are using the Body Fluids option, shall label these containers as biohazardous waste and label, handle, and dispose of the waste according to local, state, and federal regulations. Urine may be considered as biohazardous due to the potential of certain infectious agents that may or may not be present depending on a patient's medical status.**

⚠ CAUTION

- **The DxU Microscopy Series is not intended to be lifted, carried, or moved by the customer. In case any of these activities need to be carried out, they should be done by or under the supervision of a trained and experienced Beckman Coulter Representative.**

  The entire unit weighs approximately 100 lbs (45.36 kg). Choose a place to set up the unit before completing its assembly.
- **If the unit must be moved, separate the Sampler from the analyzer before moving. If these two units come apart while being carried, it may result in injury or severe damage.**
- **Always keep a distance of at least 2 inches (5 cm) between the rear of the unit and the wall. If this distance is not maintained, the connecting tubes and cables may overheat.**
- **Do NOT disassemble or modify the unit. Doing so may cause injury and/or instrument malfunction.**
- **Place the unit on a stable and level surface free of vibration. Failure to do so may cause injury or malfunction of the unit.**
- **Do NOT place the unit where it may be affected by chemicals, corrosive gases or electronic noise. Doing so may cause injury or malfunction of the unit.**
- **Do NOT place the unit where it may be affected by water, direct sunlight, or draft. This may yield incorrect results, and the unit may be damaged.**

  Select a room to set up the unit where the temperature can be controlled between 59ºF (15ºC) and 86ºF (30ºC), and humidity in a range of 20% to 80%.
- **Do not block any ventilation openings.**

⚠ CAUTION

- **Do NOT use power frequencies or voltage other than those specified in this**

document. Connection to an inappropriate power source may cause injury or fire.

Make certain that the power supply for the DxU Microscopy Series system is from a dedicated line that provides power to no other instruments or appliances. If the power is not clean and steady, a UPS and/or power conditioner is recommended.

- **Do not install the system during lightning activity. For protection during lightning storms and power surges, contact your facility electrical department.**
- **For added protection of the equipment during lightning and power surges, always unplug the power cord and the LIS connection. If the instrument is not used for a long period of time, unplug the power cord and the LIS connection.**
- **To reduce the risk of electric shock, do not remove any panel unless under the direction of qualified personnel.**
- **To reduce the risk of electric shock, do not use an extension cord, receptacle or other outlet unless the blades can be inserted completely with three-wire grounding type to prevent blade exposure.**

Electromagnetic Compatibility

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

⚠ CAUTION

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performace is affected by electromagnetic interference, correct operation may be restore by increasing the distance between the equipment and the source of the interference.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

Installation

The DxU Microscopy Series will be installed by a factory-trained Beckman Coulter Representative or an authorized distributor.

Installation Requirements

Space Requirements

The installation footprint is a continuous bench top area approximately 50 inches (127 cm) wide and 30 inches (76.2 cm) deep (an additional 18 inches [45.7 cm] is required for the printer). Optional Load and Unload stations require an additional 28 inches (71.2 cm) of bench space.

Total continuous bench top area for all equipment and loading and unloading stations is 96 inches (243.8 cm) which includes the printer.

Clearance height for the instrument is 36 inches (90 cm). Access of three feet (90 cm) around instrument is required for maintenance and service.

PC Module

The PC module is a desktop computer, video monitor, keyboard, and mouse. It requires a suitable counter or desktop that provides comfortable access and a good viewing angle. It is suggested that, if possible, the PC module, monitor, keyboard, and mouse be placed in a work area that can be semi-darkened to increase screen display visibility and reduce glare. Illumination should be indirect and subdued. Direct illumination from windows or other sources can cause glare and reduce image quality.

The data connections are made between the microscopy module, the PC module, and the chemistry system, if applicable, via the special cables provided.

Location

For most laboratories, the DxU Microscopy Series is placed near an open bench top work area which can be allocated for filling and labeling urine tubes and preparing sample racks. All data transmissions from the DxU Microscopy Series (and the chemistry system, if used) are routed to the analysis processor, which manages and controls all communications to the Laboratory Information System (LIS) via serial connections.

DxU Microscopy Series

The DxU Microscopy Series is a fully automated urine microscopy system capable of auto-identifying 12 formed elements. In addition, the operator can edit the result, thus identifying many more elements if desired. The DxU Microscopy Series allows the laboratory to increase throughput, improve workflow, and achieve a high degree of standardization in reporting microscopy results.

DxU Microscopy Series Normal Range Study

The concept of a normal range of particles in urine seems appropriate only for RBC, WBC, and casts. In all other instances, diagnostic significance has been related more to the appearance of a particle (and its abundance expressed qualitatively), or to its complete absence.

The DxU Microscopy Series has equivalent formed particle detection performance to that of the 939UDx, which has been shown equivalent to the 900UDx, and therefore the normal range determinations performed with 900UDx, as stated below, are also appropriate for DxU Microscopy Series.

Microscopic observations using the 900UDx Flow Microscope on 156 normally voided urine specimens from a population of 80 male and 76 female Iris employees and some of their family members and neighbors, and employees of neighboring companies and vendors, all with normal urine chemistry and in apparent good health, showed the following distribution of particles (see Table 1.2, Normal Range Analysis Using the 900UDx Flow Microscope).

Table 1.2 Normal Range Analysis Using the 900UDx Flow Microscope

Cumulative Percent of Population						
Cells/ HPF	**RBC**		**WBC**		**Casts/LPF**	**Male & Female**
	Male	**Female**	**Male**	**Female**		
0	57.5	34.2	68.8	32.9	0	90.4
1	83.8	71.1	85.0	55.3	<1	93.6
2	92.5	76.3	95.0	69.7	1	95.5
3	95.0	84.2	98.8	81.6	2	97.4
4	97.5	94.7	100.0	89.5	3	98.1
5	98.8	97.4		90.8	5	99.4
6	100.0	100.0			24	100.0
9				92.1		
12				96.1		
16				97.4		
24						
26				98.7		
28				100.0		

In all but one instance, all elevated WBC counts occurred in females. When these are excluded from the population, 95-percentile values appear to be 3 RBC/HPF and 2 WBC/HPF for males, and 4 RBC/HPF and 5 WBC/HPF for females, in good agreement with generally recognized normal ranges for contemporary methodology.

System Components

The DxU Microscopy Series systems consist of three modules, interlinked via cable communications:

- The DxU Microscopy Series Module
- The Results/Analysis Processor with monitor, keyboard, and mouse
- The DxU Microscopy Series Load/Unload Stations (optional)

The DxU Microscopy Series can be combined with a urine chemistry system to make a workcell, which consolidates the microscopy and chemistry results onto one review screen. The chemistry systems that can be connected to the DxU Microscopy Series include the DxU 810c Iris.

Specifications

Detected Particles

The DxU Microscopy Series detects and counts the following particles present in a specimen:

- White Blood Cells
- White Blood Cell Clumps
- Red Blood Cells
- Squamous Epithelial Cells
- Non-Squamous Epithelial Cells
- Unclassified Casts
- Hyaline Casts
- Unclassified Crystals
- Bacteria
- Yeast
- Mucus
- Sperm

The following categories can be manually identified or sub-classified:

Table 1.3 Particle Categories

Unclassified Crystals	**Unclassified Casts**	**Yeast**	**Others**
Calcium Oxalate	Granular Casts	Yeast with Pseudohyphae	Trichomonas
Triple Phosphate	Cellular Casts	Budding Yeast	Fat
Calcium Phosphate	Waxy Casts		Red Blood Cell Clumps
Leucine	Broad Casts	**Non-Squamous Epithelial Cells**	Oval Fat Bodies
Amorphous	Red Blood Cell Casts	Renal Epithelial Cells	
Uric Acid	White Blood Cell Casts	Transitional Epithelial Cells	**Unclassified**
Calcium Carbonate	Epithelial Casts		**Artifacts**
Cystine	Fatty Casts		**Dysmorphic Red Blood Cells**
Tyrosine			

Technical Specifications

Table 1.4 Technical Specifications

Specification	**Description**
Specimen Processing	Barcode or keyboard entry of ID 60 specimens walk away capability (200 specimens with optional Loading/Unloading stations) 10-tube rack system with continuous feed
Specimen Volume	Minimum volume 3 mL of un-spun urine Aspiration volume approximately 1.3 mL
Measurement Principle	Flow digital imaging
Workstation	Computer with monitor/keyboard/mouse
Data Storage	Onboard storage of up to 10,000 patient results
LIS Interface	Bi-directional with host query
Electrical Power Requirements	Microscopy module - 100-240 VAC 50/60 Hz 3.5 A max Monitor - 100-240 VAC 50-60 Hz 50 watts max PC - 100-240 VAC 50-60 Hz 100 watts max LaserJet Printer - 100-240 VAC 50-60 Hz 100 Watts max Uninterrupted Power Supply (UPS) 800VA - Require 15-ampere circuit with a Hospital Grade three wire grounded receptacle
Dimensions	Microscopy module - 58.4 H x 53 W x 64.5 D cm (23 H x 20.9 W x 25.4 D in.) Touchscreen Monitor with base- 35 H x 51.8 W x 21.8 D cm (13.8 H x 20.4 W x 8.6 D in.)

Table 1.4 Technical Specifications *(Continued)*

Specification	Description
Weight	Microscopy module - 45.4 kg (100 lbs.) CPU - 12.7 kg (28 lbs.) Monitor - 10.8 kg (23.8 lbs.) Printer - 10 kg (23 lbs.) Optional Loading/Unloading stations - 5 kg (11 lbs.) each
Fluid Waste	Waste is pumped from the instrument to a sink, floor drain or suitable container. Drain must be below or at same height as bench and should be less than 3 meters (10 feet) from the back of the instrument.
Ambient Temperature Control	Ambient temperature must be 15 to 30°C (59 to 86°F) Relative humidity must be between 20% and 80% non-condensing. DxU Microscopy Series system heat output approximately 1,200 British Thermal Units or BTUs
Acoustic Noise	This system generates less than 60 dBa sound pressure level.

Performance and Operational Characteristics

Analytical and auto particle recognition performance of the DxU Microscopy Series are measured in terms of clinical sensitivity, range agreement, formed particle sensitivity, concentration agreement (formed particle accuracy), and precision.

NOTE Performance Characteristics are identical to the iQ200 Series since there were no technology or algorithm changes.

Individual Formed Particle Sensitivity

Individual formed particle sensitivity is determined using 2 x 2 cross-tabulations to compare normal and abnormal classifications of formed particle concentration comparing quantitative microscopic results from the test method to those obtained using the reference method. A formed particle concentration is normal if it falls into the normal range of the five ranges previously assigned for the reference method. Otherwise, it is abnormal. A 2 x 2 cross-tabulation summarizes agreement between methods.

Clinical Sensitivity

An individual formed particle concentration is deemed normal if it falls within the NORMAL range. A specimen will be considered negative (normal) if all significant formed particles are within the normal range; otherwise, it is positive (abnormal).

Bacteria (BACT), mucus (MUCS), and amorphous (AMOR) are excluded from the significant formed particle group. BACT is excluded because all specimens processed by the UF-100 were positive for BACT, and some institutions consider BACT findings from non-sterile collections to be artifactual. MUCS is excluded because it is typically not pathological and is usually reported as an observation only. AMOR is excluded because specimens with excessively high concentrations of AMOR are usually flagged for treatment that dissolves the amorphous crystal and re-run. Therefore, were these formed particles included in the determination of overall specimen normality or abnormality, the resulting determination would be skewed by formed particle presence (or absence) not universally accepted as clinically significant.

Positive/negative specimen classifications by test and reference methods are compared using a 2 x 2 contingency table.

False negative rate (or equivalent sensitivity) and false positive rate (or equivalent specificity) are the most important numeric evaluation criteria. False negative rate is the fraction of abnormal specimens that will be missed by the test method. False positive rate is the fraction of normal specimens that will be declared abnormal. Depending on review criteria, this rate may be strongly related to the automation benefit provided by the test method.

A high false positive rate (low specificity) will occur in cases where the TEST METHOD is actually more sensitive than the REFERENCE METHOD. One must be careful to critically evaluate such results using appropriate statistical tests when other corroboration is unavailable. When images are available for both methods, and experts have unequivocally identified the formed particles in question for both methods, it may be more appropriate to consider the RELATIVE SENSITIVITY of each method as follows.

A 2 x 2 cross-tabulation is constructed which compares those specimens or formed particles judged to be normal and abnormal by the test and reference methods. When the intent of the study is to evaluate the performance of two methods, without making the assumption that all specimens determined *normal* and *abnormal* via the reference method are *true positives* and *true negatives*, respectively, the comparison table summary presumes that ALL specimens determined to be abnormal by either method are true positives, and presents the sensitivity calculations for both the test and reference methods accordingly.

Table 1.5, Definition of Cross-Tabulation Entries in Comparison with Computing Relative Sensitivity shows the definition of cross-tabulation entries in a comparison table for computing relative sensitivity.

Table 1.5 Definition of Cross-Tabulation Entries in Comparison with Computing Relative Sensitivity

Reference Method	**Test Method**		
	Negative	**Positive**	**Total**
Negative	Negative Both (NB)	Negative Reference/ Positive Test (NRPT)	Reference Negative (NB+NRPT)
Positive	Positive Reference / Negative Test (PRNT)	Positive – Both (PB)	Reference Positive (PRNT+PB)
Total	Test Negative (NB+PRNT)	Test Positive (NRPT+PB)	Grand Total (GT) = (NB + PRNT + NRPT + PB)

TEST METHOD SENSITIVITY:	100 * (PB + NRPT) / (PB + NRPT + PRNT)
REFERENCE METHOD SENSITIVITY:	100 * (PB + PRNT) / (PB + NRPT + PRNT)
AGREEMENT:	100 * (NB + PB) / GT
ANY METHOD POSITIVE:	100 * (PB + NRPT + PRNT) / GT

Formed Particle Accuracy

Linear regression analyses of the specimen-by-specimen counts from the DxU Microscopy Series and a competitor's automated system against counts from the 939UDx Urine Pathology System expert edits and DxU Microscopy Series APR against counts from the DxU Microscopy Series expert edits were used to evaluate the data summarized in scatter plots for those formed particles which were enumerated and which provided an appropriate range of test values. The following criteria were used to evaluate the quality of the regression line:

- R^2 (R Square) the square of the correlation coefficient between the test method (DxU Microscopy Series, competitor) and reference method (939UDx expert edit), and between the DxU Microscopy Series APR and DxU Microscopy Series human edit reference method. A correlation coefficient of 1 would signify perfect correlation resulting from identical values for both test and reference methods. The entire regression scheme must be carefully considered when evaluating the meaning of correlation coefficients. High values can result from a single point with a large value and many poorly correlated points with low values. On the other hand, a relatively low correlation coefficient may result when the comparison is based only on many low value points even though they are well within statistical limits of each other. Thus, it is possible to have good agreement with a low correlation coefficient and vice versa.
- The slope of the regression line. A value close to one indicates that the two methods produce identical numerical results. While this is desirable, it is by no means necessary. As long as the relationship is consistent, a multiplicative factor may be used to adjust values to produce identical numerical results.
- The intercept of the regression line. Ideally, this should be zero. Any other significantly large value indicates a fixed bias between methods, independent of the measured value.

All regression analyses were carefully evaluated for the presence of outliers and recomputed if necessary with the exclusion of outliers to provide a truer assessment of the inter-method comparison.

Precision: Sample-to-Sample

Sample-to-sample consistency was evaluated using a paired t-test to test the hypothesis that the average of the paired differences for each formed element type detected with each method is zero. The t-statistic was computed for the competitive method replicates as well for reference purposes. Statistical parameters determined are the following:

- **t-value**: Value of the t-statistic computed for the paired replicates. A lower absolute t value indicates closer agreement of the replicate results.

- **t-sig:** Probability of a t-value less than or equal to that observed under the null hypothesis. To reject the null hypothesis (that the two groups are the same) at the 5% significance level, this value must be less than 0.05.
- **pmean:** Average difference between paired values. t-value is based on this difference and the corresponding sample variance. If the variance is large, a larger value of pmean will yield the same value of the t-value as a smaller pmean and variance and thus in both cases the two methods will be judged identical.

DxU Microscopy Series Analytical Performance Summary

This study is based on 506 specimens run in duplicate, for a total of 1,012 individual results per instrument. By the 939UDx Urine Pathology System reference method, 194 of the 506 specimens had one or more of the abnormal formed elements or concentrations present. A total of 312 of the 506 specimens did not meet any of the criteria for abnormality according to the reference method.

Table 1.6, DxU Microscopy Series and 939UDx Results Comparison shows the DxU Microscopy Series System Human Expert formed particle concentrations/levels for comparing results from test systems to the reference system 939UDx Urine Pathology System operator edits.

Table 1.6 DxU Microscopy Series and 939UDx Results Comparison

DxU Microscopy Series System PARTICLE CATEGORICAL BOUNDS (Particles per Microliter)						
Particle	**Title**	**Normal**	**+1**	**+2**	**+3**	**+4**
RBC	RBCs	16.5	55.0	137.5	275.0	>275.0
WBC	WBCs	27.5	55.0	137.5	275.0	>275.0
SQEP	Squamous Epithelial Cells	27.5	55.0	110.0	165.0	>165.0
HYAL	Hyaline Casts	0.7	1.7	3.4	8.6	>8.6
UNCC	(Unclassified) Pathologic Casts	0.3	1.7	3.4	8.6	>8.6
BACT	Bacteria	6.8	13.8	27.7	55.6	>55.6
BYST	Hyphae or Budding Yeast	11.0	27.5	82.5	137.5	>137.5
NSE	Non-squamous Epithelial Cells	4.0	19.8	39.6	79.2	>79.2
UNCX	Unclassified Crystals	13.6	54.6	136.4	272.8	>272.8
SPRM	Spermatozoa	5.5	55.0	137.5	550.0	>550.0
WBCC	White Cell Clumps	1.4	3.4	6.9	10.3	>10.3
MUCS	Mucus	27.5	55.0	110.0	165.0	>165.0
AMOR	Amorphous	55.0	275.0	550.0	2750.0	>2750.0

Sensitivity/Specificity

Individual formed particle sensitivity for the DxU Microscopy Series Automated Urine Microscopy System human edit results and results from a competitor's instrument with respect to 939UDx Urine Pathology System human edits are compared in Table 1.7, DxU Microscopy Series Numbers

Computed as the Average of Two DxU Microscopy Series Instruments. Sensitivity and specificity are computed from the 2x2 cross-tabulations.

Sensitivity of DxU Microscopy Series for all formed particles is uniformly better than that of the competitor. (100% sensitivity for the competitor's instrument for bacteria is not meaningful since the corresponding specificity is zero.) Average sensitivity of the DxU Microscopy Series of 90.3% significantly exceeds the 55.4% of the competitor's instrument.

Specificity of the DxU Microscopy Series for RBC, WBC, SQEP, BYST, and UNCX exceeds that of the competitor's instrument. The DxU Microscopy Series sensitivity is equal to or greater than the competitor's instrument, indicating unequivocally better performance (100% specificity for SPRM corresponds to 0% sensitivity for the competitor's instrument).

Only for casts (HYAL and UNCC) and NSE is DxU Microscopy Series specificity significantly less than that of a competitor's instrument, even though in all these cases the competitor's sensitivity is lower than that of the DxU Microscopy Series.

Table 1.7, DxU Microscopy Series Numbers Computed as the Average of Two DxU Microscopy Series Instruments shows a summary of formed particle sensitivity and specificity of DxU Microscopy Series results based on human edits and competitor's instrument compared to 939UDx Urine Pathology System human edits showing that DxU Microscopy Series sensitivity is uniformly better for all formed particles. DxU Microscopy Series specificity is also better except for those cases for which the other method's sensitivity is significantly lower than that of the DxU Microscopy Series. Thus, the DxU Microscopy Series formed particle sensitivity performance is substantially equivalent to or better than the 939UDx Urine Pathology System.

Table 1.7 DxU Microscopy Series Numbers Computed as the Average of Two DxU Microscopy Series Instruments

Analyte	Expert		False Negative		False Positive		Sensitivity (%)		Specificity (%)	
	Pos	Neg	DxU Micro-scopy Series	Competitor	DxU Micro-scopy Series	Competitor	DxU Micro-scopy Series	Competitor	DxU Micro-scopy Series	Competitor
RBC	90	416	2.5	18	13	55	97.2	80	96.9	86.7
WBC	66	440	2.5	6	10	20	96.2	90.9	97.7	95.4
SQEP	11	495	0	0	11.5	19	100	100	97.7	96.1
HYAL	10	496	0.5	7	87.5	41	95	30	82.4	91.7
UNCC	23	483	1.5	16	113.5	15	93.5	30.4	76.5	96.9
BACT	86	420	15.5	0	7.5	419	82	100	98.2	0
BYST	14	492	2	7	8	18	85.7	50	98.4	96.3
NSE	44	462	10.5	38	41.5	2	76.1	13.6	91	99.6
UNCX	42	464	5	17	7.5	12	88.1	59.5	98.4	97.4
SPRM	9	497	1	9	0	0	88.9	0	100	100
WBCC	16	490	1		23		93.8		95.3	
AMOR	39	467	5		5.5		87.2		98.8	
					Average		90.3	55.4	94.3	86.0

Of the 194 specimens classified positive by the 939UDx expert, 185.5 are positive by expert edit of DxU Microscopy Series data, yielding corresponding sensitivity of 95.6%. By comparison, competitor's sensitivity is 85.1%.

Of the 312 specimens classified negative by the 939UDx expert, 219 are negative by expert edit of DxU Microscopy Series data, yielding corresponding specificities of 70.1%. Corresponding competitor's specificity is 88.5%.

Examination of the ostensible DxU Microscopy Series false positive specimens shows that the specimens called positive by expert edit of DxU Microscopy Series data and negative by expert edit of 939UDx data are in fact positive for hyaline casts (HYAL) and/or pathological casts (UNCC) and/or non-squamous epithelial cells (NSE) by direct observation of the image data captured by DxU Microscopy Series. Thus, the DxU Microscopy Series has improved sensitivity for the detection of hyaline casts, pathological casts, and non-squamous epithelial cells.

To quantify this improved sensitivity one may examine the relative sensitivity of the methods. While the relative sensitivity of the DxU Microscopy Series manual edits compared to the 939UDx manual edits is 97.0% that of the competitor's instrument is 87.4%. This indicates that the DxU Microscopy Series is significantly more sensitive analytically (visually confirmed) than the competitor's instrument.

DxU Microscopy Series expert relative sensitivity: 97.0 %

Competitor's instrument relative sensitivity: 87.4 %

Table 1.7, DxU Microscopy Series Numbers Computed as the Average of Two DxU Microscopy Series Instruments shows that the two instruments have different sensitivity and specificity for individual formed particles, making the comparison more difficult. Fixing the sensitivity of both instruments at, for instance, 90%, and recalculating their respective specificity shows a clearer picture.

Table 1.8 Specificity of the DxU Microscopy Series and Competitor with Sensitivity for Each Set at 90%

Specificity (%) at 90% Sensitivity		
Analyte	**DxU Microscopy Series**	**Competitor's Instrument**
RBC	97.4	71.4
WBC	99.2	96.8
SQEP	99.3	98.0
HYAL	89.6	19.7
UNCC	88.0	52.9
BACT	97.1	49.2
BYST	95.2	21.8
NSE	61.0	62.1
UNCX	97.9	13.1
SPRM	89.0	10.0

Table 1.8 Specificity of the DxU Microscopy Series and Competitor with Sensitivity for Each Set at

Specificity (%) at 90% Sensitivity		
Analyte	**DxU Microscopy Series**	**Competitor's Instrument**
WBCC	97.2	
AMOR	84.8	

With the exception of non-squamous epithelials (NSE), which is essentially equivalent, the DxU Microscopy Series specificity is uniformly greater than that of the competitor's instrument.

Accuracy

Linear regression of DxU Microscopy Series expert edit concentration versus 939UDx Urine Pathology System expert edit concentration was performed for each formed particle.

The quality of each DxU Microscopy Series regression and how it compared to the quality of each competitor's regression for which the competitor's reports quantitative results was evaluated using the criteria described in the first section.

In each case except BACT, R^2 for the DxU Microscopy Series is generally high, most often greater than 0.9, and comparable to or greater than that of the competitor's instrument. With the exception of WBC, for which agreement is comparable, DxU Microscopy Series concentrations agree more closely with the 939UDx expert than those of the competitor's instrument.

The slope of the DxU Microscopy Series regression line for RBC and WBC for both instruments is closer to the ideal value of 1 than the slope of the 939UDx AAR. Also, the intercept value for the DxU Microscopy Series is closer to zero than that of the competitor's instrument.

The slope of the DxU Microscopy Series regression line for SQEP and UNCC for both instruments is significantly greater than 1, while the slope of the competitor's instrument is significantly less than 1 for UNCC. This is yet another confirmation of the increased sensitivity of the DxU Microscopy Series to casts and SQEP.

Thus, in general, concentrations reported by the DxU Microscopy Series, based on expert identification of formed particle images, agree well with those based on expert identification of 939UDx Urine Pathology System formed particle images or are greater because of increased sensitivity. In each case, the reported concentrations agree more closely with the 939UDx expert than those of the competitor's instrument. Accuracy of the DxU Microscopy Series is therefore substantially equivalent to or better than that of the 939UDx Urine Pathology System, based on expert edits or the competitor's instrument.

Table 1.9 Linear Regression Results for DxU Microscopy Series Expert Edit Compared with Competitor Instrument

Analyte	R^2		Slope		Intercept	
	DxU Microscopy Series	Competitor	DxU Microscopy Series	Competitor	DxU Microscopy Series	Competitor
RBC	0.970	0.914	1.107	1.063	-2.4215	5.161
WBC	0.954	0.974	0.9865	1.003	0.792	2.711
SQEP	0.924	0.687	1.634	1.562	0.369	2.875
UNCC	0.737	0.126	2.929	0.142	0.317	0.056
BYST	0.939		0.6325		0.969	
NSE	0.638		0.7305		0.772	
UNCX	0.806		0.424		1.3785	
SPRM	0.956		0.525		0.0365	
WBCC	0.905		3.6725		0.2055	

Precision: Sample-to-Sample Repeatability

Paired t-test results for each formed particle are summarized below. For DxU Microscopy Series, the null hypothesis cannot be rejected at a 0.094 significance level or greater for all formed particles, except WBCC for which the significance level is 0.042. For the competitor's instrument, the null hypothesis cannot be rejected at a 0.065 significance level or greater for all formed particles reported quantitatively.

Thus, since significance levels are usually chosen to be 0.05, 0.025, or 0.01, we have that on an absolute basis the null hypothesis cannot be rejected for either DxU Microscopy Series instrument for all formed particles.

Therefore, sample-to-sample repeatability of the DxU Microscopy Series formed particle concentrations, based on expert edit, is substantially equivalent to that of the competitor's instrument.

Table 1.10 Paired t-test Values of Samples from DxU Microscopy Series Compared with Competitor

Analyte	DxU Microscopy Series			Competitor		
	t-value	t-sig	pmean	t-value	t-sig	pmean
RBC	-1.679	0.094	-2.182	0.182	0.856	0.135
WBC	0.292	0.771	0.211	-0.385	0.7	-0.097
BACT	1.25	0.212	0.893	1.848	0.065	17.26
SQEP	-1.413	0.158	-0.457	-1.398	0.163	-0.123
UNCC	-0.611	0.541	-0.055	-1.272	0.204	-0.007
HYAL	-0.634	0.527	-0.036	-0.094	0.925	-0.001
BYST	-1.413	0.158	-0.457			

Table 1.10 Paired t-test Values of Samples from DxU Microscopy Series Compared with Competitor *(Continued)*

Analyte	DxU Microscopy Series			Competitor		
	t-value	t-sig	pmean	t-value	t-sig	pmean
SPRM	-0.634	0.527	-0.036			
NSE	-0.777	0.438	-0.069			
UNCX	-0.895	0.371	-0.241			
MUCS	-1.575	0.116	-1.312			
WBCC	2.038	0.042	0.176			

DxU Microscopy Series Auto-Particle Recognition Performance Summary

Evaluation of Auto Particle Recognition performance is based on comparing the DxU Microscopy Series Auto Particle Recognition results with those of the DxU Microscopy Series expert human edit results. As a measure of accepted performance, the 939UDx Auto Analyte Recognition and the competitor's instrument results are compared to those of the 939UDx expert edit results.

Of the 506 study specimens, 457 contained normal levels of amorphous. These 457 specimens were used to evaluate the Auto Particle Recognition performance of the DxU Microscopy Series compared to its human expert edits relative to the Auto Analyte Recognition performance of the 939UDx Urine Pathology System compared to its human expert edits.

The DxU Microscopy Series amorphous recognition algorithm correctly identified about 75% of the amorphous specimens and 95% of the non-amorphous specimens. By comparison, the 939UDx AAR correctly identifies only 41% of non-amorphous specimens if its decision threshold is set to detect 75% of the amorphous specimens. Thus, the amorphous detection capability of the DxU Microscopy Series APR is significantly better than that of the 939UDx AAR. In order to eliminate any influence of amorphous particles in comparing the two methods only non-amorphous specimens were considered.

Table 1.11, DxU Microscopy Series Auto Particle Recognition for Comparison of APR Results to Human Expert Edit Results shows DxU Microscopy Series Auto Particle Recognition formed particle concentrations/levels used to compare DxU Microscopy Series APR results to the DxU Microscopy Series Human Expert Edit results.

Table 1.11 DxU Microscopy Series Auto Particle Recognition for Comparison of APR Results to Human Expert Edit Results

Particle	Title	Normal	+1	+2	+3	+4
RBC	Red Blood Cells	10.5	35.0	87.5	175.0	>175.0
WBC	White Blood Cells	15.1	30.2	75.5	151.0	>151.0
SQEP	Squamous Epithelial Cells	13.3	26.5	53.0	79.5	>79.5
HYAL	Hyaline Casts	3.5	8.8	17.5	43.8	>43.8
UNCC	(Unclassified) Pathologic Casts	2.3	11.3	22.5	56.3	>56.3
BACT	Bacteria	3.9	7.9	15.8	31.7	>31.7
BYST	Hyphae or Budding Yeast	11.0	27.5	82.5	137.5	>137.5

Table 1.11 DxU Microscopy Series Auto Particle Recognition for Comparison of APR Results to Human Expert Edit

Particle	Title	Normal	+1	+2	+3	+4
NSE	Non-squamous Epithelial Cells	1.8	8.8	17.5	35.0	>35.0
UNCX	Unclassified Crystals	17.3	69.0	172.5	345.0	>345.0
SPRM	Spermatozoa	1.8	17.5	43.8	175.0	>175.0
WBCC	White Cell Clumps	3.8	9.4	18.8	28.1	>28.1
MUCS	Mucus	27.5	55.0	110.0	165.0	>165.0
AMOR[7]	Amorphous	55.0	275.0	550.0	2750.0	>2750.0

NOTE Specimen is flagged as amorphous if amorphous concentration exceeds specified level.

Sensitivity/Specificity

Individual formed particle sensitivity for the DxU Microscopy Series auto particle recognition results with respect to DxU Microscopy Series human edits, and 939UDx AAR and the competitor's instrument results with respect to 939UDx Urine Pathology System human edits are compared below. Sensitivity and specificity are computed from the 2-by-2 cross-tabulations.

Sensitivity of the DxU Microscopy Series APR for all formed particles is uniformly better than either 939UDx AAR or the competitor's instrument, with the exception of the DxU Microscopy Series WBC sensitivity which is greater than that of the competitor's instrument but less than that of 939UDx AAR. (100% sensitivity of the competitor's instrument for bacteria is not meaningful since the corresponding specificity is zero.)

Average sensitivity with the DxU Microscopy Series of 76.1% significantly exceeds the 47.7% and 54.5% of the 939UDx AAR and the competitor's instrument respectively.

Specificity of the DxU Microscopy Series for RBC, WBC, and SQEP is comparable to or better than both the 939UDx AAR and the competitor's instrument even though the DxU Microscopy Series sensitivity is equal or greater.

For the remainder of the formed particles, DxU Microscopy Series APR specificity is typically less than that of 939UDx AAR or the competitor's instrument. In these cases 939UDx AAR and the competitor's sensitivity is significantly lower than DxU Microscopy Series APR sensitivity, in many cases 50% or more lower than that of the DxU Microscopy Series APR.

Table 1.12 Overview of Sensitivity and Specificity Results by Formed Particle for the DxU Microscopy Series APR, 939UDx AAR, and the Competitor's Instrument

Analyte	Instrument	Sensitivity (%)	Specificity (%)	Abnormal	False Negative	False Positive
RBC	DxU Microscopy Series APR	89.4	89.2	94.5	10	39
	939A	84.9	85.2	86	13	55
	Competitor	80.2	87.9	86	17	45
WBC	DxU Microscopy Series APR	93.9	88.8	65.5	4	44
	939A	94.9	89.9	59	3	40
	Competitor	89.8	95.7	59	6	17
SQEP	DxU Microscopy Series APR	100.0	97.7	20.5	0	10
	939A	55.6	100.0	9	4	0
	Competitor	100.0	96.0	9	0	18
HYAL	DxU Microscopy Series APR	54.4	92.1	91	41.5	29
	939A	0.0	99.8	7	7	1
	Competitor	28.6	92.7	7	5	33
UNCC	DxU Microscopy Series APR	44.6	90.3	121	67	32.5
	939A	16.7	98.4	18	15	7
	Competitor	27.8	97.7	18	13	10
BACT	DxU Microscopy Series APR	93.9	88.1	66	4	46.5
	939A	58.1	99.7	74	31	1
	Competitor	100.0	0.0	74	0	383
BYST	DxU Microscopy Series APR	57.9	88.6	19	8	50
	939A	42.9	100.0	14	8	0
	Competitor	50.0	96.8	14	7	14

Table 1.12 Overview of Sensitivity and Specificity Results by Formed Particle for the DxU Microscopy Series APR, 939UDx AAR, and the Competitor's Instrument *(Continued)*

Analyte	Instrument	Sensitivity (%)	Specificity (%)	Abnormal	False Negative	False Positive
NSE	DxU Microscopy Series APR	48.5	90.1	65	33.5	39
	939A	24.3	98.3	37	28	7
	Competitor	8.1	99.8	37	34	1
UNCX	DxU Microscopy Series APR	82.5	90.8	40	7	38.5
	939A	52.6	100.0	38	18	0
	Competitor	60.5	97.6	38	15	10
SPRM	DxU Microscopy Series APR	93.8	94.5	8	0.5	24.5
	939A	44.4	99.1	9	5	4
	Competitor	0.0	100.0	9	9	0
WBCC	DxU Microscopy Series APR	78.5	90.9	32.5	7	38.5
	939A	50.0	99.8	14	7	1
Average	DxU Microscopy Series APR	76.1	91.0			
	939A	47.7	97.3			
	Competitor	54.5	86.4			

NOTE DxU Microscopy Series numbers are computed as the average of two DxU Microscopy Series systems.

To avoid the ambiguity of comparing specificities of instruments operating at different sensitivity levels, one may fix the sensitivity and compare specificities at that sensitivity level. This comparison is summarized below for a fixed sensitivity of 90%.

From the Table 1.13, Specificity of DxU Microscopy Series APR, 939UDx AAR, and Competitor with Sensitivity Set at 90%, one observes that generally, the specificity of the DxU Microscopy Series is comparable to or greater than that of 939UDx AAR.

Specificity of the DxU Microscopy Series APR is greater than or essentially equivalent to that of the competitor's instrument for all formed particles except UNCC and NSE.

Table 1.13, Specificity of DxU Microscopy Series APR, 939UDx AAR, and Competitor with Sensitivity Set at 90% shows the specificity of the DxU Microscopy Series APR, the 939UDx AAR and the competitor's instrument when the sensitivity of each is set at 90%.

Table 1.13 Specificity of DxU Microscopy Series APR, 939UDx AAR, and Competitor with Sensitivity Set at 90%

Analyte	Specificity (%) at 90% Sensitivity		
	DxU Microscopy Series APR	939 AAR	Competitor
RBC	88.6	81.3	74.1
WBC	93.4	91.6	94.2
SQEP	99.5	100.0	98.0
HYAL	64.5	11.3	13.9
UNCC	34.8	15.6	62.1
BACT	91.4	86.1	49.1
BYST	62.8	22.7	22.0
NSE	38.4	33.7	64.3
UNCX	83.3	93.6	14.6
SPRM	92.1	17.8	10.0
WBCC	80.8	34.4	

Accuracy

Linear regression of the concentration determined from DxU Microscopy Series Auto Particle Recognition against DxU Microscopy Series expert edit was performed for each formed particle. The quality of the DxU Microscopy Series APR regression and how it compared to the quality of each 939UDx Urine Pathology System AAR regression and the competitor's instrument regression for which the competitor's reports quantitative results was evaluated.

R^2, slope, and intercept for the formed particles under consideration are shown in Table 1.14, Linear Regression for DxU Microscopy Series Compared with 939UDx AAR and Competitor, for the concentrations reported by the DxU Microscopy Series based on Auto Particle Recognition identification of captured formed particle images, as well as those for 939UDx Urine Pathology System AAR and those for the competitor's instrument. In each case where the regression is valid, (standard error of the estimate smaller, ideally much smaller, than standard deviation of the predicted value), R^2 for the DxU Microscopy Series instruments is generally high, often greater than 0.9, and comparable to or greater than that of the 939UDx AAR, indicating that concentrations reported by the DxU Microscopy Series APR agree very well with those resulting from expert human identification of DxU Microscopy Series images. With the exception of WBC, for which agreement is comparable, DxU Microscopy Series concentrations agree more closely with the DxU Microscopy Series expert edit than those of the competitor's instrument.

The slope of the DxU Microscopy Series regression is typically less than 1 since the Auto Particle Recognition algorithm assigns an image to a formed particle class only if its certainty measure is high, typically 0.9 or greater. Thus, some fraction of images identified as formed particles by the human observer will be classified as artifact by the APR algorithm. Concentrations reported by the APR algorithm are adjusted appropriately.

For the case of BACT, when the regression and scatter plots are computed limiting values to no more than 500 per microliter, results for the DxU Microscopy Series APR and the 939UDx AAR are quite comparable. The competitor's instrument shows poor correlation with visually identified bacteria.

Thus, in general, concentrations reported by the DxU Microscopy Series based on Auto Particle Recognition identification of formed particle images agree at least as well with those based on expert identification of DxU Microscopy Series formed particle images as concentrations reported by the 939UDx Urine Pathology System based on Auto Analyte Recognition agree with those based on expert identification of 939UDx formed particle images.

Table 1.14, Linear Regression for DxU Microscopy Series Compared with 939UDx AAR and Competitor shows linear regression values by formed particle for DxU Microscopy Series APR compared with those for 939UDx AAR and competitor's instrument.

Table 1.14 Linear Regression for DxU Microscopy Series Compared with 939UDx AAR and Competitor

Particle Type	R^2			Slope			Intercept		
	DxU Microscopy Series APR	939 AAR	Competitor	DxU Microscopy Series APR	939 AAR	Competitor	DxU Microscopy Series APR	939 AAR	Competitor
RBC	0.982	0.967	0.916	0.571	0.850	1.064	4.157	8.452	4.273
WBC	0.962	0.913	0.977	0.549	0.759	1.004	6.072	8.481	2.254
SQEP	0.969	0.965	0.728	0.729	0.972	1.594	0.465	0.500	2.622
BACT <500 per µL	0.610	0.583	0.031	0.319	0.224	1.787	2.632	0.140	336.20
BYST	0.727	0.941		0.224	0.090		4.910	0.159	
UNCX	0.602	0.437		0.494	0.200		8.803	2.635	
SPRM	0.552	0.671		0.155	0.196		0.392	0.126	

Precision: Sample-to-Sample Repeatability

Paired t-test results for each formed particle are summarized below.

For DxU Microscopy Series, the null hypothesis cannot be rejected at a 0.150 significance level or greater for all formed particles except BACT for which the significance level is 0.046.

For 939UDx AAR, the null hypothesis cannot be rejected at a 0.070 significance level or greater for all formed particles. Finally, for the competitor's instrument, the null hypothesis cannot be rejected at a 0.207 significance level or greater for all formed particles reported quantitatively, except BACT for which the significance level is 0.012.

Thus, since significance levels are usually chosen to be 0.05, 0.025 or 0.01, we have that on an absolute basis the null hypothesis cannot be rejected for the DxU Microscopy Series instrument for all formed particles at the 0.025 and 0.01 significance levels, and almost at the 0.05 level since DxU Microscopy Series APR BACT significance level is 0.046.

By comparison, for the competitor's instrument, the null hypothesis significance level for BACT is 0.012.

Table 1.15, Paired t-test for Each Formed Particle for DxU Microscopy Series APR Compared with 939UDx AAR and Competitor shows a paired t-test for each formed particle for the DxU Microscopy Series APR compared with those for 939UDx AAR and a competitor's instrument.

Table 1.15 Paired t-test for Each Formed Particle for DxU Microscopy Series APR Compared with 939UDx AAR and Competitor

Analyte	DxU Microscopy Series APR			939UDx AAR			Competitor		
	t-value	t-sig	pmean	t-value	t-sig	pmean	t-value	t-sig	pmean
RBC	-1.441	0.150	-1.179	-1.35	0.178	-3.454	0.529	0.597	0.403
WBC	-0.543	0.588	-0.199	0.324	0.746	0.469	-0.055	0.956	-0.014
BACT	-1.999	0.046	-0.265	-0.317	0.751	-1.143	2.521	0.012	22.776
SQEP	-1.141	0.255	-0.066	0.291	0.771	0.033	-1.263	0.207	-0.119
UNCC	-1.447	0.149	-0.206	0.092	0.927	0.001	-0.117	0.907	-0.002
HYAL	-1.015	0.311	-0.074	1.132	0.258	0.009	-0.883	0.378	-1.211
BYST	-1.141	0.255	-0.066	0.308	0.758	0.060			
SPRM	-1.015	0.311	-0.074	1.814	0.070	0.433			
NSE	1.36	0.174	0.114	1.532	0.126	0.281			
UNCX	1.509	0.132	0.234	1.638	0.102	0.585			
MUCS	-0.462	0.644	-0.125	0.34	0.734	0.025			
WBCC	-0.291	0.771	-0.026	0.064	0.949	0.002			

Limitations

Specimens

Use only fresh urine specimens, as defined in *CLSI (Clinical and Laboratory Standards Institute) GP16-A3 protocol, Urinalysis and Collection, Transport and Preservation of Urine Specimens, Approved Guideline, Second Edition*, good laboratory practices, and the laboratory's procedure manuals.

Collect urine in clean containers. If a specimen is not processed within an hour after collection, cap the container tightly and store at 35.6 to 46.4° F (2 to 8° C). Bring the specimen to room temperature before testing.

Mix specimen well before testing.

Do **NOT** add disinfectant or detergent to the specimen.

Keep specimens out of direct sunlight.

Do **NOT** centrifuge urine specimens.

Specimen Volume

The minimum volume of liquid specimen for analysis by both the DxU 810c Iris and DxU Microscopy Series is 4.0 mL. The DxU Microscopy Series alone requires 3.0 mL and the DxU 810c Iris alone requires 2.0 mL.

Questionable Differentiation of Cellular Casts

Cellular casts in urine, as viewed on the monitor, may not always exhibit sufficient structural detail for complete differentiation. Hyaline casts in low concentrations may not have sufficient contrast to be imaged by the system in some cases.

⚠ CAUTION

When differentiation is questionable, a wet mount of the specimen should be examined more thoroughly by conventional slide microscopy.

Motility/Flagella

Motility cannot be determined using the DxU Microscopy Series. This may hinder the identification of flagellates in urine. When abnormal concentrations of white blood cells occur and all of the following conditions are met, the presence of microorganisms is indeterminate.

- Yeast are not evident
- Bacteria are not evident
- The chemical test for nitrite is negative

The identification of flagellates is uncertain.

In these cases, specimens should be examined by conventional slide microscopy in order to determine the presence or absence of microorganisms.

Fat Globules

The extent of fat globules in specimens must be examined via wet mount after staining with Sudan Black or Oil Red O (also known as Solvent Red 27).

Observing Pyuria

White blood cells may lyse more quickly when the pH of urine exceeds 8.0. If the specimen is more than two hours old and these conditions are known to exist, a fresh specimen should be collected and examined immediately in the DxU Microscopy Series.

High Concentration of One Particle Type

When concentrations of red or white blood cells exceed 1,000 cells per field, they may preclude the detection of other particles present in much lower concentrations.

Very Dense or Viscous Specimens

It is possible that specimens having sufficiently high particle counts may clog the flow cell. Very viscous specimens may require dilution.

White Blood Cell Differentiation

When white blood cell differentiation is desired, this should be performed by slide microscopy using conventional Wright's stain.

Particle Counter Greater Than 1,000 Per µL

The DxU Microscopy Series performs linearly up to 1,000 cells per microliter. As particle counts increase, particle to particle interaction occurs, affecting positional distribution. Counts greater than 1,000 per µL may lose accuracy.

Large Particles

The presence of more than a few very large particles in a given specimen may warrant examination of that specimen by slide microscopy.

Specimens at Room Temperature

The specimen should always be tested at room temperature. If the specimen temperature is outside this range, the specific gravity as indicated may be inaccurate. Allow all refrigerated specimens to equilibrate to room temperature before testing.

Hematuria

Gross hematuria may cause incorrect results in subsequent samples. Do not test specimens exhibiting gross hematuria.

DxU Series Automated Urine Microscopy Systems

The DxU Series Automated Urine Microscopy System is a bench top instrument. It has its own power supply, PC processor, and multiple micro controllers to control its operations, a barcode reader to identify samples, motors to drive mechanical portions of the system, a fluidic system to pipette samples from specimen tubes, and a communication link to the Analysis Processor.

When connected to an automated chemistry system via the Sample Bridge Kit, sample racks can be transferred automatically from the chemistry system to the DxU Microscopy Series, or they can be loaded directly onto the sampler of the DxU Microscopy Series. When connected to a semi-automated chemistry system, samples must complete their analysis on the chemistry system before their rack is placed on the DxU Microscopy Series systems.

If there are more than 60 specimens in a batch, up to an additional 140 specimens can be loaded onto the optional Load Station for transfer to the Sampler, the system module(s), and then Unload Station. The DxU Microscopy Series systems aspirate samples, collect images from samples using digital image capture of particles presented in a flow microscope, and perform image processing to isolate individual particles.

Figure 1.1 DxU Series Automated Urine Microscopy Systems

Sampler

The Sampler is located on the front of the DxU Microscopy Series and is similar to the sampler used on the automated chemistry system. A bridge connection can be installed between the two systems allowing automatic transfer of sample racks after they have been processed on the chemistry system.

Sample racks, each capable of holding 10 tubes, are loaded on the right side of the sampler. To start the transport of the racks to the pipetting station, press the Start Button.

Load/Unload Station (Optional)

This consists of sample loading and unloading stations on either side of the system. The stations are connected directly to the sampler. The load station facilitates the movement of the sample rack onto the sampler and the unload station allows the removal of the rack from the sampler after tests are completed. The sample racks are placed into a removable tray and the tray is loaded onto the load station. The tray holds up to 14 racks. This is in addition to the six racks that can be placed directly on the sampler. Sensors located on the Load Station detects the presence of the tray and the sample racks.

To start the transport of the racks to the pipetting station, press the Start Button. Once the testing is completed, the racks move to the Unload Station where you can remove them. The load station can be continuously loaded provided there is sufficient space on the sampler or the unload station.

Barcode Reader

The barcode reader is located inside the instrument, facing the pipetting station. The barcode reader scans the barcode label on a sample tube and its identification is sent to the Laboratory Information System (LIS) via the analysis processor for skip/run instructions, based on user-defined configuration.

Pipetting Station

The pipetting station is located on the front of the DxU Microscopy Series. When running instructions have been received from the analysis processor, the pipettor mixes the sample, and then aspirates approximately 1mL of sample.

Optic System

The optic system is composed of the following elements:

- Strobe Lamp
- Microscope
- CCD Camera
- Flowcell

The strobe lamp is attached to the microscope, which is mounted horizontally. The strobe lamp flashes are synchronized with the CCD camera. A collimator focuses the light.

Each picture captured by the CCD camera represents the view of a small quantity of sample as the strobe lamp illuminates the field of view. Each of these pictures or *frames* represents a precisely measured volume of uncentrifuged specimen present in the flowcell under magnification.

Waste

The waste pump discards the fluids into a drain or waste container.

Start Button

The Start button is located on the bottom left of the DxU Microscopy Series. This button starts the sample processing after the sample racks have been loaded onto the sampler.

Beacon Lights

Beacon lights are reflective of the instrument screen status.

Located on the instrument exterior, from left to right:

- Green light indicates Standby mode
- Blue light indicates Measure mode
- Red light indicates Error mode

PC Module

The PC module contains two major software functions:

- Results Processor
- Analysis Processor

Results Processor

The results processor controls the mechanical functions of the DxU Microscopy Series for specimen transport and fluid handling. Captured images are received from the CCD camera. The image processing software digitizes captured frames of electronic images. Within a frame, individual objects are detected, the edge of each object is traced, and its size is identified.

After processing, the following data is sent to the analysis processor for completion and report of microscopy results:

- Barcode identification
- Sample rack number - tube position
- Date and time of test, status
- Particle images

Analysis Processor

The analysis processor provides the user interface, and completes particle image classification.

The analysis processor receives the barcode information from the microscopy unit and, if interfaced to a Lab Information System (LIS), queries the host computer for orders. The order may be to perform microscopy, to not perform microscopy or to reflex microscopy based on the chemistry results (if connected to an automated chemistry system). In the later situation, chemistry results are received from the chemistry system, and based on user-defined criteria, the analysis processor directs the microscopy module on appropriate microscopic processing of a given specimen.

The sample processing data are received, like particles are grouped and tabulated, and morphological features are used to specifically identify and report the particle as 1 of 12 categories.

The analysis processor consolidates results from the automated chemistry system (or another source of chemistry results via the LIS) with microscopy results into the database for automatic reporting of results or for operator review and edit of particle images, if necessary.

Keyboard

Use the physical or virtual keyboard to enter alphanumeric specimen identifiers and data input.

Mouse

Use the mouse to navigate the monitor screen.

Monitor

Use the monitor to view your selections on the screen.

Software Functions

Beckman Coulter software is intended for use with Beckman Coulter/Iris urinalysis instruments to perform functionality associated with the automated urinalysis testing.

The analysis processor software provides the following functions:

- Automatically classifies microscopic particles in each specimen and determines if the results can be auto-reported, based on user-defined configuration.
- Controls the User Interface:
  - Provides edit functions to reclassify particle images based on operator decisions.
  - Archives and displays images of microscopy results from each sample for operator review, on demand.
  - Consolidates, generates, prints, and electronically transmits reports.
  - Maintains a list of flagged specimens identifying those requiring further intervention due to missing IDs, missing chemistry results, or other analytical or processing situations.
  - Provides an export/import function for long-term storage and easy retrieval of combined chemistry results and microscopy images.
  - Provides a means of backup or system restoration.

User Interface

The user interface software is composed of three main screens:

- Instrument screen
- Specimen screen
- Work List screen

DxU Microscopy Series Status

Located on the top left side of the screen, displays:

- Status light indicator:
  - Grey = OFF
  - Green = Standby
  - Blue = Measure
  - Red = Error
- Identification of the currently logged operator
- Identification of the currently aspirated tube (if any) Rack# - Position#
- Icon of the highest priority alarm (if any) and short description of the error condition

Table 1.16 DxU Microscopy Series Status

Status	Icon
Low priority	
Medium priority	
High priority	

View Selector

The view selector is located on the top right side of the screen.

The view selector lets you access the following screens when you select the applicable button:

- Specimen
- Work List
- Instrument

Instrument Screen

DxU Microscopy Series - Stand-alone

The instrument screen is accessed by selecting **Instrument** and is composed of the following elements: DxU Microscopy Series Status Area, View Selector Area, Information Pane, Screen-Level Functions Area, and Task-Level Information Area.

The Side Panel is located on the farthest right side of the instrument screen.

Side Panel displays:

- IFUs
- Notepad
- Reader (Contains information documents, Memory Joggers, Help PDFs, etc.)
- Videos

The DxU Microscopy Series Status Area is located on the top left of the Instrument screen, while the View Selector is located on the top right of the screen and includes options for Specimen, Worklist, and instrument screen options. The Information Pane is located mid-right-hand side of the instrument screen, while the Screen-Level Functions Area is located on the bottom of the screen. The Task-Level Information Area is located between Manual Orders and the System Status.

DxU Microscopy Series and Chemistry System

This Instrument screen is composed of the following elements: DxU Microscopy Series Status Area, Chemistry System Status Area, View Selector Area, Information Pane, Screen-Level Functions Area, and Task-Level Information Area.

The Side Panel is located on the farthest right side of the instrument screen.

Side Panel displays:

- IFUs
- Notepad
- Reader (Contains Encyclopedia, Memory Joggers by default. Can be used to load any PDF files.)
- Videos

The DxU Microscopy Series Status Area is located on the top left of the Instrument screen, while the Chemistry System Status Area is located immediately to its right. The View Selector is located on the top right of the screen and includes options for Specimen, Worklist, and Instrument screen options. The Information Pane is located mid-right-hand side of the Instrument screen, while the Screen-Level Functions Area is located on the bottom of the screen. The Task-Level Information Area is located between Manual Orders and the System Status.

Main Screen

Table 1.17 Main Screen

Field	Display	Button
Operator	Currently logged on operator, if any.	**Logon** **Logoff**
Last Micro Calibration	Date/time of the last valid microscopy calibration, if any	N/A
Last Micro QC	Date/time of the last microscopy valid control run, if any	N/A
Last Micro Auto Focus	Date/time of the last microscopy valid Focus operation, if any	N/A
Last Reflectance Check	Date/time of the last successful reflectance calibration check (DxU 810c Iris)	N/A

Table 1.17 Main Screen *(Continued)*

Field	Display	Button
Last SG/Color/Clarity Check	Date/time of the last successful specific gravity, color, and clarity calibration check (DxU 810c)	N/A
Last Chem QC	Date/time of the last successful chemistry quality control (DxU 810c Iris)	N/A
LIS	LIS status	**Check LIS**
Manual Orders	Displays racks enabled in Manual Orders	**Clear All**
RMS/Enrollment/RDS Status	Connected/Enrolled/Inactive	**Stop RDS**
System Status	Online Offline (displayed in red)	**Go Off line** **Go On line**

Alarms

Alarms appear in the Information Pane of the screen and display the detailed list of unresolved alarms, sorted by priority, then date/time.

Screen-Level and Side Panel Functions

Table 1.18 Screen-Level Functions

Button	Function
Manual Orders	Access the Manual Orders screen. See Manual Orders in CHAPTER 7, Manual Orders for more information.
Consumables	Access the Consumables window. See Consumables Information in CHAPTER 17, Consumables Traceability for more information.
Quality Review	Access the Quality Review screen. See Quality Control Review in CHAPTER 4, Quality Control for more information.
QC Statistics	Access the QC Statistics screen. See QC Statistics in CHAPTER 4, Quality Control for more information.
Settings	Access the Settings screen for user-defined instrument setup. See Settings Screen in CHAPTER 9, Setup for more information.
Maintenance	Access the Maintenance screen for: • Reflectance Check Chemistry Service (Chemistry System) • Backup • Restore (Manager Only) • System Info • Tallies • Errors • Shutdown • Restart • Defragment • Check Disk • See Maintenance Options in CHAPTER 10, Troubleshooting for more information.

Table 1.18 Screen-Level Functions *(Continued)*

Button	Function
Sequence #	Access to a Sequence number screen where the next sequence number to be used can be entered. See Sequence Number in CHAPTER 9, Setup for more information.
Banner	The Banner is located on the lower left side of the main screen. It contains icons for: • Windows Explorer • Virtual Keyboard • Sticky Notes • Snipping tool • Paint

Table 1.19 Side Panel Functions

Button	Function
IFU	Access to the IFU tab to read or review onboarded IFUs.
Notepad	Access to the Notepad tab to have pasting images and screenshots as well as notepad capability.
Reader	Access to the Reader tab to have helpful PDFs stored on the USER drive.
Video	Access to the Video tab to review onboarded videos.

Work List Screen

The work list contains only unreleased results. The Work List screen is accessed by selecting the **Work List** button. The work list displays the specimen ID, date, and time at which the specimen was processed, rack, and tube position numbers, and status of each specimen. Selecting a specimen ID and selecting the Specimen tab, or double-clicking the specimen ID opens the Result Specimen screen for that sample. If the Body Fluids module is enabled, an additional column is displayed identifying the type of fluid, body fluid, or body fluid controls.

From the Work List, while online, you can:

- Sort the Work List
- Delete a specimen
- Un-delete a specimen
- Correct/modify the specimen ID
- Edit patient demographics
- Print the Work List

From the Work List, while offline, you can:

- Export specimens results
- Import specimens results

The **Search** button allows you to search results by ID and sequence number, operator ID, date/time, demographics, body fluid type (if the body fluid module is enabled), specimen awaiting transmission, released specimens, or incomplete specimens.

The results are displayed in the *Found List*. Selecting the **Search** button toggles between the Work List and the Found List. When the Found List is displayed, selecting the **Search** button displays the Work List.

From the Found List, while offline, you can re-report specimen results, and import/export specimen results.

For more information about the Work List screen, see Work List Screen in CHAPTER 6, Data Review.

Specimen Screen

The Specimen screen shows a summary of the results for the specimen chosen from the Work List/Found List. The Specimen screen button is located at the top right of the instrument display. Double click to open the Specimen screen and reveal contents.

The Main Area is located at the left-hand side of the Specimen screen.

The Main Area displays:

- **Particle** button showing the short name of the particle category.
- **Concentration** button showing the particle concentration.
- Graphical representation of the results for each particle with normalized user-defined thresholds. Results in the Normal Range are green; those in the Abnormal Range are red. If the Auto-Release function was enabled, results needing to be reviewed by the operator are displayed in yellow. See Editing a Specimen with Yellow Range Indicator in CHAPTER 16, Auto-Release (Edit-Free Release).

The Information Area is located at the right-hand side of the Specimen screen.

The Information Area displays:

- Current status for the specimen.
- Specimen ID - patient demographics (if enabled).
- Time at which the specimen was aspirated by the DxU Microscopy Series.
- Rack number and tube position number, (sequence number).
- Dilution ratio
- Red blood cells section and dysmorphic RBCs (if enabled)
- Urine Culture Indicator Checklist section showing LEU and NIT results if connected to a chemistry system, along with WBC, bacteria and all Small Particles count.
- Chemistry results, if enabled.
- Comment, if any, entered by the operator.
- If the Auto-Release function was enabled, placing the mouse cursor over the Info Pane area displays more information regarding the result tag. See Editing a Specimen with Yellow Range Indicator in CHAPTER 16, Auto-Release (Edit-Free Release).
- Active/cleared flag, if any, priority icon, and whether or not the flag can be resolved.

For more information about the Specimen screen, see Specimen Screen in CHAPTER 6, Data Review.

CHAPTER 2

Operation Principles

Theory of Operation

The DxU Microscopy Series auto-identifies and processes specimens in 10-position racks by mixing, sampling, and analyzing automatically. The DxU Microscopy Series presents a specimen sandwiched between enveloping layers of lamina to a microscope coupled to a CCD (charge coupling device) video camera. This lamination positions the specimen exactly within the depth of focus and field of view of the objective lens of the microscope. Lamination is the planar equivalent of axial hydrodynamic focusing, used to position cells in certain types of blood cell counters and flow cytometers. It has the added advantage of achieving orthoscopic particle orientation, thereby presenting asymmetric particles with their largest profile facing the direction for image capture.

A CCD digital camera captures five hundred frames per sample, as each microscopic field of view is illuminated by the flash of a strobe lamp. The resulting pictures are digitized and delivered to the Analysis Processor computer. A previously stored image of a blank background is subtracted from the individual fields of view, enhancing the morphology of the captured particle.

Individual particle images are isolated within each frame. The Auto-Particle Recognition (APR) software, a highly trained neural network, uses size, shape, contrast and texture features to classify each image into one of 12 categories: RBCs, WBCs, WBC Clumps, Hyaline Casts, Unclassified Casts, Squamous Epithelial Cells, Non-squamous Epithelial Cells, Bacteria, Yeast, Crystals, Mucus, and Sperm. Additionally, 27 predefined sub-classifications are available for identifying specific types of casts, crystals, non-squamous epithelial, dysmorphic, and others.

Particle concentration is calculated using the number of particles images and the volume analyzed. User-defined release criteria are checked and results are sent to an operator review screen or directly uploaded to the LIS based on these criteria. Specimen results can be edited, imported, and exported.

Calculation of Results

The DxU Microscopy Series is designed to provide uniform specimen flow past the microscope objective. The true volume is determined by using a calibration solution having a known concentration of particles and counting the number of those particles seen per frame. Thus, the known particle concentration divided by the particle count per frame equals the volume per frame. Since the volume per frame is consistent and always known, particle counts are accurately measured as particles per microliter by the system, and can be reported in this manner, if desired.

Results for microscopic particles can also be reported as particles per field of view, as typically done in urinalysis, if the equivalent volume observed in one field with slide microscopy is known. The volume of one field of view in manual microscopy was determined experimentally by measuring the average volume of a drop of normal urine delivered by a Pasteur pipette. This volume spreads out beneath the cover slip. This volume divided by the area of the cover slip determines the thickness

through, which particles settle before they are viewed on the slide. The numerical aperture of the objective lens determines the area viewed at any one time. This area multiplied by the average wet mount thickness, is the effective observed volume equivalent seen in one field of view.

Auto-Classification of Particles

Particles are classified using neural network pattern recognition by the Auto-Particle Recognition software (APR). In most cases, the auto classification can be performed with high confidence and therefore, the specimen result can be automatically reported without operator review or intervention.

In cases requiring visual review, all the particle images are sorted and displayed into the auto-classified categories, which speeds up the reviewing process. While the classification of particles is computer-aided, human judgment can still be exercised.

Auto-Release of Results

The Auto-Release feature allows you to automatically release results obtained by the software and the APR without human intervention according to user-defined parameters. Results are released to the selected destination. See Auto-Release (Edit-Free Release Settings) in CHAPTER 16, Auto-Release (Edit-Free Release) for more information about this feature.

Microscopic Particle Identification

Table 2.1, Auto-Classification Categories is provided to help in identifying the type of particle images displayed on the screen. The particle image examples show what can be expected to be seen on the edit screens.

Auto-Classification Categories

The APR will classify and report the following categories.

Table 2.1 Auto-Classification Categories

Category	Abbreviation	Picture (Example Only)
Red blood cells	RBC	
White blood cells	WBC	

Table 2.1 Auto-Classification Categories *(Continued)*

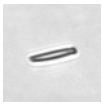
Category	Abbreviation	Picture (Example Only)
White blood cell clumps	WBCC	
Squamous epithelial cells	SQEP	
Non-squamous epithelial cells	NSE	
Bacteria	BACT	
Crystals	UNCX	   
Hyaline Casts	HYAL	
Unclassified Casts	UNCC	
Yeast	BYST HYST	

Table 2.1 Auto-Classification Categories *(Continued)*

Category	Abbreviation	Picture (Example Only)
Sperm	SPRM	
Mucous	MUCS	

Individual images that do not classify as any of the above types are identified as UNCL (Unclassified).

In order to differentiate and identify types/subtypes of crystals, casts, non-squamous epithelial cells, or yeast, the operator must review the images and manually sub-classify these particles using the Specimen screen.

For laboratories not requiring further differentiation of the auto-classified categories listed above, routine review of auto-classified specimens is not needed. Each laboratory can configure its own manual review thresholds and criteria to ensure that specimens that fail to meet such criteria are properly reviewed and confirmed by a trained technologist.

CHAPTER 3
Startup

Logon

The **Logon** button is located on the top right side of the Instrument screen. Until someone is logged on, the **Specimen**, **Work List**, **Manual Orders, Consumables,** and **Instrument** buttons are inactive.

1 Select **Log On**. The Log On screen is displayed.

2 Type the user name in the *Identifier* field or use the drop-down arrow on the right side of the field to display and select the user name.

3 Type the user password in the *Password* field.

4 Select **OK** to log on.

CHAPTER 4

Quality Control

Quality Control

The Quality Control program is used to collect QC data and display QC reports and statistics. These functions are used to obtain data, verify and monitor proper system operation.

You can confirm frame volume reproducibility at any time by running controls having known particle concentrations, such as iQ Positive Control.

Control Material (DxU Microscopy Series)

iQ Control/Focus Set is used to focus and control the instrument.

iQ Positive Control is used as an abnormal, and iQ Negative Control is used as a normal control to verify accurate counting by the instrument. iQ Focus is used to check light level and focus the instrument. Barcode labels that contain lot number, expiration date, and expected range are provided for each product.

iQ Positive Control and iQ Focus are suspensions of fixed human red blood cells in a buffered, isotonically balanced solution. A highly accurate concentration count of these cells is certified and the expected counting reference value is printed on each label.

NOTE For Body Fluid Control information, see Quality Control in CHAPTER 15, iQ Body Fluids Module.

Control Material (When Connected to DxU 810c Iris)

Beckman Coulter recommends using IRISpec CA/CB/CC. Any control material having the necessary analytes and specific gravity for urine chemistry quality control can be used.

Control Frequency

All controls should be run at least once every 24 hours or as specified in the Laboratory's QC Procedure manual.

iQ Focus should be performed at least once every 24 hours, preferably before running the iQ controls and following the cleansing.

Handling QC Material (DxU Microscopy Series)

iQ Positive Control and iQ Focus should be refrigerated for long-term storage and brought to room temperature before use. After opening, these products should be stored between 2 to 8° C (35.6 to 46.4° F) refrigeration. Shake the bottle as described below before each use to maintain consistent particle concentration.

iQ Negative Control is a particle-free solution. It should be stored between 2 to 28° C (35.6 to 82.4° F) and SHOULD NOT be shaken before use. After opening, this product should be stored between 2 to 28° C (35.6 to 82.4° F).

Preparing DxU Microscopy Series Quality Control Rack

1 Clean and focus the instrument once per day:

- **a.** Place tubes in positions 1, 2, 3, and 5. Leave position 4 empty.
- **b.** Place 3 ml of Iris Cleanser in tube in position 1.
- **c.** Place 3 ml of Iris Diluent in tube in position 2.
- **d.** Place 3 ml of Iris Diluent in tube in position 3.
- **e.** Shake the iQ Focus bottle. Hold the bottle upside down and give it five hard shakes followed by five gentle inversions. Let sit about one minute until the air bubbles are dispersed.
- **f.** Place a Focus Barcode Label on the tube, add 6 ml of iQ Focus into the tube, and place the tube in Position 5 of the QC rack.

2 Shake the iQ Positive Control bottle. Hold the bottle upside down and give FIVE HARD SHARP SHAKES followed by five gentle inversions. Let sit about one minute until the air bubbles are dispersed.

NOTE Do not use plastic tubes or pipetting devices. The laboratory is responsible for validating the polystyrene plastic tubes for use with QC.

3 Place a Positive Control Barcode Label on the tube, add 3.0 mL of iQ Positive Control into a tube, and place the tube in Position 6 of the QC Rack (orange insert).

4 **DO NOT SHAKE** the Negative Control bottle. Place a Negative Control Barcode Label on another tube, add 3.0 mL of iQ Negative Control in the tube, and place that tube in Position 7 of the QC Rack (light blue insert).

5 If running a second lot of iQ Positive Control and iQ Negative Control, place the second iQ Positive Control in Position 8 and the second iQ Negative Control in Position 9. Be certain to use the barcode labels from the box containing the new lot on these tubes.

NOTE Do not place a tube in position 10. This will shut down the system.

6 Place the QC rack on the DxU Microscopy Series Sampler. See Control Rack in CHAPTER 10, Troubleshooting.

Primary control positions, 6 and 7, require that both Positive and Negative Controls be run together.

Secondary control positions, 8 and 9, are optional and intended to allow the laboratory to run controls in parallel for new lots.

Any control rack containing a tube in Position 8 and 9 must contain tubes in Positions 6 and 7.

Handling QC Material (Chemistry System)

See your urine chemistry system operator's manual for instructions on running QC.

Running QC (DxU Microscopy Series)

NOTE Beckman Coulter recommends running Iris System Cleanser available as Iris System Cleanser Pack, Iris Diluent available as Iris Diluent Pack, and Iris Focus available as Focus iQ Control Focus Set, at least once per 24 hours. The optimal time to do this is while running a QC rack.

1 Place the QC Rack onto the DxU Microscopy Series Sampler and press Start. The QC Rack will automatically be processed.

The system compares the expiration date of the QC material and chemistry strip (if connected to a workcell) to the current instrument date/time, to verify that the material or chemistry strip is valid for use.

When control testing is completed, the results are sent to the LIS and/or printed as indicated in Settings.

The results will also automatically move to the QC Review and QC Statistics screens.

2 If the results are within the allowable range, the date and time of the QC will be displayed on the Last QC field of the Instrument screen. Proceed to patient testing.

3 If the results are out of range, repeat the controls using fresh aliquots of both iQ Positive and iQ Negative Controls. If the results are still out of range, use new bottles. If the results remain out of range, contact your Beckman Coulter Representative.

QC/CAL Result Flags

QC/CAL ID

CAUSES	REMEDIES
The barcode reader did not read the appropriate label on a specific tube from a QC/Calibration rack. A patient barcode was read on a tube in the QC/Cal rack. The rack was ejected and the system taken offline.	Entering a manual ID is not possible. Make sure barcode labels are present and correctly oriented. Select **Go On line**. Re-run the QC rack from the misread tube on. Example: if the Focus ID was not read, remove the Cleanser and Diluent tubes and run Focus, Positive and Negative. If the Negative Control fails, however, both Positive and Negative Controls must be re-run.

QC/CAL Out of Order

CAUSES	REMEDIES
On the control rack, at least one tube with the provided QC/CAL barcode label was in the wrong position.	Control rack Make sure the tubes are in the correct positions. Repeat the run for the control rack. Calibration rack Run a control rack with 6.00 mL of Focus tube in position 5. Refill and repeat the run for calibration rack.

Quality Control Review

1 Select **Instrument**.

2 Select **Quality Review**. The Quality Review screen is displayed.

The currently used QC lot is displayed as long as it is being used. Other lots are removed on first in, first out basis.

Data can be sorted by selecting a column header. A repeat click will toggle between ascending (^) and descending (V) order. The default is Date/Time – ascending order.

Column headers include: Lot ID, Date-Time, Type, Status, and REF. Options located at the bottom of the screen include: Search, Print List, Re-Report, Remove, Save, and OK.

Search Button

The **Search** button allows access to the QC Search screen. You can search the QC database using specific criteria.

- **Microscopic** and **Chemistry** button searches for both microscopic and chemistry controls.
- **Microscopic** button searches only for microscopy controls.
- **Chemistry** button searches only for chemistry controls.

Lot Field

Displays the control lot information.

Type Field

Displays the control type (positive or negative, primary or secondary).

Status Field

Displays the status (passed-failed).

Date-Time-Combo-Box

Check **Use Date-time** to display the *From* and *To* drop-down options available for selection.

Select the specific criteria for the Search, and then select **OK** to display the results.

Print List Button

Select **Print List** to print all the QC results on the list.

Re-Report Button

The **Re-Report** button allows you to select a destination to re-report Quality results. The following options can be selected:

- Current Row
- Individual Reports for all rows
- Screen, LIS, and/or printer

---

1 Select the row for the Quality results to be re-reported.

---

2 Select **Re-Report**. The Re-Report screen is displayed.

3 Select the desired option, and then select **OK**.

NOTE Row options includes Current Row and All Rows options includes Individual Reports, Consolidated Reports, and Urine Culture Candidates Report. Destination options include Screen, LIS, and Printer.

Remove

The **Remove** button allows a manager to remove a known human error (e.g., Negative Control in Positive position or similar type error). The operator with manager status logged in at the time is documented and the reason for removal should be documented. The removed data will remain in QC Review but will not be part of the QC statistics.

1 Select the result to be removed and then select **Remove**. The Comment screen will be displayed.

2 A comment must be entered before validation of the removal by selecting **OK**.

3 After selecting **OK**, the status will be changed to reflect the fact that the result has been removed and is no longer included in the statistics.

4 During the process of removing QC data, the **Remove** button changes to **Restore** to allow restoring the removed QC data.

5 During the removal process, a dialog box (Edit Comment) will appear, prompting the operator to free-text a comment about why the result was removed. The operator's log on name is captured in the Comment field.

Save Button

This option allows you to save QC results for long term storage in HTML format, which can be opened and saved on virtually any computer.

QC Report

DxU Microscopy Series QC Report

1 The QC report for the DxU Microscopy Series can be reviewed by highlighting the desired ID and by selecting Re-report.

2 A screen is displayed where the QC report destination can be selected. See Re-Report Button.

3 The DxU Microscopy Series QC report will display the Control name, operator identifier, analysis time stamp, lot ID, expiration date, and status (pass/fail). The report will also indicate the results count, lower and upper limit of acceptance and status (pass/fail).

If an expired material was used, mention of it is displayed in red for the chemistry instrument only. See CHAPTER 9, Setup for more information.

4 A manager-level operator can enable the Expired Consumable Lockout Override function in order to run samples on the instrument. See Expired Consumable Lockout Override in CHAPTER 9, Setup.

Chemistry System QC Report

1 The QC report for the chemistry system can be reviewed by highlighting the desired ID and by selecting **Re-report**.

2 A screen is displayed where the QC report destination can be selected.

3 The Chemistry QC report will display the Control name, operator identifier, analysis time stamp, rack position #, lot ID, expiration date, test strip lot ID, test strip expiration date, and status (pass/fail). The report will also indicate the results for all the analytes, lower and upper limit of acceptance and status (pass/fail). The overall status will be indicated as fail if any one of the analytes has failed.

Print Button

Select **Print** to send the report to the printer.

Save Button

This option allows you to save QC results for long term storage in HTML format, which can be opened and saved on virtually any computer.

Saving QC Results

Saving All QC Results

Follow the steps below to save QC with Windows 10:

NOTE Drive E is not an available option with Windows 10. A new drive called User (U:) is available.

1. Select **Instrument**.
2. Select **Quality Review**. The Quality Review screen is displayed.
3. Select **Save** to display the Windows save screen.
4. Select the User (U:) drive to save the file.
5. Select the folder and enter the file name of the QC file to be saved.
6. Select **Save**. Select **OK** to exit.

Retrieving Saved QC Results

To retrieve saved file (as needed):

1. Select  and **D**. The User (U:) drive is displayed.
2. Double-click to access the User (U:) drive.
3. Find the file.
4. Highlight the saved file. Right-click and select **Open with > Internet Explorer**.

5 Saved File contents (Quality Review List Report) is displayed. Click **X** to close windows.

Saving a Specific QC Result

NOTE Drive E is not an available option with Windows 10. A new drive called User (U:) is available.

1 Select **Instrument**.

2 Select **Quality Review**. The Quality Review screen is displayed.

3 Highlight a specific QC result to be saved, and then select **Re-Report**.

4 Select the Re-Report Destination and select **OK**.

5 The Report Results screen for the selected QC is displayed. Select **Save** to display the Windows Save screen.

6 Select the User (U:) drive to save the file.

7 Select the folder and enter the file name of the QC file to be saved.

8 Select **Save**. Select **OK** to exit.

NOTE Data is saved just as it is displayed on the screen. Chemistry QC will display result, reference range (if any) and pass/fail. Microscopy QC will display the numerical result along with pass/fail.

Saving QC Results with Specific Search Criteria

NOTE Drive E is not an available option with Windows 10. A new drive called User (U:) is available.

1 Select **Instrument**.

2 Select **Quality Review**. The Quality Review screen is displayed.

3 Select **Search**. The Quality Search screen is displayed.

4 Choose desired search criteria.

5 Select **OK**; All results meeting the selected search criteria will be displayed.

6 Select **Save** to display the Windows save screen.

7 Select the User (U:) drive to save the file.

8 Select the folder and enter the name of the QC file to be saved.

9 Select **Save**. Select **OK** to exit.

Saving on USB Ports or External Hard Drive

The procedure is identical to Saving QC Results. See Saving QC Results.

QC Statistics

1 Select **Instrument**.

2 Select **QC Statistics**. The QC Statistics screen is displayed.

3 To view a specific report, select the control lot number. The report is displayed.

Microscopy QC Only

Each type/lot specific report contains the control identifier, report time stamp, lot number, mean value, standard deviation, coefficient of variation, minimum and maximum counted values, target value, and the upper and lower acceptable limits.

Chemistry QC Only

Chemistry QCs are plotted by QC Lot number.

Each type/lot specific report contains the control identifier, report time stamp, lot number, and expiration date.

Chemistry QC chart indicates when chemistry strip lot changes occurred.

Chemistry QC chart do not display SD, Mean, and Target lines.

You can search QC statistics for the currently selected QC material by selecting a specific time frame.

The next section is the Levey-Jennings chart (L-J chart), which displays the last 100 points or 60 days of each lot number.

Below the L-J chart is a list of each point on the chart with its status. Printing this list on the same date every month will provide the laboratory with complete documentation of QC activity.

1. Place the cursor over a data point on the Levey-Jennings chart to display the data for that point.
2. To print the report, select **Print**.
3. To save QC results for long term storage in HTML format, which can be opened and saved on virtually any computer, select **Save**.
4. To close the screen, select **OK**.

CHAPTER 5

Sample Analysis

Specimen Preparation

Use only fresh urine specimens, as defined in *CLSI (Clinical and Laboratory Standards Institute) GP16-A3 protocol, Urinalysis and Collection, Transport and Preservation of Urine Specimens, Approved Guideline, Second Edition*, good laboratory practices, and the laboratory's procedure manuals.

Collect urine in clean and/or sterile containers. If a specimen is not processed within an hour after collection, cap the container tightly and store at 35.6 to 46.4° F (2 to 8° C). Bring the specimen to room temperature before testing.

Mix specimen well before testing.

Do NOT add disinfectant or detergent to the specimen.

Keep specimens out of direct sunlight.

Do NOT centrifuge urine specimens.

Specimens at Room Temperature

The specimen should always be tested at room temperature. If the specimen temperature is outside this range, the specific gravity as indicated may be inaccurate. Allow all refrigerated specimens to return to room temperature before testing.

Hematuria

Gross hematuria may cause incorrect results in subsequent samples. Do not test specimens exhibiting gross hematuria, dilute such specimens before testing or follow such specimens with a tube containing Iris Diluent to eliminate any possible carryover.

Very Dense or Viscous Specimens

Very viscous or very dense specimens may cause flow errors or clogs and require dilution before being run on the DxU Microscopy Series.

Specimen Volume

Specimen volume for analysis by both the automated chemistry system and the DxU Microscopy Series should be at least 4 mL.

The DxU Microscopy Series alone requires 3.0 mL. See the chemistry system operator's manual for more information concerning the specimen volume requirement as a stand-alone. The specimen

volume, when it reaches the DxU Microscopy Series should not exceed the maximum allowed volume based on the tube type indicated in the next section.

Sample Tube Specifications

Dimensions: 16mm X 100mm glass or polystyrene plastic tubes

Examples of tubes that may be used and their maximum volumes

Table 5.1 Sample Tube Specifications

Total Tube Volume (mL)	Type of Tube	Maximum Allowable Volume without Spillage
15 mL	**Fisherbrand Borosilicate Culture Tubes	12 mL
9.5 mL	*Urine collection Conical Base Tubes with no stabilizer, (Greiner Bio-one)	7.5 mL
15 mL	*Hycor KOVA Tubes, Hycor Biomedical Inc.	12 mL
8 mL	*BD Vacutainer Plus UA Preservative Tubes	6 mL
10 mL	*BD Vacutainer Plus UA Tubes without preservative, round bottom	8 mL
12 ml	**Greiner Bio-one (polystyrene) tubes; 16mm x 100mm	9 ml
12 ml	**Globe Scientific (polystyrene) tubes; 16mm x 100mm	9 ml
12 ml	**Alpha Laboratories tubes (polystyrene)	9 ml
12 ml	**Plastic (polystyrene) tubes from Beckman Coulter	9 ml
12 ml	**Any round bottom glass tube (16mm x 100mm)	9 ml

* Validated for use with patient samples.

** Validated for use with iQ control/focus, calibrators, and patients.

Preparing Sample Racks

1 Apply barcode labels to sample tubes, placing the start of the barcode (not the barcode label), approximately ½ inch below the top of a 16x100mm tube or just below the flare of a Kova or Kova-like tube.

2 Transfer at least 3.0 mL of well-mixed, native urine into the barcoded tubes. You may add more if needed, but do not exceed the maximum volume indicated based on the tube type.

3 Place the barcode labeled tubes in the sample racks.

Barcode Labels

Barcodes accepted are Code 128, Code 39, Codabar, and Interleaved 2 of 5 (I 2 of 5).

NOTE Make sure the barcode labels are properly oriented in the rack. The sample tubes must be placed straight and resting in the middle of the grommets located in the base of the rack.

Running Samples

⚠ CAUTION

The instrument should be allowed to warm up for 1 or 2 hours if it was turned off for more than 6 hours.

Normal Workflow With Automated Chemistry System Connected

1 Ensure that sufficient supplies and consumables are available to complete the anticipated workload.

2 Run the Maintenance/QC rack for the DxU Microscopy Series and the QC on the chemistry system. Place the QC rack containing the DxU Microscopy Series Controls on the DxU Microscopy Series Sampler and the Control rack containing the chemistry Controls on the chemistry system Sampler.

3 Press the Start button on each instrument. Refer to the Quality Control section of their respective manuals for details.

4 While the controls are running, transfer patient specimens into barcode labeled tubes and place the tubes into sample racks.

5 When QC results are satisfactory for both instruments, place the sample racks containing specimens on the right side of the chemistry system Sampler.

6 If the chemistry system is in Standby (green light lit), press the Start button. If the chemistry system is in Measure (blue light lit), block the sensor at the front of the Sampler, and the rack will move to the sampling position automatically.

Normal Workflow with Automated Chemistry System and Load/Unload Stations Connected

1 First load a maximum of 6 racks on the right side of the chemistry system. If the Load/Unload Stations are attached, load the racks on the tray and place the tray on the Loading Station on the right. Do not place the rack directly on the Loading Station. Do not place any rack at the front line where the sensor is located. (Load up to a maximum of 14 racks in the tray.)

2 If the chemistry system is in Standby (green light lit), press the Start button. If the chemistry system is in Measure mode (blue light lit) the racks will move automatically when the rack blocks the sensor.

The sample will move across the bridge to the chemistry system sampler and then to the sampling position. The green standby lamp in front of the loading station will blink, as the rack is moving.

After sample processing is completed on the DxU Microscopy Series, the sample racks can be unloaded from the left side of the DxU Microscopy Series Sampler and/or the Unload Station. Never attempt to remove a moving rack.

The testing will be suspended until the full unload tray is removed and replaced by an empty unload tray.

⚠ CAUTION

When using the optional Load/Unload Stations, avoid removing a moving rack or the entire tray if the standby lamp is blinking as it may cause an error and stop the movement. This error will be indicated by a blinking amber light located below the Standby light on the loading station. If an error occurs, turn off the switch at the back of the Load Station, clear the problem then turn the switch back on.

Normal Workflow with Stand-Alone DxU Microscopy Series

1. Run the Maintenance/QC rack on the DxU Microscopy Series. Place the QC rack containing the DxU Microscopy Series Controls on the DxU Microscopy Series Sampler and press Start. See Running QC (DxU Microscopy Series) in CHAPTER 4, Quality Control for details.

2. While the controls are running, transfer patient specimens into barcode labeled tubes and place the tubes into sample racks.

3. When QC results are satisfactory, place the sample racks containing specimens on the right side of the DxU Microscopy Series Sampler.

4. Press the Start button located on the upper left of the DxU Microscopy Series.

5. After sample processing is completed, the sample rack may be unloaded from the left side of the DxU Microscopy Series Sampler.

Normal Workflow with Stand-Alone DxU Microscopy Series with Load/Unload Stations

1. First load a maximum of 6 racks on the right side of the DxU Microscopy Series.

2. When connected to the optional Load/Unload Stations, load the racks on the tray and place the tray on the Load Station on the right. Do not place the racks directly on the Load Station. Do not place any rack at the front line where the sensor is located. (Load up to a maximum of 14 racks in the tray.)

   The sample will move across the bridge to the DxU Microscopy Series sampler and then to the sampling position.

The testing will be suspended until the full unload tray is removed and replaced by an empty unload tray.

Dilutions

When to Dilute

Beckman Coulter recommends that dilutions be performed on grossly bloody, heavy mucoid or very dense specimens, and short samples, in order to avoid clogging the specimen filter.

Dilution Barcode Labels

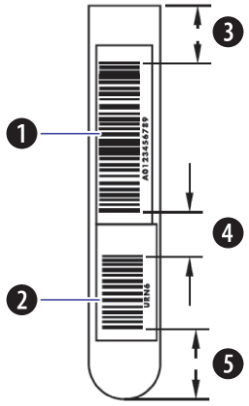
In order to use the dilution factors entered in the Setup (see Editing Dilution Codes in CHAPTER 9, Setup), a secondary barcode label printed in code 128 must be used. The barcode is composed of 4 digits, URN followed by the line number of the desired dilution ratio, with a leading symbol that identifies it as a dilution barcode to the instrument.

Dilution - Specimen Preparation

Chemistry specimens must be run using the dilution rack number 23. This rack is specially labeled not to be processed by the DxU Microscopy Series analyzer. This rack will skip the sampling station and be transferred automatically to the unloading station for retrieval.

1. Fix identical patient barcode labels onto two specimen tubes.
2. Pour 3 mL of urine into one tube.
3. Place the tube onto the dilution rack number 23.
4. Load the dilution rack onto the chemistry sampler for processing.

5 Fix the dilution barcode label on the second tube, as indicated below.



Number	Description	Number	Description
1	Specimen Identification Label	4	10 mm minimum white space between barcodes
2	Dilution Label	5	20 mm minimum white space between end of dilution barcode and bottom of tube
3	14 mm minimum white space between top of tube and patient barcode		

6 Prepare the dilution using Iris Diluent. Pour sample from either the original container or the chemistry tube.

7 Load the dilution tube onto a regular sample rack, other than rack #23.

8 Load the rack on the DxU Microscopy Series sampler, and then press Start.

CHAPTER 6

Data Review

Reviewing Results

Unreleased results can be reviewed using the Work List Screen.

Released results can be reviewed using the Found List Screen after a search has been performed.

Work List Screen

The Work List screen allows you to quickly identify specimens with flags or needing operator review. A vertical scrollbar can be used if all specimen results cannot be displayed on the screen.

The Work List screen displays:

- Specimen ID
- Date/Time of analysis
- Rack number and Tube position (sequence number)
- Specimen status

To display the Work List, select **Work List** located on the top right side of the screen. A number in parentheses indicates the number of specimen results in the Work List. The following descriptions also apply to the Found List. The Work List contains only unreleased results. To find a released result, select **Search** and enter the search criteria.

NOTE Criteria from a previous search is retained when the search screen is reopened. Select **Clear** on the Search screen before initiating a search.

The results will be displayed on the Found List. When the Found List is displayed, select **Search** to return to the Work List.

NOTE The sequence number for a specimen with microscopy results is displayed as 0.

To review a specimen, double-click the specimen row, or select the row and select **Specimens**.

Sort Work List

The work list can be sorted by Specimen ID, Date/Time of analysis, Rack number and tube position, or Specimen status in ascending or descending order. Sorting can be done by using the **Sort Work List** button or by selecting the header.

NOTE The header of the column selected as sort criteria displays ascending or descending order. Double-click the header of the desired criteria to change the sort criteria or reverse the order.

1 Select **Sort Work List**. The Sort Work List screen is displayed.

2 Select the primary sort criteria.

3 Press **OK**. The Work List displays the sorted results.

The ascending sort order for the Status column is:

- STAT
- Flag
- Review

NOTE For DxU Microscopy Series analyzers that are configured and connected to an automated chemistry system, samples can be designated as STAT on the Work List by placing them in positions 1 through 7 of the Chemistry Control/Stat rack. The STAT designation must be initiated by first processing on the automated chemistry system and then the microscopy analyzer. When the Work List or Found List is viewed for STAT samples, these samples appear at the top of either the Work or Found List. The Rack position on the Work List or Found List displays as Rack 28.

Delete Specimen

This function allows you to delete specimen results from the Work List or Found List depending on the status.

1 Select the specimen results to be deleted, and then select **Delete Specimen**. A pop-up box appears prompting to confirm the deletion.

2 Select **Yes**. The specimen results are removed from the Work List. They are transferred to the Delete list where they are stored until the system deletes them on a first in first out basis.

Un-Delete Specimen

This function allows you to restore deleted specimen results to the Work List.

1 Select **Un-Delete Specimen**. The Un-Delete Specimen screen is displayed. Specimen results are displayed in a date/time order, oldest at the top.

2 Select the specimen results to be un-deleted. If multiple results need to be restored, hold the **Shift** key on the keyboard and left-click the results.

3 When all the required results are selected, select **OK**.

Correct Specimen ID

A manager can modify a specimen ID that does not have an ID error flag. Any logged-in operator can correct the ID of a specimen with an ID error flag.

If the patient demographics are being obtained from the LIS, ensure that the patient demographics are corrected whenever a specimen ID is corrected.

1 From the Work List, highlight the Specimen ID to be corrected.

2 Select **Correct Specimen ID**.

3 Enter the correct ID in the Specimen Identifier window.

4 Select **OK**. The Work List now reflects the correct specimen ID.

5 Edit patient demographics for the sample whose specimen ID was corrected before releasing results.

Edit Demographics

If a specific demographic is missing (see Obtain Patient Demographics Information from LIS in CHAPTER 9, Setup), the specimen will be processed and the result will be flagged on the Specimen screen. Even if the Demographics option was not required from the LIS, an operator will be able to add or edit data to all demographics fields.

1 Select the specimen results to be edited, and then select **Edit Demographics**. The Edit Demographics screen is displayed. The header includes the specimen ID, run date/time, and rack number/position.

The Edit Demographics screen includes: Last Name, First Name, Middle Name, Use Date of Birth Option, Date of Birth, Location, Medical Record Number, and Gender.

2 Enter the desired patient demographics, select each day, month, and year to change the date, and then select **OK**. The patient demographics will be displayed on the Specimen screen, printed on the printout reports, and transmitted to the LIS.

Print List

Select **Print List** to print the entire Work List.

Re-Report

The Re-Report function, enabled on the Found List only, allows you to select a destination to re-report specimen results already released. The following options can be selected:

- Individual Reports
- Consolidated Report (more than a single specimen report per page)
- Urine Culture Candidates Report

NOTE Only current row or individual reports can be re-reported to the LIS. The Urine Culture Candidates report is available only if **Additional criteria** was selected for the Search.

1 Select the row for the specimen results to be re-reported.

2 Select **Re-Report**. The Re-Report Destination screen is displayed.

The Re-Report Destination screen includes the option for Current Row under Row, Individual Reports, Consolidated Report, and Urine Culture Candidate Report under All Rows, and Screen, LIS, and Printer under Destination.

3 Select **Current Row**. If more than one row is desired, in the *All Rows* field, select the specific option for the re-report, **Individual**, **Consolidated**, or **Urine Culture Candidates Report**.

4 Select the re-report destination (more than one destination can be selected).

5 Select **OK** to re-report the results and close the screen.

Search

The Search function allows you to search specimen results according to specific criteria.

From the Work List screen, select **Search**. The Search screen will be displayed.

Search by Specimen ID

1 To search specimens within a range:

- Enter the first specimen ID # in the *From* edit box.
- Enter the last specimen ID # in the *To* edit box.
- Select **OK**.

2 To search a specific specimen #:

- Enter the specimen ID # in the *From* edit box.
- Select **OK**.

Search by Sequence Number

1 To search specimens within a sequence range:

- Enter the first specimen sequence # in the *From* edit box.
- Enter the last specimen sequence # in the *To* edit box.
- Select **OK**.

2 To search a specific sequence #:

- Enter the sequence # in the *From* edit box.
- Select **OK**.

Search by Operator ID

1 To search specimens released by a specific operator:

- Use the pull-down button to select the operator ID.
- Select **OK**.

2 To search specimens released for all operators:

- Leave the field blank to obtain a complete search.
- Select **OK**.

Search by Date-Time (Range)

1 Clear all previous search entries by selecting **Clear**.

2 Select the **Date-time** check box.

3 To search specimens within a range:

- Enter the date or select the down arrow and select a date from the calendar.
- Select the hour and use the arrows to change. Minutes and seconds can be done the same way.
- Select **OK**.

4 To search specimens processed during the last 24 hours, select **24 Hours.** The Date-time range automatically displays the last 24 hours range.

5 To search specimens processed during the current day, select **Today**. The Date-time range automatically displays the current day range from 0:00:00 to the current time.

6 To search specimens for a specific lot number, see Consumables Search in CHAPTER 17, Consumables Traceability.

Search by Demographics

Last Name

1 To search for a specific last name:

- Enter the last name in the first edit box.
- Select **OK**.

2 To search within a specific last name range:

- Enter the initial last name in the first edit box.
- Enter the final last name in the *To* edit box.
- Select **OK**.

First Name

1 To search for a specific first name:

- Enter the first name in the first edit box.
- Select **OK**.

2 To search within a specific first name range:

- Enter the initial first name in the first edit box.
- Enter the final first name in the *To* edit box.
- Select **OK**.

Age

1 To search for a specific age:

- Enter the age in the first edit box. To search for a specific age, the age must be reflected as a decimal value (i.e. 10 years 3 months = 10.25 yrs; 10 years, 6 months = 10.5 years)
- Select **OK**.

2 To search within a specific age range:

- Enter the initial age in the first edit box.
- Enter the final age in the *To* edit box.
- Select **OK**.

Specific Location

NOTE When entering the specific location, make sure to use the same terminology and spelling as used by the LIS.

1 Enter the location in the edit box.

2 Select **OK**.

Search with a Combination of Parameters

NOTE Any combination of parameters can be used for a search. Each field can be entered using either specific data or a specific range. For example, it is possible to search using a range of last names, a range of first names, a specific age and/or a specific location. Specimen results corresponding to the defined criteria entered in the Search screen will be displayed in the Found List.

1 To search with specific parameters:

- Enter the specific data only in the first edit box.
- Repeat as necessary for the other search parameter edit boxes.
- When all the necessary data has been entered, select **OK**.

2 To search within parameter ranges:

- Enter the initial data in the first edit box.
- Enter the final data in the *To* box.
- Repeat as necessary for the other search parameter edit boxes.
- When all the necessary data have been entered, select **OK**.

Search with Urine Additional Criteria

1 Check the **Additional criteria** check box.

2 Select **Re-Report**.

3 Select the down arrow and select **Urine Culture Candidates**. See Urine Culture Candidates Report.

4 To select a report with no urine culture indicators observed, select **No Urine Culture Indicators Observed**.

5 Select **OK**.

Select Body Fluid Type

See Search Features in CHAPTER 15, iQ Body Fluids Module.

Show Specimens Awaiting Transmission Only.

This option can be combined with the other search options.

1 Select the checkbox to restrict the search to results pending transmission.

2 Select **OK**.

Show Released Specimens Only

This option can be combined with the other search options

1 Select the checkbox to restrict the search to released specimen.

2 Select **OK**.

Show Incomplete Specimens Only

This option can be used to find the status of specimen pending completion.

1 Select the checkbox to restrict the search to incomplete specimen.

2 Select **OK**.

Clear Button

The last search parameters entered in the Search screen are displayed to facilitate the next search. The **Clear** button removes the previously used search parameters from the search fields.

Specimen Screen

The following data are displayed in the Specimen screen:

The main area displays:

- **Particle** button showing the short name of the particle category
- **Concentration** button showing the particle concentration

- Graphical representation of the results for each particle with user-defined thresholds. Results in the normal range are green, those in the abnormal range are red. If no threshold was selected, the concentration bar will be grey.

The Particle Button is located on the left-hand side of the Specimen screen, while the Concentration Button is located immediately to the right of the Particle Button.

The Information area displays:

- Current status for the specimen.
- Specimen ID and Patient Demographics (if enabled).
- Date/Time of specimen aspiration by the DxU Microscopy Series.
- Rack number and position number (sequence number).
- Dilution Ratio (1:1 is the default. One part in one part = no dilution).
- Red blood cells section and dysmorphic RBCs (if enabled)
- URINE CULTURE INDICATOR CHECKLIST - provides information that can indicate the need of urine culture. These indicators include Nitrite and Leukocyte esterase results (if connected to the DxU 810c Iris only) as well as the Bacteria and WBC results, and all small particles count for the microscopy.
- Chemistry results, if enabled.
- Comment, if one was entered by the operator.
- Active/cleared flag, if any.

All AMOR Button

Select **All AMOR** to classify all the particles in the specimen as amorphous. Any cells that are not Amorphous must all be accounted for by the operator.

Other... Button

Select **Other...** to open a pop-up box with three options:

- All ART which classifies all the particles in the specimen as artifact. All cells that should not be called Artifact must all be accounted for by the operator.
- Separate chemistry and microscopy results.
- Edit chemistry. See Editing Chemistry Results.

Edit Comment Button

Select **Edit Comment** to display the Edit Comment screen, where you can enter a single line of comment for the specimen. The comment will be transmitted to the LIS.

Turbo Edit Button

Turbo Edit on the DxU Microscopy Series is a statistical sampling procedure that reduces the number of images shown without significantly reducing sensitivity or precision. When the text inside the orange **Turbo Edit** button changes color between black and white, the operator will review the sample in Turbo Edit mode. If the number of images for a sample is below the set Turbo limit (500 pictures for the specimen), the results will be displayed in Full Edit.

Full Edit Button

In Full Edit mode, all particles are available for review. Each specimen may be changed to Full Edit and back to Turbo Edit, if desired, by selecting **Turbo Edit** and selecting again.

Edit Button

Select **Edit** to review images from the first particle category displayed in the Results screen. If the Auto-Release function was enabled, the first category needing to be reviewed by the operator is displayed in yellow. See Editing a Specimen with Yellow Range Indicator in CHAPTER 16, Auto-Release (Edit-Free Release).

Redo Button

Select **Redo** to restore the particle classifications to the instrument classifications and settings.

Skip Button

Select **Skip** to display the next specimen on the Work List/Found List.

Hold Button

The **Hold** button is enabled when an edit has been made by the operator. Select **Hold** to save all edits made to this specimen. The operator can then exit the specimen screen without losing their edits or accepting the results.

Before leaving the Specimen screen, select **Hold**.

Accept Button

Table 6.1 Specimen - Accept

If...	Select Accept to...
The specimen was flagged and the **Review Flag Specimen** button was used	Assign the new identifier to the specimen if it had the ID flag Clear the specimen's flags and display the next specimen on the Work List
The specimen was flagged and the **Delete Flagged Specimen** button was used	Delete the specimen and display the next specimen on the Work List
The specimen was not flagged	Release the specimen results with any changes made and display the next specimen on the Work List
The specimen was selected for separation of chemistry and microscopy results	Separate the specimen results Release the chemistry results to the printer and the LIS, Display the released chemistry result on the Work List Place the microscopy results on the Work List pending review

Save or Print a Result Screen

This option allows you to create a bitmap (bmp) file from a specimen results screen. The file can be sent to Beckman Coulter via e-mail for the purpose of diagnosing issues and/or additional customer training.

1 From the Specimens screen, select **Print Screen** to print the screen displayed on the monitor.

2 Select **Save Screen** to save the currently displayed screen as a BMP file. A Save As Windows screen is displayed.

- Select the destination.
- Name the file.
- Select **Save**.

Zoom Feature

This feature allows you to enlarge an image.

1 Display an isolated image on the Specimen screen.

2 Hover over the isolated image.

3 Right-click on the selected isolated image.

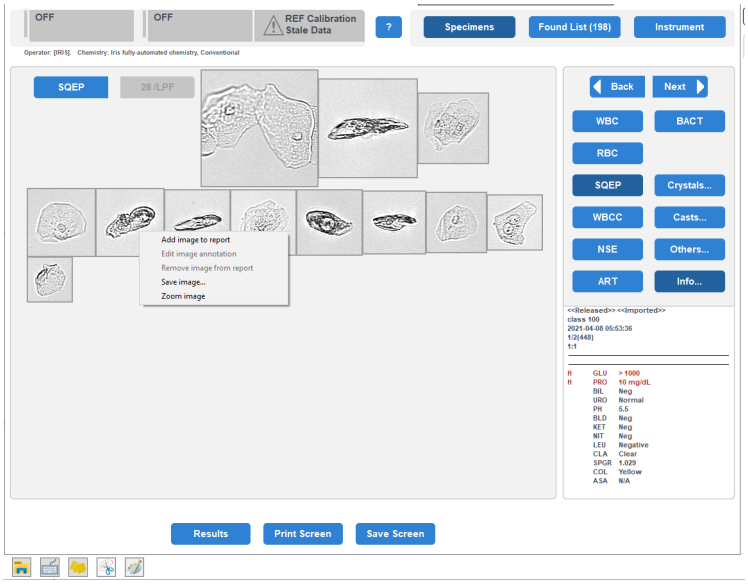
4 Select **Zoom Image**. The selected particle will appear on a separate screen for closer review.

5 Choose symbols to decrease or increase the image as desired (- or +). The zoom function limit is 8X.

6 Select **OK** to exit the screen and continue with your specimen review.

Saving Particle Image

Figure 6.1 Particle Image Screen



NOTE Drive E is not available option with Windows 10. A new drive called User (U:) is available.

1 Go to the Work List or Found List, select the desired specimen ID and select **Specimens**.

2 From the Specimen Review Screen, select a particle button to display the particle images.

3 Right-click on the image to be saved. A dialog box will be displayed.

4 Select **Save image**. A standard save Windows dialog box will be displayed.

5 Select the User (U:) drive to save the file.

6 Select the folder or drive, and then type the name for the file to be saved (if different from the default).

7 Select **Save**. The selected image will be saved in BMP (bitmap) format.

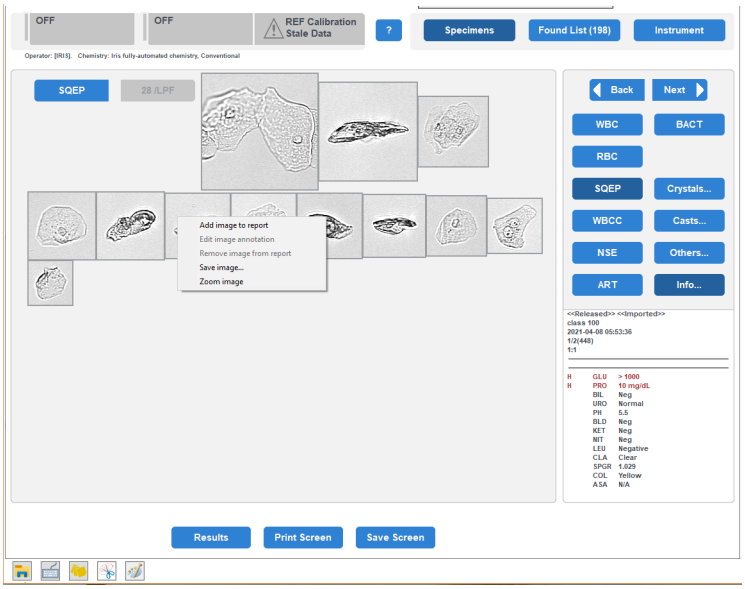
Adding Images to a Report

BEFORE Releasing the Specimen Results

After editing the microscopy results and before releasing the specimen results, particle images can be added to a report for printout.

1 From the Specimen Review screen, select a particle button to display the particle images.

2 Select an image to add to the report, and then right-click. A dialog box will be displayed.



3 Select **Add image to report**. The top right corner of the image will be marked in red indicating that this image has been selected to be displayed on the report.

AFTER Releasing the Specimen Report

1 From the Instrument screen, select **Go Off line**.

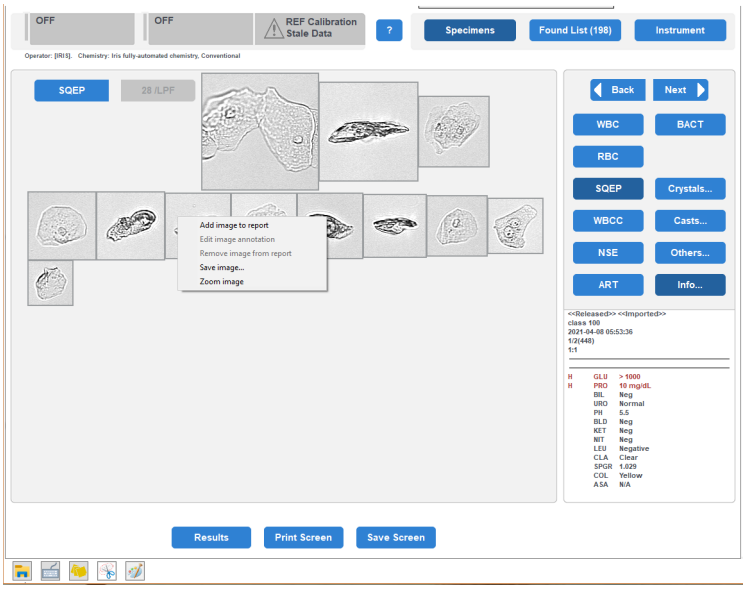
2 Go to the Work List or Found List and select **Search** (as needed) until the Search screen appears.

3 Select **Clear**, enter Search criteria to find released specimen to add images, then select **OK**.

4 From the Found List, select the desired specimen ID and select **Specimens**.

5 From the Specimen screen, select a particle button to display the particle images.

6 Right-click on the image to be saved. A dialog box will be displayed.



7 Select **Add image to report**. The right corner of the particle box will be marked in red.

8 Select **Results**.

9 Select **Accept**.

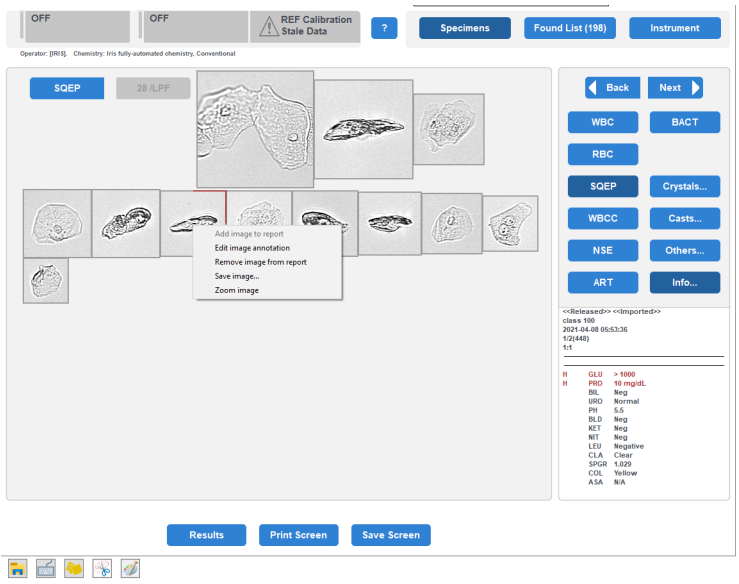
Optional: To view revised report, select: **Work List or Found List** > **Search** > **Clear** > enter Specimen ID > **OK** > **Re-Report** > **Re-Report Destination** > **OK**. Select **OK** to exit.

Adding Annotation to an Image

After an image has been selected to be included into a report (indicated by a red line on the top right corner), a single annotation can be added if necessary. Placing the cursor over an image that has an annotation will display the annotation.

1 Select the image for which the annotation will be added, and then right-click.

2 Select **Edit image annotation**.



3 Using the keyboard, enter the annotation for the selected image on the Edit Comment dialog box.

4 Select **OK**.

Isolated Particle Image Size

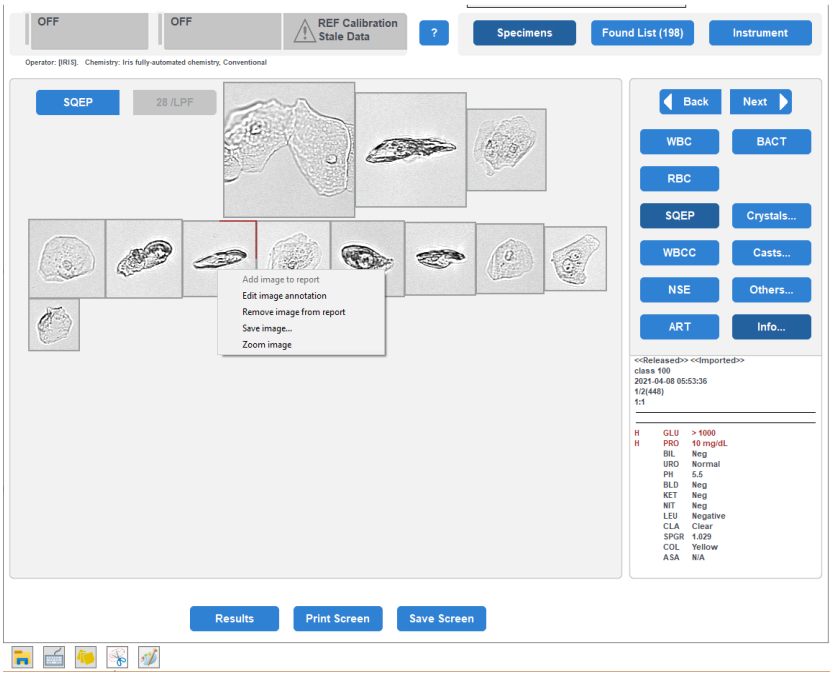
1 Hover the cursor above the isolated particle to determine the size of the image.

2 View the diameter of the particle size.

NOTE If the software is unable to determine the size of the isolated particle, a question mark (?) will be displayed.

Removing an Image from a Report

1 Select an image to be removed from the report, and then right-click it. A dialog box will be displayed.



2 Select **Remove image from report**. The top-right corner of the image marked in red will be removed indicating that this image has been removed from the report.

3 Select **Accept** to save the change.

Verification of Results

The Auto-Release setup screen allows a manager-level operator to automatically release results obtained by the software and the APR without human intervention according to user-defined parameters.

All specimens displayed on the Work List need to be accepted.

To review a specimen, double-click the specimen row or highlight the row and select **Specimens** to display the Results screen.

NOTE Flag conditions must be resolved before accessing the Results screen for that specimen.

Auto-Release Settings Enabled

On the Results screen, particles to review are signaled by their indicator range(s) displayed in yellow.

1 Select **Edit** to review images for the first yellow particle category displayed in the Results screen.

2 To display the previous or next yellow particle, select ◄ **Back** or **Next** ►. If there is no previous or next yellow particle, the Results screen is displayed.

IMPORTANT The **Back** button must not be utilized to exit the Results screen or after reclassification of an entire category has been made. This can lead to unexpected results including loss of data or loss of a category.

NOTE When images for a yellow range have been accessed, the particle range indicator is no longer yellow.

3 To access a non-yellow particle category, from the Results screen, select the particle name's button.

Auto-Release Settings Not Enabled

1 Select the button for the particle to be reviewed. The images for this particle are displayed and the corresponding button is highlighted in the task area.

2 Verify that the images displayed in the classification are appropriate for the titled classification. If needed, reclassify the particles. See Reclassification of Particle Images.

Bacteria

Auto-Classification

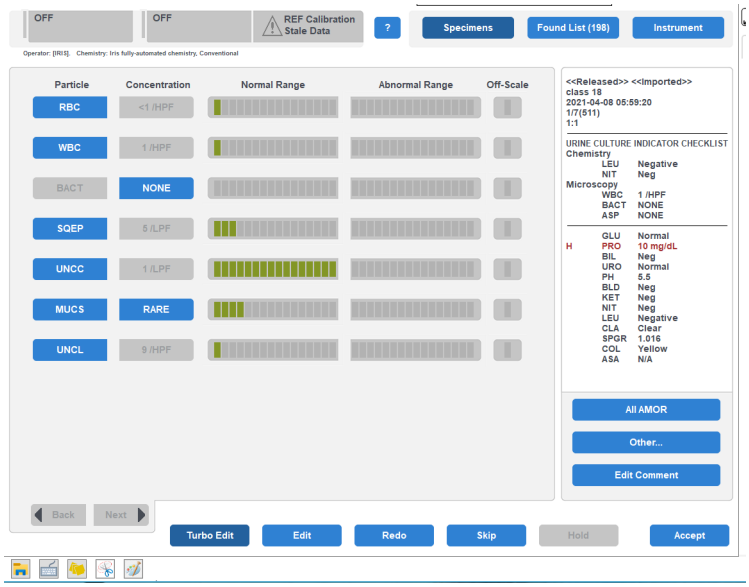
Bacteria <3 microns in size are too small to be automatically identified by APR and require a technician to identify and grade. APR will auto-classify bacilli >3 microns in size as isolated images.

The operator is responsible for verifying that the classified particles displayed match their appropriate auto-classification.

The presence/absence of clinically significant bacteria changes the verification process.

Urine Culture Indicator Checklist - No Bacteria

Figure 6.2 Auto-Classification Screen - No Bacteria

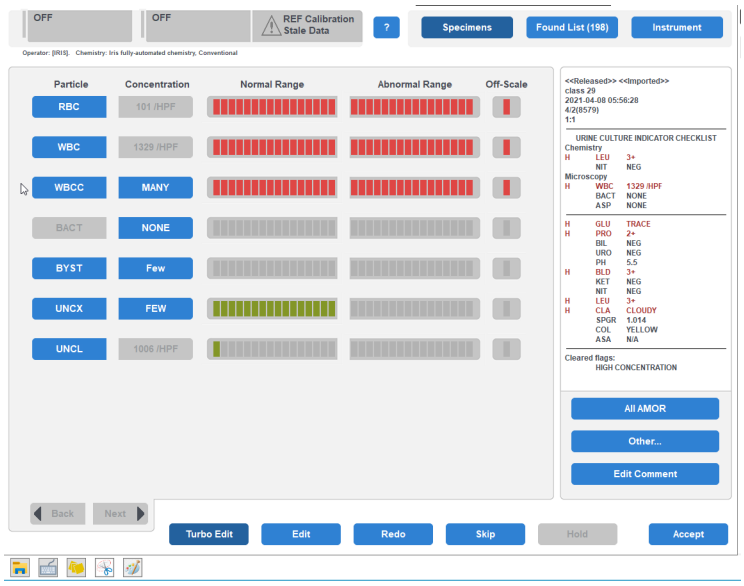


- Verify that the auto-classified particle images match the categories in which they are displayed.
- Reclassify particles when it will make a clinical difference.
- Sub-classify particles classified in the NSE, UNCC, and/or UNCX categories.
- Account for all new particles (in accordance with your laboratory policy), casts, renals, and transitionals displayed in UNCL.

NOTE When using minimum to auto-classify to prevent reporting of a particular particle, remember that the images of that particle will still be displayed in the UNCL category.

Urine Culture Indicator Checklist - Presence of Bacteria

Figure 6.3 Auto-Classification Screen - Presence of Bacteria



- Verify that the auto-classified particle images match the categories they are displayed within.
- Manually grade bacteria based on what is observed within the backgrounds of the WBC, WBCC, SQEP, and MUCS classifications.
- Reclassify particles when it will make a clinical difference.
- Sub-classify particles classified in the NSE, UNCC, and/or UNCX categories.
- Account for all new particles (in accordance with your laboratory policy), casts, renals, and transitionals displayed in UNCL.

NOTE When using auto-classify to prevent reporting of a particular particle remember that the images of that particle will still appear in UNCL.

Reclassification of Particle Images

For specimens with severely abnormal/pathologic particles, a trained operator may visually confirm the identification of the particles based on their morphological detail as displayed on the screen.

The images presented for operator review are sufficient so that a trained operator can easily recognize the particle images. In cases requiring visual review, all the particle images are sorted and displayed in the auto-classified categories, which enhances the verification process. While the classification of particles is computer-aided, human judgment should still be exercised.

NOTE Images should only be reclassified if the edit will change the clinical significance of the result.

There are two scenarios for which to reclassify one or more images:

1 Perform the applicable tasks for one of the following scenarios: All images displayed for that class must be moved (e.g. UNCX to CAOX).

- To move all images displayed, that class must be moved (for example, UNCX to CAOX):
  - Select the particle name in the task area and select the button below or **Results** to leave the current screen. This sends all images to the highlighted particle name displayed in the task area.
  - When all images are being reclassified, do not use the **Back** button after selecting a particle name or to leave the screen as unexpected results may occur.
  - Go to step 2.

OR

- To reclassify a portion of the images:
  - In the taskbar, select the particle name button that represents the fewest number of images to reclassify.
  - Select the corresponding images.
  - Select the classification name found in the upper left corner of the screen. This will reclassify the selected images and retain the images that the operator did not want to reclassify.
  - Go to step 2.

NOTE Remember that leaving the screen sends all images on the screen at this time to the category highlighted when you exit the screen.

2 Proceed until all desired images for the displayed particles are reclassified.

3 When all desired particle images have been reviewed, select **Results**, ensure that all categories are as desired, then select **Accept** to release the results.

Crystals, Casts, Yeast, and Others Buttons

Select **Crystals, Casts, or Others** to display a sub-category of particles available for reclassification of particle images.

The following categories can be manually identified or sub-classified:

Table 6.2 Particle Categories

Unclassified Crystals	**Unclassified Casts**	**Yeast**	**Others**
Calcium Oxalate	Hyaline Casts	Yeast with Pseudohyphae	Trichomonas
Triple Phosphate	Granular Casts	Budding Yeast	Fat
Calcium Phosphate	Cellular Casts		Red Blood Cell Clumps
Leucine	Waxy Casts	**Epithelial Cells**	Oval Fat Bodies
Amorphous	Broad Casts	Renal Epithelial Cells	
Uric Acid	Red Blood Cell Casts	Transitional Epithelial Cell	**Unclassified**
Calcium Carbonate	White Blood Cell Casts		Dysmorphic RBCs
Cystine	Epithelial Casts		
Tyrosine	Fatty Casts		

Info Button

Select **Info** to display the specimen information in the task area.

Releasing Results

See Accept Button.

Reports

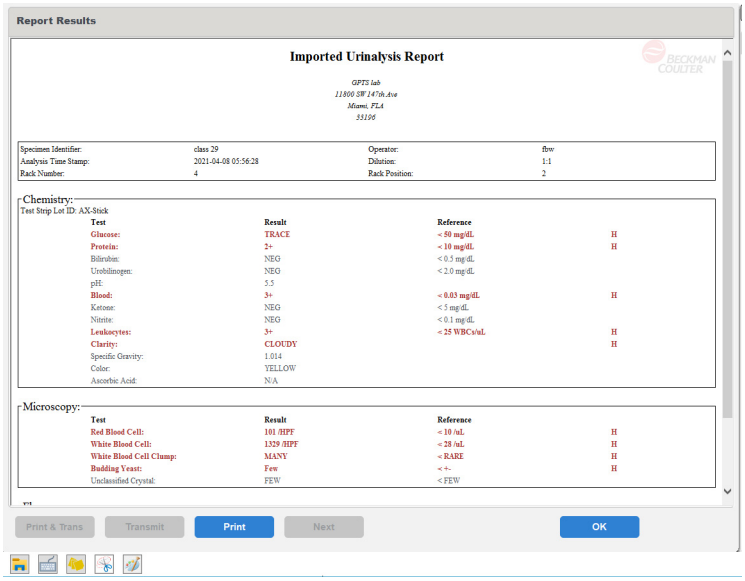
After the results have been accepted, a urinalysis report will be generated, printed and/or transmitted depending on the user-defined configuration.

To view a released report:

1 Select **Work List**, and then perform a Search for the specimen results to be found.

2 From the Found List, select the desired specimen results, and then select **Re-Report**.

3 From the Re-Report window, select the screen option and then select **OK**.



Patient Demographics

If this option was enabled (see Obtain Specimen Information from LIS in CHAPTER 9, Setup), the patient's demographics will be displayed on the report.

Operator

The logged-in operator who last released the specimen results will be displayed.

Analysis Time Stamp

This is the time at which the instrument read the barcode label.

Dilution

Dilution ratio applied to the sample, 1:1 means no dilution.

Rack Number - Position

Rack number into which the sample tube was loaded, and tube position on the rack.

Audit Trail

This field lists the operator's user ID who has saved the edits for the specimen, and the date and time at which this happened. The most recent operator is located at the top of the list.

Detailed Audit Trail

If the Enable detailed audit trail option was selected, any change made to the specimen is indicated with the date/time and the operator who made the change.

mh @ 2010-02-26 08:55:13 - Altered the following results:
Edited pH from *5.0* to *6.0*.
Edited RBC from *2 /µL* to *1 / µL*.
Edited SQEP from *None* to *<1 / µL*.
Edited ASP from *0 / µL* to *None*.
mh @ 2009-08-13 14:12:12
mh @ 2009-08-13 14:12:11 Cleared flags. Changed ID.
[auto] @ 2009-08-13 14:05:28
mh @ 2009-08-13 14:05:28 Cleared flags. Changed ID.

Report Results Buttons

Print & Trans

This button releases the current report to the LIS and a printout is generated on the DxU Microscopy Series printer.

Transmit

This button releases the current report to the LIS.

Print

This button prints the current report on the DxU Microscopy Series printer.

Next

This button displays the next available report results from the Found List if **Re-report all** was selected.

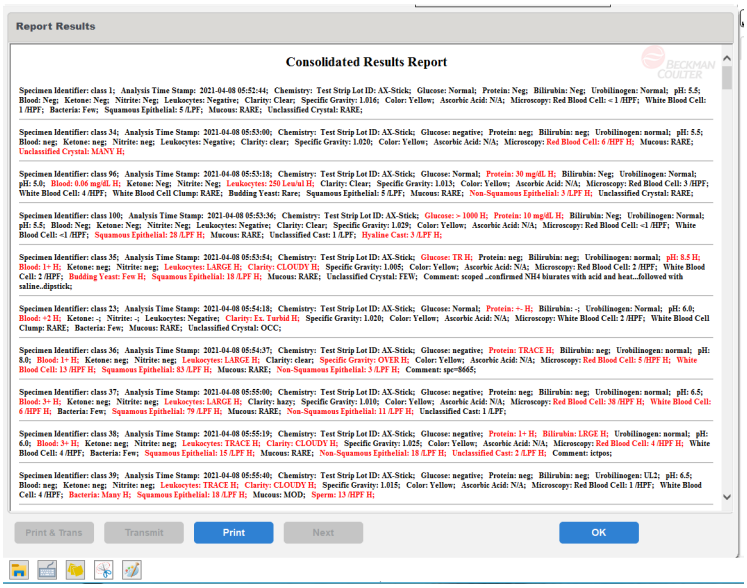
OK

This button closes the Report Results screen.

Consolidated Reports

The format of reports can accommodate consolidated chemistry and urine or body fluids microscopy reports. See the format below:

Figure 6.4 Consolidated Results Report



Urine Culture Candidates Reports

Urine Culture Candidates Reports are designed to streamline the UTI testing workflow by generating work lists of possible UTI patient sample values for review and possible release or reflex to Microbiology for urine culture analysis, based upon user-defined thresholds.

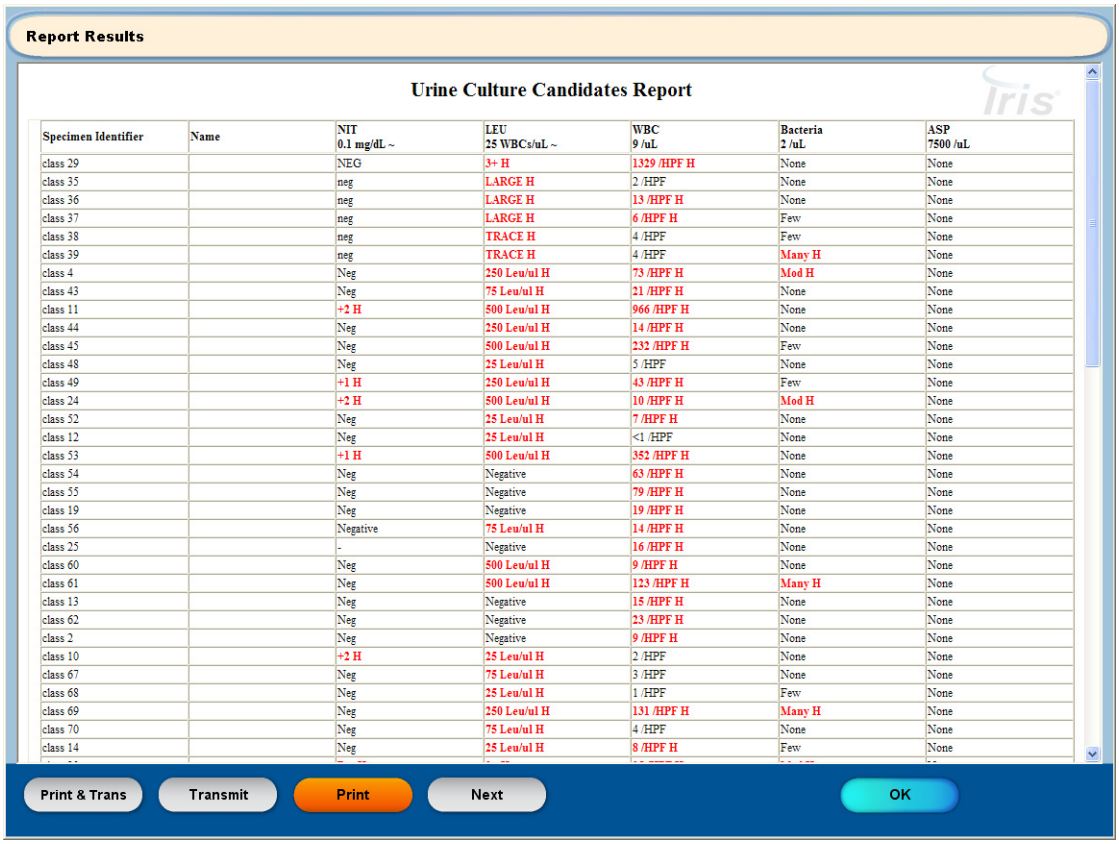
The Urine Culture Candidates Reports display patient sample identification and a summary of combined urine chemistry and microscopy* values for Leukocyte Esterase, Nitrite, White Blood Cells (WBC), Bacteria, and All Small Particles (ASP), consistent with the on-screen Urine Culture Indicated Checklist. Results can be reviewed on-screen, or printed out for future reference.

Urine Culture Candidates Report

A sample is included on the Urine Culture Candidates Report when at least one of the five bacteriuria parameter values **exceeds** the user-defined (or default) instrument thresholds. At or above threshold patient values are displayed on-screen in bold red text for easy review; this rule does not apply for ASP.

A sample is included on the No Urine Culture Indicators Observed Report when the values for all of the five bacteriuria parameters are below the user-defined (or default) instrument thresholds.

Figure 6.5 Example of Urine Culture Candidates Report for Chemistry and Microscopy

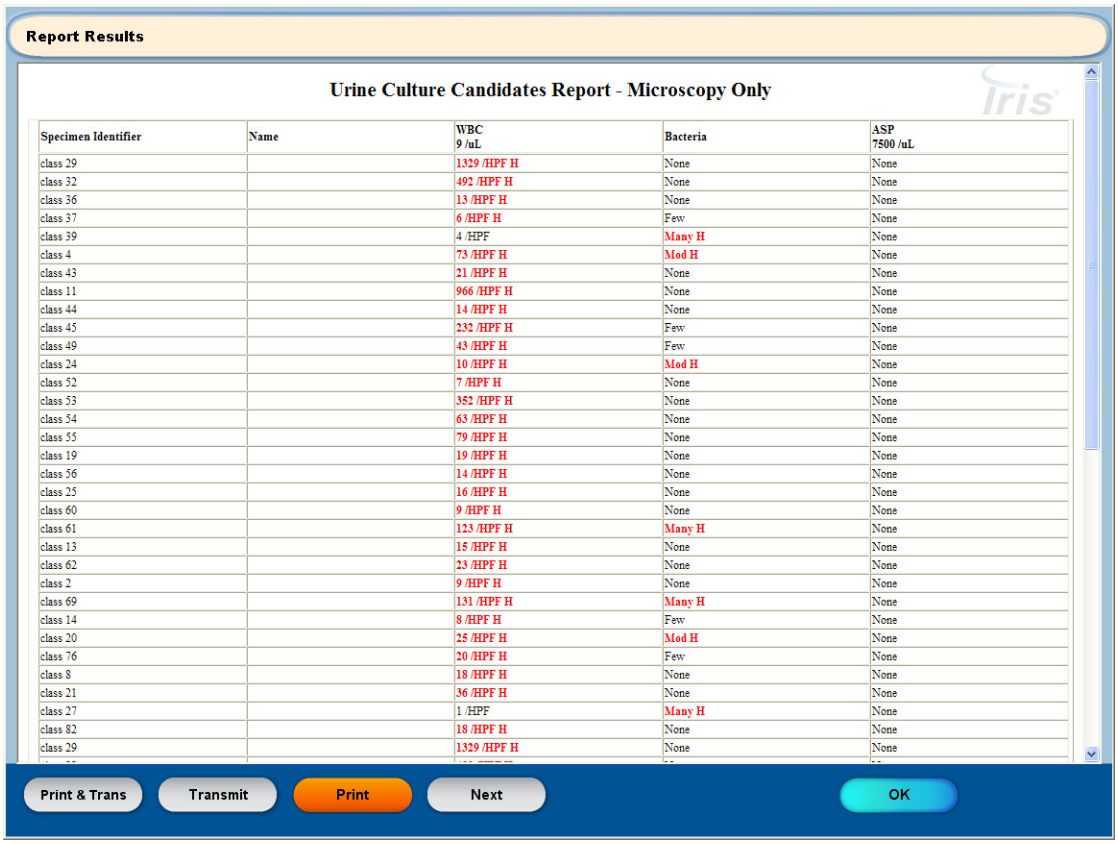


Specimen Identifier	Name	NIT 0.1 mg/dL ~	LEU 25 WBCs/uL ~	WBC 9 /uL	Bacteria 2 /uL	ASP 7500 /uL
class 29		NEG	3+ H	1329 /HPF H	None	None
class 35		neg	LARGE H	2 /HPF	None	None
class 36		neg	LARGE H	13 /HPF H	None	None
class 37		neg	LARGE H	6 /HPF H	Few	None
class 38		neg	TRACE H	4 /HPF	Few	None
class 39		neg	TRACE H	4 /HPF	Many H	None
class 4		Neg	250 Leu/ul H	73 /HPF H	Mod H	None
class 43		Neg	75 Leu/ul H	21 /HPF H	None	None
class 11		+2 H	500 Leu/ul H	966 /HPF H	None	None
class 44		Neg	250 Leu/ul H	14 /HPF H	None	None
class 45		Neg	500 Leu/ul H	232 /HPF H	Few	None
class 48		Neg	25 Leu/ul H	5 /HPF	None	None
class 49		+1 H	250 Leu/ul H	43 /HPF H	Few	None
class 24		+2 H	500 Leu/ul H	10 /HPF H	Mod H	None
class 52		Neg	25 Leu/ul H	7 /HPF H	None	None
class 12		Neg	25 Leu/ul H	<1 /HPF	None	None
class 53		+1 H	500 Leu/ul H	352 /HPF H	None	None
class 54		Neg	Negative	63 /HPF H	None	None
class 55		Neg	Negative	79 /HPF H	None	None
class 19		Neg	Negative	19 /HPF H	None	None
class 56		Negative	75 Leu/ul H	14 /HPF H	None	None
class 25		-	Negative	16 /HPF H	None	None
class 60		Neg	500 Leu/ul H	9 /HPF H	None	None
class 61		Neg	500 Leu/ul H	123 /HPF H	Many H	None
class 13		Neg	Negative	15 /HPF H	None	None
class 62		Neg	Negative	23 /HPF H	None	None
class 2		Neg	Negative	9 /HPF H	None	None
class 10		+2 H	25 Leu/ul H	2 /HPF	None	None
class 67		Neg	75 Leu/ul H	3 /HPF	None	None
class 68		Neg	25 Leu/ul H	1 /HPF	Few	None
class 69		Neg	250 Leu/ul H	131 /HPF H	Many H	None
class 70		Neg	75 Leu/ul H	4 /HPF	None	None
class 14		Neg	25 Leu/ul H	8 /HPF H	Few	None

The ASP value is compared to the auto-release threshold which is user-defined (default = 99,999).

*DxU Microscopy Series instruments without direct connection to a urine chemistry analyzer will generate Urine Culture Candidates Reports that include a summary of relevant microscopy values (White Blood Cells, Bacteria, and All Small Particles).

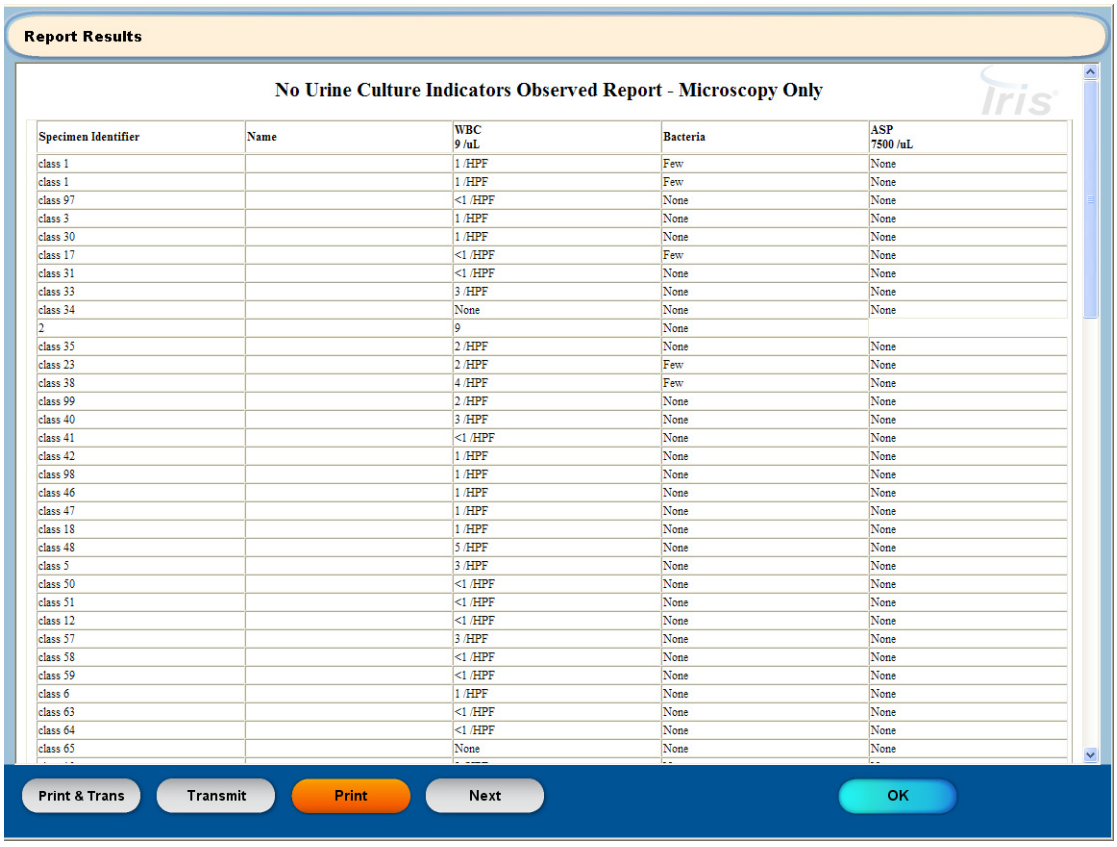
Figure 6.6 Example of Urine Culture Candidates Report - Microscopy Only



Specimen Identifier	Name	WBC 9 /uL	Bacteria	ASP 7500 /uL
class 29		1329 /HPF H	None	None
class 32		492 /HPF H	None	None
class 36		13 /HPF H	None	None
class 37		6 /HPF H	Few	None
class 39		4 /HPF	Many H	None
class 4		73 /HPF H	Mod H	None
class 43		21 /HPF H	None	None
class 11		966 /HPF H	None	None
class 44		14 /HPF H	None	None
class 45		232 /HPF H	Few	None
class 49		43 /HPF H	Few	None
class 24		10 /HPF H	Mod H	None
class 52		7 /HPF H	None	None
class 53		352 /HPF H	None	None
class 54		63 /HPF H	None	None
class 55		79 /HPF H	None	None
class 19		19 /HPF H	None	None
class 56		14 /HPF H	None	None
class 25		16 /HPF H	None	None
class 60		9 /HPF H	None	None
class 61		123 /HPF H	Many H	None
class 13		15 /HPF H	None	None
class 62		23 /HPF H	None	None
class 2		9 /HPF H	None	None
class 69		131 /HPF H	Many H	None
class 14		8 /HPF H	Few	None
class 20		25 /HPF H	Mod H	None
class 76		20 /HPF H	Few	None
class 8		18 /HPF H	None	None
class 21		36 /HPF H	None	None
class 27		1 /HPF	Many H	None
class 82		18 /HPF H	None	None
class 29		1329 /HPF H	None	None

No Urine Culture Indicators Observed Report

Figure 6.7 Example of No Urine Culture Indicators Observed Report - Microscopy Only



Report Results

No Urine Culture Indicators Observed Report - Microscopy Only

Specimen Identifier	Name	WBC 9 /uL	Bacteria	ASP 7500 /uL
class 1		1 /HPF	Few	None
class 1		1 /HPF	Few	None
class 97		<1 /HPF	None	None
class 3		1 /HPF	None	None
class 30		1 /HPF	None	None
class 17		<1 /HPF	Few	None
class 31		<1 /HPF	None	None
class 33		3 /HPF	None	None
class 34		None	None	None
2		9	None	
class 35		2 /HPF	None	None
class 23		2 /HPF	Few	None
class 38		4 /HPF	Few	None
class 99		2 /HPF	None	None
class 40		3 /HPF	None	None
class 41		<1 /HPF	None	None
class 42		1 /HPF	None	None
class 98		1 /HPF	None	None
class 46		1 /HPF	None	None
class 47		1 /HPF	None	None
class 18		1 /HPF	None	None
class 48		5 /HPF	None	None
class 5		3 /HPF	None	None
class 50		<1 /HPF	None	None
class 51		<1 /HPF	None	None
class 12		<1 /HPF	None	None
class 57		3 /HPF	None	None
class 58		<1 /HPF	None	None
class 59		<1 /HPF	None	None
class 6		1 /HPF	None	None
class 63		<1 /HPF	None	None
class 64		<1 /HPF	None	None
class 65		None	None	None

Print & Trans | Transmit | Print | Next | OK

A Bacteria Present pop-up will be displayed when:

- This feature is enabled AND
- Any entity that is listed in the Urine Culture Indicators Checklist field is displayed in red (past threshold)

A specimen is considered to be Urine Culture Candidates when:

- The WBC result is positive.
- ASP is greater than auto-release threshold (user-defined).
- Bacteria result is positive.
- Chemistry criteria: result positive for Leucocyte Esterase or Nitrite.

A specimen is considered to be No Urine Culture Indicators Observed when:

- The WBC result is negative.
- ASP is less than auto-release threshold (user-defined).
- Bacteria result is negative.
- Chemistry criteria: result negative for Leucocyte Esterase or Nitrite.

The All Small Particles (ASP) category is used by the DxU Microscopy Series APR to classify particles smaller than 3µm. Particles classified in the ASP category may be cellular, crystal, or bacteria in nature. The ASP value alone should not be used to identify clinical conditions.

All Small Particles (ASP) and Urine Culture Indicated Checklist

The Urine Culture Indicated Checklist is a feature of the Beckman Coulter/Iris Urinalysis workcell that uses five clinically relevant urine chemistry (Leukocyte esterase, Nitrite) and urine microscopy (WBC, Bacteria, and ASP) values to assist the operator in making an assessment regarding UTI and whether the sample should be sent to urine culture. Laboratories wishing to introduce a routine urinalysis screen will need to validate the effectiveness of an UTI screening algorithm versus urine culture, to establish thresholds and understand how to interpret results.

Recent peer-reviewed publications from Europe have demonstrated that elevated ASP counts, in combination with the other parameters of the Urine Culture Indicated Checklist (WBC, Bacteria, Leukocyte esterase, and Nitrite), can provide important information regarding the possibility of infection.[39] [40] [41] [42]

To request English translations of these publications, contact your Beckman Coulter Representative.

Generating a Urine Culture Indicated Report

See Search with Urine Additional Criteria.

Flagged Specimens

On the Work List screen, flags are indicated in the Status column.

To view the flag condition, double-click the flagged specimen's row. The Specimens screen is displayed.

Flags are displayed in the right side of the Specimen screen. There are two types of flags: recoverable and non-recoverable.

Recoverable Flag

If a flag is recoverable, the **Review Flagged Specimen** and the **Delete Flagged Specimen** buttons are displayed.

Select **Review Flagged Specimen** and **Accept**. The Specimen Results screen is refreshed and you can edit as usual.

If the results match the auto-release criteria and the flag was ID ERROR or an *auto clear* flag, the results will be automatically transmitted to the printer and/or LIS after the flag is cleared.

The Deleted Flagged Specimen and Review Flagged Specimen buttons will be active.

Review Flagged Specimen Button

1 Select **Review Flagged Specimen**.

2 Enter a valid ID.

3 Select **Accept** to clear the flag.

Non-Recoverable Flag

If a flag is non-recoverable, only the **Delete Flagged Specimen** button is displayed. The cause of the flag needs to be resolved before the specimen can be run again.

The Deleted Flagged Specimen button will be active while the Review Flagged Specimen will be disabled.

Delete Flagged Specimen Button

1 Select **Delete Flagged Specimen**. The Task information signals that selecting **Accept** will delete the specimen.

2 Select **Accept** to delete the specimen results.

Consolidation of Microscopy and Chemistry Results

This function can be used to consolidate Microscopy and chemistry results if an ID flag is reported.

1 From the Work List screen, double-click the specimen to open the Specimen screen.

2 Select **Review Flagged Specimen**. The Edit Specimen Identifier screen is displayed.

3 Enter the specimen ID in the **Specimen identifier** edit box.

4 Check the **Consolidate microscopy and chemistry** check box.

5 Select **OK**. The software will search for the other half of the results and consolidate both results. If the system cannot find the other half, a pop-up will warn you.

6 Select **Accept**.

The Specimen screen refreshes and displays the new consolidated specimen results. If the other half of the results was present on the Work List screen, the Specimen screen for this result will be blank confirming that the consolidation was successful. The other half of the results will be automatically removed from the Work List when the Work List is updated.

The consolidated specimen results can be released.

Separation of Consolidated Results

This option can be used if separation of consolidated results is necessary, in order to repeat microscopic analysis with micro-dilution for example.

NOTE If the specimen results were flagged, the flag condition must be cleared before separating the results. Once the specimen results have been separated, they cannot be consolidated together again within the iQ software. The chemistry will consolidate with a microscopy result if it is run within the consolidation window. See Consolidation Window in CHAPTER 9, Setup. These results will only merge if the other half is run and obtains an ID_ERROR.

1 From the Work List/Found List screen, double-click the specimen to open the Specimen Review screen.

2 Select **Other...** A pop-up screen is displayed. The following options appear on the Other screen:

- **All AMOR**
- **Separate chemistry and microscopy results**
- **Edit Chemistry**

3 Select **Separate chemistry and microscopy results**, and then select **OK**.

The Specimen screen will display in red: *Click Accept to separate chemistry and microscopy results* just above the **All AMOR** button.

4 Select **Accept**. The results will be displayed on two separate screens. Chemistry results will be automatically released to the printer and the LIS, depending on the system configuration. Both results will be available on the Work List for review.

Editing Chemistry Results

In order to be able to edit Chemistry Results, the function Enable Detail Audit Trail must be selected. See Enable Detail Audit Trail in CHAPTER 9, Setup. The operating system for the DxU Microscopy Series must be Windows 10.

The original result is displayed as part of the audit trail on the printed report or on the screen when re-reported, but is not displayed in the specimen review window.

A single comment field is available for all changes. If multiple changes are made, all of them share the same comment field.

NOTE The user ID of the operator currently logged, the date/time, and ALL changes made to the original chemistry results will be listed in the Detailed Audit Trail section of the report. See Audit Trail.

Selecting a Chemistry Result Value

This option can be used to edit chemistry results obtained from a chemistry analyzer connected to the DxU Microscopy Series.

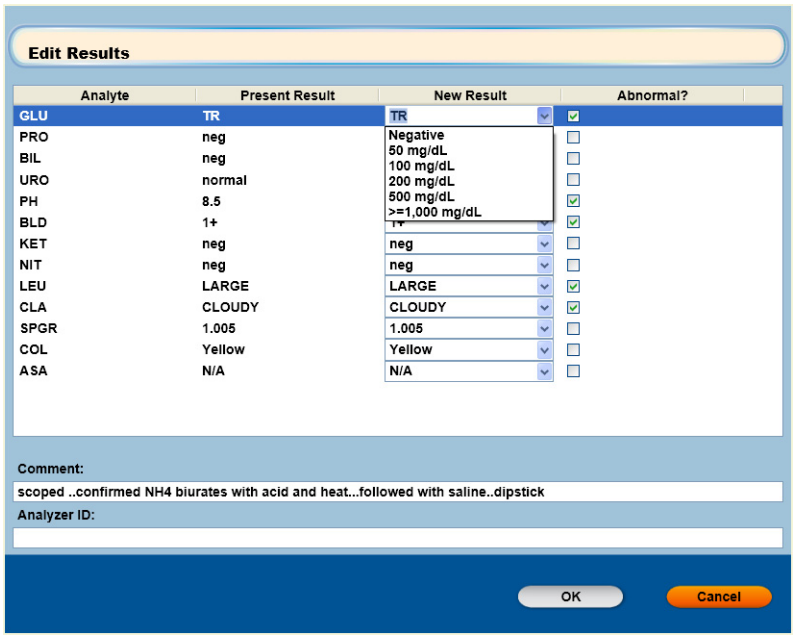
1 From the Work List screen, double-click the specimen row, or select the row and select **Specimens**. The Specimen screen is displayed.

2 From the Specimen screen, select **Other...** The Other... screen is displayed.

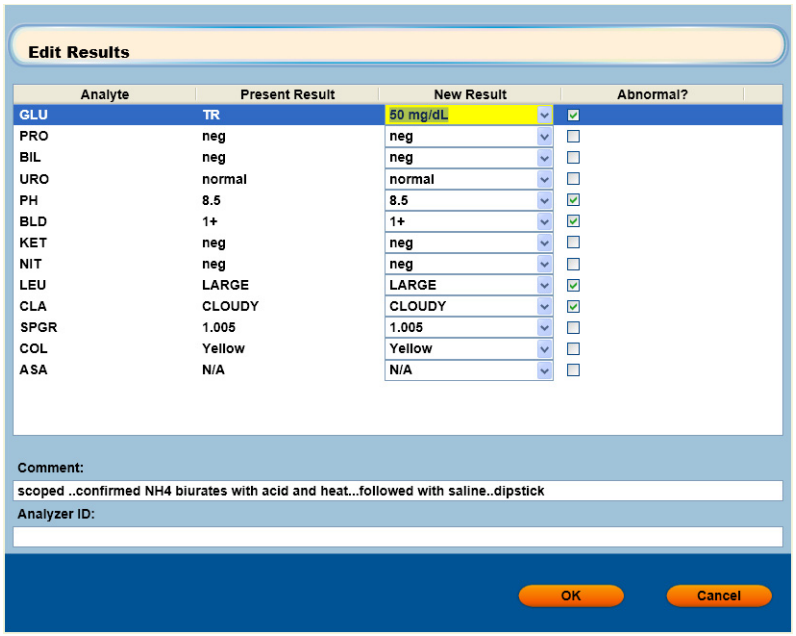
The Other screen will include the following options: All ART, Separate Chemistry and Microscopy Results, and Edit Chemistry.

3 Select **Edit chemistry**. The Edit Results screen is displayed. The Present Result column displays the results obtained by the chemistry analyzer.

4 To edit a result, select the drop-down option corresponding to the analyte to modify.



5 Select the new result from the drop-down list. The new value is highlighted in yellow, indicating that a change was made. If necessary, check the new value for abnormal result.



6 When all results have been entered, enter a comment in the *Comment* field according to the Laboratory Protocol.

7 Enter the analyzer identification from which the chemistry results were obtained.

NOTE On the workcell instrument, the DxU 810c Iris serial number is populated automatically.

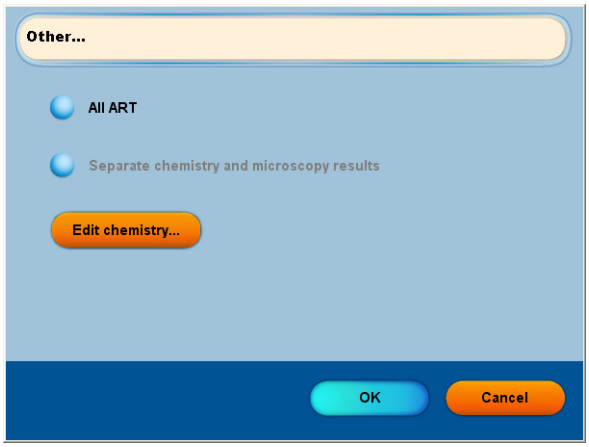
8 Select **OK** to validate the changes and update the results report.

Manually Entering a Chemistry Result Value

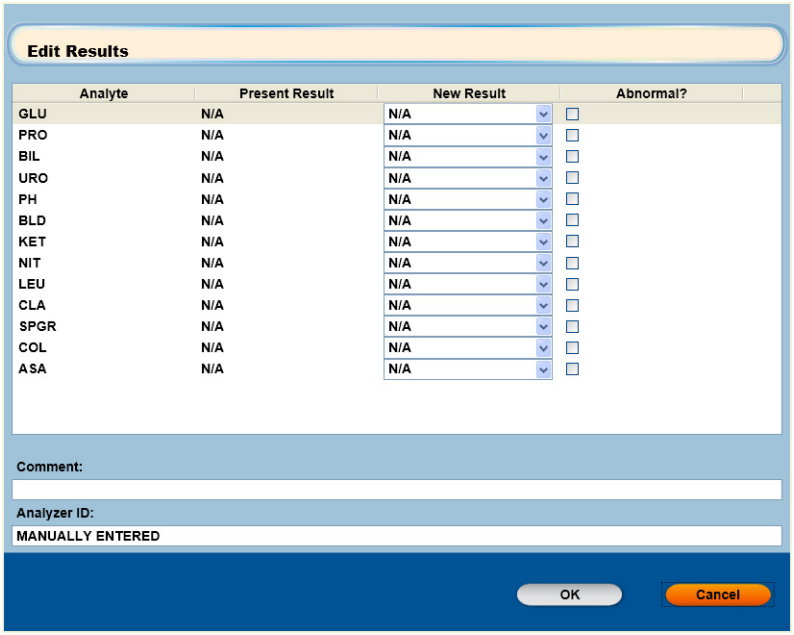
This option can be used to manually enter chemistry results to be associated to specific microscopy results, in the case of an DxU Microscopy Series analyzer used as a stand-alone, with chemistry results from another source.

1 From the Work List screen, double-click the specimen row, or select the row and select **Specimens**. The Specimen screen is displayed.

2 From the Specimen screen, select **Other...** The Other... screen is displayed.



3 Select **Edit chemistry**. The Edit Results screen is displayed.



4 Using the keyboard, enter the chemistry result in the *New Result* field corresponding to the line of the desired analyte.

NOTE **Manually Entered** is the default entry.

5 When all results have been entered, enter a comment in the *Comment* field according to the laboratory protocol.

6 Enter the analyzer identification from which the chemistry results were obtained.

7 Select **OK** to validate the changes and update the results report.

8 Select **Accept** to save your changes.

Flags

Chemistry Flags

CHEMTRANSLATE

CAUSES	REMEDIES
One or more chemistry name or result received from the chemistry analyzer does not match the expected name or result (data entered in the input settings). See Chemistry Settings in CHAPTER 9, Setup. DO NOT change chemistry input values without assistance from your Beckman Coulter Representative.	1. Make sure the displayed results are valid values. 2. Check the setup map for the specific chemistry. Add that value if valid. 3. If the result is valid, but the map settings were wrong, clear the flag and accept.

CHEM CONFIRM

CAUSES	REMEDIES
One or more of the chemistry results exceeded the user-defined confirmation threshold. The results that met or exceeded the confirmation threshold will be displayed in italics on the Results screen.	1. Clear the flag. 2. Confirm the results according to Laboratory Protocol. 3. The confirmation results may be added in the Edit Comment box, if desired.

CHEM N/A

CAUSES	REMEDIES
Chemistry results were expected but not available. Check any associated flag or error message. If the DxU Microscopy Series is set up to communicate and a specimen is placed on the microscopy module only, the Chem N/A flag will appear. The flag will also appear if one or both barcodes are not read or if a specimen is run without a barcode label. If this flag occurs under other circumstances, refer to Remedies below.	1. Make sure the rack was placed for processing on the chemistry system. 2. Make sure the barcode label is correctly affixed to the tube, that it is not smudged or damaged. 3. Make sure the barcode label is correctly oriented so that it faces the barcode reader. 4. Make sure the LIS connection is up. 5. Make sure the chemistry instrument is set to communicate with the DxU Microscopy Series software. 6. When all settings are correct, the chemistry results can be re-run or re-transmitted.

Microscopy Flags

Demographics

CAUSES	REMEDIES
A Demographics flag occurs when a specific patient demographic (last name, first name, middle name, date of birth, location, record number, or gender) has been defined by the user to be obtained from the LIS (see LIS Interface Settings), but the LIS is not sending that specific demographic. This flag will hold associated results on the Work List and will prevent Auto-Release. Result release requires operator intervention.	Select **Settings** > **LIS Interface** > **Obtain information from LIS** > **Obtain patient demographics information from LIS** > **DEMOGRAPHICS** to determine which patient demographics are user-defined to be obtained from the LIS. Compare these selected entries to the patient demographics obtained from the LIS. Edit and resolve any entry in which what is expected to be obtained from the LIS (as selected on the Demographics screen) is different from what is actually being received from the LIS. To edit information, select **EDIT DEMOGRAPHICS.**

Flow

CAUSES	REMEDIES
The flowcell may be obstructed or the fluids slowed due to the specimen, an obstruction, a clogged specimen filter, or a pinched tube in one of the peristaltic pumps.	**1.** Reject the flag to remove the results from the Work List. **2.** Run a control rack with Iris System Cleanser and Iris Diluent. **3.** Re-run the specimen.

ID

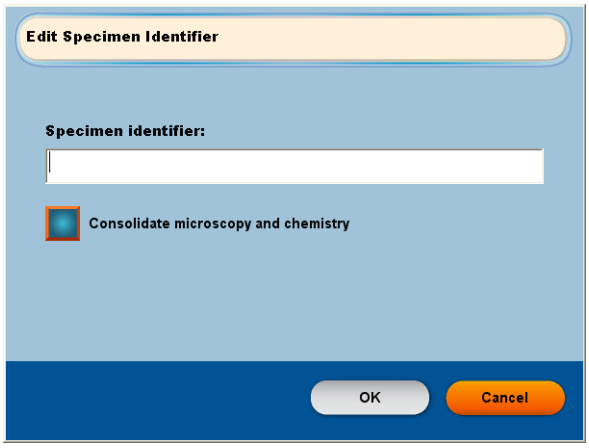
CAUSES	REMEDIES
The barcode reader was not able to read the barcode label.	1. From the Work List screen, double-click the specimen to open the Specimen Review screen. 2. Select **Review Flag Specimen**. The Edit Specimen Identifier screen is displayed.  3. Enter the specimen ID in the *Specimen identifier* edit box. 4. Select **OK**. The screen closes and the Specimen screen displays the new specimen ID. 5. Select **Accept** to clear the ID flag and refresh the screen.

Image Acq

CAUSES	REMEDIES
Images were not received by the Results Processor.	1. Check the connection of the large cable connecting the Microscopy Module to the 50 pins connector on the back of the Results Processor. 2. Run a control rack, including Positive and Negative Controls. 3. Re-run the specimen.

LIS ID

CAUSES	REMEDIES
A request for information about a specimen was sent to the LIS. This ID is unknown to the LIS.	1. Compare the displayed ID with the ID on the sample tube. 2. Make sure the information concerning this specimen was entered in the LIS. 3. If the ID was entered, contact the LIS Manager.

LIS T/O

CAUSES	REMEDIES
The request for information from the LIS was not answered within the expected time interval.	**1.** Select **Check LIS** on the Instrument screen. **2.** If the connection failed, contact your LIS Manager. **3.** If the connection was successful, re-run the sample.

Run

CAUSES	REMEDIES
The results file is corrupted or missing. This is a non-recoverable flag.	**1.** Select **Delete Flagged Specimen** to remove the specimen results from the Work List. **2.** Re-run the specimen.

Short Sample

CAUSES	REMEDIES
There was not enough specimen in the sample tube or distilled water was run. The probe tip was not 4mm from the bottom of the tube.	**1.** Reject the flag to remove the results from the Work List. **2.** Refill the sample tube with at least 3.0 mL of specimen. **3.** Re-run the specimen.

High Concentration

CAUSES	REMEDIES
When the file used to analyze the images exceeds 10 MB, the sampling volume will be truncated and concentrations are calculated from the reduced volume. This flag indicates that the specimen contained a high concentration of at least one particle type. As with a dilution, it is possible that other particles in low concentrations may be missed, but the sample does not need to be diluted. The Laboratory should develop its own protocols for accommodating such possibilities.	When this flag is present, there is a higher chance of carryover into the next sample. **1.** If the following sample is abnormal and the chemistries support the microscopic results, do not rerun. **2.** If the following sample is reporting abnormal results for the same particles seen in the High Concentration sample and the chemistries do not match the microscopic results, rerun the sample.

Possible Amorphous

CAUSES	REMEDIES
This flag alerts the operator that the specimen may contain significant quantities of amorphous, which could possibly alter the APR concentration.	

Previous Sample Had Sperm

All systems with reusable probes can have carryover issues, especially when dealing with a sticky substance such as sperm. As a result, subsequent tubes may contain sperm from a previous specimen. Such carryover can result in a reportable event depending on the age and gender of the individual from which the contaminated sample came from.

To ensure accuracy and minimize risk of misreported results, Beckman Coulter/Iris implemented *Flags* in the software. These *Flags* will alert you to the presence of sperm in a specimen or inform the operator when sperm was auto classified in the previous specimen. *Flags* serve as reminders for laboratory technicians to verify a sample before releasing its results, as flagged samples require operator intervention.

Flags are displayed on the Results screen. Before verifying results, operators must acknowledge and take action to clear the flag.

Recommendations

- Any low level detection of sperm in the specimen immediately following the specimen with a high concentration of sperm should be considered a suspicious sample.
- For suspicious samples, you should retrieve the original specimen container and re-test to confirm presence of sperm.
- An effective verification process should be put into place by the laboratory to avoid incorrectly reporting positive sperm counts on certain specimens that due to gender and/or age considerations may result in a criminally reportable event (using the patient demographics feature will assist in this).
- If reporting sperm, you should set minimum to auto-classify to 1/HPF.

If sperm is NOT reported, you should set auto-classify to 999999/HPF.

CAUSES	REMEDIES
This flag is displayed if this option was enabled during the system configuration. See Specimen Settings in CHAPTER 9, Setup. This flag is present if the previous specimen had sperm results or Sperm Present flag. The flag is used to signal a possible carryover. It will not be printed on the report and will not be transmitted to the LIS.	Review the flagged specimen and accept or delete the specimen results.

Sperm Present

CAUSES	REMEDIES
This flag is generated by the software at the time the sample is run, and is displayed only if this option was enabled during the system configuration. See Specimen Settings in CHAPTER 9, Setup. The flag will not be printed on the report and will not be transmitted to the LIS.	Review the flagged specimen and accept or delete the specimen results.

DUPLICATE SPECIMEN ID (SAME MEDICAL RECORD NUMBER) Flag

NOTE This flag is a recoverable flag. Deleted samples are excluded from the duplicate Specimen ID detection. This flag may occur when running diluted samples or consolidating microscopy with chemistry results.

CAUSES	REMEDIES
This flag appears when a duplicate Specimen ID with the same Medical Record Number is run within the Duplicate Specimen ID Delection Configuration time frame established by the laboratory.	**1.** Duplicate Specimen ID flags must be resolved before releasing results. If a duplicate Specimen ID flag appears on the Specimen Results screen, exit the screen and search for the duplicate of the flagged specimen ID. Do not select Review Flagged Specimen or Delete Flagged Specimen until the duplicate specimen ID issue has been resolved. **2.** If a duplicate Specimen ID flag appears during your review, perform the following steps: Review the Work List for the duplicate: Sort Specimen IDs by selecting the **Specimen ID** button. If duplicate Specimen ID(s) are displayed, resolve based on whether the duplicate Specimen ID is expected or not expected. If expected, proceed to step 3. If not expected, proceed to step 4. If duplicate Specimen ID(s) are not found on the Work List, review the Found List: From the Work List, select **Search** to display the Found List. Select **Clear** > enter the Specimen ID > **OK**. Review the Found List for the duplicate Specimen ID of the flagged sample. If duplicate Specimen ID(s) are displayed, resolve based on whether the duplicate Specimen ID is expected or not expected. If expected, proceed to step 3. If not expected, proceed to step 4.

CAUSES	REMEDIES
	3. To accept and report the sample results: Highlight the flagged specimen to review and select **Specimens**. From the Specimens Result screen, select **Review Flagged Specimen** > **Accept** to review. The Specimens Result screen refreshes. Verify results as usual. After verifying results, select **Accept**. If Auto-Release is enabled, samples that meet the auto-release criteria are auto-released. The flag will transmit to the LIS. **4.** To delete the sample results: Highlight the flagged specimen to review and select **Specimens**. From the Specimens Results screen, select **Delete Flagged Specimen** > **Accept** to delete. The next specimen on the list diplays.

DUPLICATE SPECIMEN ID (DIFFERENT MEDICAL RECORD NUMBER) Flag

NOTE This flag is a recoverable flag. Deleted samples are excluded from the duplicate Specimen ID detection.

CAUSES	REMEDIES
This flag appears when a duplicate Specimen ID with a different Medical Record Number is run within the Duplicate Specimen ID Delection Configuration time frame established by the laboratory.	**1.** Duplicate Specimen ID flags must be resolved before releasing results. If a duplicate Specimen ID flag appears on the Specimen Results screen, exit the screen and search for the duplicate of the flagged specimen ID. Do not select Review Flagged Specimen or Delete Flagged Specimen until the duplicate specimen ID issue has been resolved. **2.** If a duplicate Specimen ID flag appears during your review, perform the following steps: <u>Review the Work List for the duplicate:</u> Sort Specimen IDs by selecting the **Specimen ID** button. If duplicate Specimen ID(s) are displayed, resolve based on whether the duplicate Specimen ID is expected or not expected. If expected, proceed to step 3. If not expected, proceed to step 4.

CAUSES	REMEDIES
	If duplicate Specimen ID(s) are not found on the Work List, review the Found List: From the Work List, select **Search** to display the Found List. Select **Clear** > enter the Specimen ID > **OK**. Review the Found List for the duplicate Specimen ID of the flagged sample. If duplicate Specimen ID(s) are displayed, resolve based on whether the duplicate Specimen ID is expected or not expected. If expected, proceed to step 3. If not expected, proceed to step 4. **3.** To accept and report the sample results: Highlight the flagged specimen to review and select **Specimens**. From the Specimens Result screen, select **Review Flagged Specimen** > **Accept** to review. The Specimens Result screen refreshes. Verify results as usual. After verifying results, select **Accept**. If Auto-Release is enabled, samples that meet the auto-release criteria are auto-released. The flag will transmit to the LIS. **4.** To delete the sample results: Highlight the flagged specimen to review and select **Specimens**. From the Specimens Results screen, select **Delete Flagged Specimen** > **Accept** to delete. The next specimen on the list diplays.

Pop-Ups

Pop-ups are a means of getting the technologist's attention for certain conditions when the operator has selected **Accept** on the Results screen.

Pop-ups are displayed in a dialog box requiring the operator response in order to proceed. If Auto-release is enabled, pop-ups will not stop result transmission to the LIS.

Pop-ups are not recorded in the database or any reports (printer or LIS).

Potential Carryover

The following analyte types will not cause the Potential Carryover pop-up to appear:

- UNCL

- ART
- Any type of crystal

CAUSES	REMEDIES
The Potential Carryover pop-up is displayed when all the following conditions apply: • This feature is enabled. See Specimen Settings in CHAPTER 9, Setup. • The previous run has an analyte with a result exceeding the linearity limits. • The operator has displayed the sample on the Results screen and depressed the **Accept** button. • The analyte(s) that have exceeded the linearity limits is identified in the pop-up.	Select **OK** to accept the specimen or select **Cancel** to return to the Results screen.

Chem/Micro Correlation Alert

The Chem/Micro Correlation Alert pop-up is displayed when:

- This feature is enabled (see Specimen Settings in CHAPTER 9, Setup) AND
- The condition is defined by Table 6.3, Chemistry to Microscopy Results, Table 6.4, Correlation Criteria Using Threshold for Each Row in Table 6.3, and Table 6.5, Complex Multirule.

Table 6.3 Chemistry to Microscopy Results

Chemistry Results to Compare to...	Microscopy Results
Blood	RBC
LEU	WBC
Nitrite	Bacteria

Table 6.4 Correlation Criteria Using Threshold for Each Row in Table 6.3

Chemistry Result	Microscopy Result	Correlation Pop-Up?
Below abnormal threshold	Below abnormal threshold	No
At or above abnormal threshold	At or above abnormal threshold	No
Below abnormal threshold	At or above abnormal threshold	Yes
At or above abnormal threshold	Below abnormal threshold	Yes

NOTE If protein results are below the threshold and casts are present, the Chem/Micro correlation pop-up will be generated.

Table 6.5 Complex Multirule

pH is...	And these types of crystals are present...
1 ≤ pH ≤ 6 (acidic)	Triple phosphate, Calcium phosphate, Calcium Carbonate. These crystals are present in an alkaline environment.
8 ≤ pH ≤ 14 (alkaline)	Calcium Oxalate, Cystine, Tyrosine, Uric acid, Leucine. These crystals are present in an acidic environment.

Select **OK** to accept the specimen or select **Cancel** to return to the Results screen.

Bacteria Present

CAUSES	REMEDIES
The Bacteria Present pop-up is displayed when: • This feature is enabled. See Specimen Settings in CHAPTER 9, Setup. • Any entity listed in the Urine Culture Indicated Checklist has past the threshold (displayed in red). • The operator has displayed the sample on the Results screen and selected **Accept**.	Select **OK** to accept the specimen or select **Cancel** to return to the Results screen.

Minimum to Auto-Classify Overridden

CAUSES	REMEDIES
The Minimum to Auto-Classify Overridden pop-up is displayed when: • This feature is enabled. See Specimen Settings in CHAPTER 9, Setup. • An APR class contains a concentration below the minimum threshold necessary by APR to automatically create the class. This may be due to: — The operator has created an APR class with a concentration below the minimum threshold necessary by APR to automatically create the class. See the *Enable Minimum to Auto-Classify Overridden* pop-up. — The operator has moved cells out of an APR class which has resulted in a concentration below the minimum threshold necessary for APR to automatically create that class.	Select **OK** to accept the specimen or select **Cancel** to return to the Results screen.

Export Import Specimen Results

Exporting Specimen Results

NOTE Drive E is not an available option with Windows 10. A new drive called User (U:) is available.

Specimen results can be exported for storage or for training purposes.

1 From the Instrument screen, **Go Off line**.

2 Go to the Work List or Found List and select **Search** (as needed) until the Search screen appears.

3 Select **Clear**, enter Search criteria to find released specimen, then select **OK**.

4 From the Found List screen, select the specimen result to export and then select **Export**.

NOTE Only released specimen results can be exported.

5 To export all results displayed in the Found List, select **Export All**.

The Select Export Destination screen will display indicating the space required for storing the selected results.

A drop-down will allow you to select the drive used for the CD-R. The space required to perform the export process will be displayed.

6 Select the Destination from the drop down drive options.

7 Select **OK**.

Exporting Results to a CD

1 Select **OK** on the Export screen. The Export Status window will display:

- Number of specimen results to export is displayed.
- Number of specimen results successfully exported is displayed.
- Number of specimen results export failures is displayed.

2 When the procedure is complete, select **OK**.

3 Open the CD drive. Label and store the CD-R disc. Close the CD drive.

Importing Specimen Results

The system can import specimen results that have been previously generated on the same or different instrument of the same model from a CD-ROM. The instrument must be OFFLINE to import results.

1 Select **Work List**.

2 From the Work List screen, select **Import**. The system prompts you to identify which drive to import from.

3 Select the drive to import the results from and make sure the results are available on that drive.

NOTE If you select **OK** before the CD Ready box appears, the following message will be displayed: *D:\\Archive: The volume for a file has been externally altered so that the opened file is no longer valid.* Select **OK** and wait for the CD Ready box to be displayed.

The Select Specimens to Import screen is displayed. This screen will include a list of specimens that can be exported.

4 Hold the **Shift** key on the keyboard and use the mouse to select a series of results to import, and/or hold the **CTRL** key to select discontinuous results and then select **OK**. The Import Status screen is displayed.

The system copies the results from the selected source and displays the status of the import procedure:

- Number of specimen results to import.
- Number of specimen results successfully imported.

5 To display the imported results, perform a search by the current day, few minutes before and few minutes after the import procedure. The imported results are differentiated from the specimen results for the time frame by displaying the *Imported* status.

The Import Status screen will display the following: Total to Import, Successes, and Failures.

6 When the procedure is complete, select **OK** and remove the data device.

CHAPTER 7
Manual Orders

Manual Orders

When an LIS is not available for any reason, this function allows you to manually enter a Work List for microscopies.

Accessing Manual Orders

1 To access the Manual Orders Menu, select **Instrument** on the top right side of the main screen.

2 Select **Manual Orders** located on the lower left side of the Instrument screen. The Manual Orders screen will be displayed.

Entering Manual Orders

1 Select the first rack number to be used.

NOTE Racks # 25, 26, and 27 are reserved for the iQ Body Fluids Module and will only be displayed if the Body Fluids Module is enabled.

2 Enter the specimen information:

- Specimen Identifier - Patient ID can be entered in this field. If a barcode label is present on the tube, the results will be displayed with the information from the barcode. The Work Order option will change to *Run*.
- Fluid Type - select **URN**.
- Dilution - select the appropriate dilution for the sample.
- Work Order - default No Order
  - — No Order

    The sample will be processed according to the user-defined criteria. See Specimen Information from LIS in CHAPTER 9, Setup.
  - — Run

    The sample will be processed by the microscopy module.
  - — Skip

    The sample will not be processed by the microscopy module.

— Reflex

The sample will be processed according to the user-defined gating criteria. See Urine Gating Settings in CHAPTER 9, Setup.

3 When the specimen information is entered, place the sample tube into the corresponding position of the selected sample rack.

4 Repeat for each specimen to be run for the selected sample rack.

5 If more than one rack is to be run, select a new rack number and then enter the specimen information.

6 Select **OK** to save the manual entries only or select **OK & Print** to save the entries and print a report.

7 The rack numbers for which a manual order has been requested will be flagged with an asterisk and highlighted by color on the Manual Orders screen and will be displayed on the Instrument screen.

Clearing Specimen Information

From the Manual Orders Screen

Clear Rack Button

When analysis of the last specimen for a specific rack is completed (status is processed), select the rack on the Manual Orders screen and then select **Clear Rack** to clear all specimen information entered for the selected rack.

Clear All Button

When analysis for all sample racks are completed, select **Clear All** to clear all specimen information for these racks.

From the Instrument Screen

When analysis for all Manual Orders sample racks are completed, select **Clear All** on the Manual Orders line to clear all specimen information for these racks.

CHAPTER 8

Shutdown

Power Off

It is strongly recommended that the instrument remain on at all times. The Microscopy module requires one to two hours for the internal temperature to stabilize after being turned off for six or more hours. The instrument goes into a power conserving sleep mode after five minutes of non-use.

If you must power off for maintenance or to re-boot, turning the power off for less than an hour should not affect operation.

Short-Term Shutdown

1 Select **Go Off line**.

2 From the Instrument Screen, select **Maintenance**, then **Shutdown**. When the confirm window appears, select **Yes**.

3 Press the Power Standby/ON button on the bottom left of the instrument.

Long-Term Shutdown

To preserve instrument integrity, all liquids must be removed from the instrument for long-term shut down. Contact your Beckman Coulter Representative for instructions.

Power Up

Initial Installation or From Long-Term Shutdown

The DxU Microscopy Series must be turned on in the following order to achieve correct communication between the instrument and the computers.

1 Start the PC Module.

2 At initial start-up or if the instrument has been turned off completely, start the DxU Microscopy Series by pressing the ON switch on the back of the Microscopy Module. During routine use, this button will remain on.

3 If an automated chemistry system is attached, at initial start-up or if the instrument has been turned off completely, start the chemistry analyzer by pressing the ON switch at the back of the Chemistry Module.

4 When the Instrument Screen appears on the monitor, turn on the Microscopy Module by pressing the power switch on the front of the Microscopy Module. The button light will turn green.

5 If an automated chemistry system is attached, turn on the power by pressing the Standby power switch located on the front of the instrument. The button light will turn green.
If the optional Load/Unload Stations are attached, they should be empty during power up.

6 If the optional Load/Unload Stations are attached, turn on the power by pressing the power switch at the rear of the Load/Unload Station.

Re-Booting

NOTE When re-booting the DxU Microscopy Series, it is not necessary to reboot the load/unload stations and the chemistry system unless otherwise indicated.

The DxU Microscopy Series must be turned on in the following order to achieve correct communication between the instrument and the computer:

1 Start the PC Module.

2 If using the optional Load/Unload Stations, make sure the Load and Unload Stations are empty.

3 When the Instrument screen is displayed, start the DxU Microscopy Series by pressing the Standby power switch on the front of the Microscopy Module. The button light will turn green.

4 If using the optional Load/Unload Stations, turn on the power by pressing the power switch at the rear of the Load Station. Make sure the standby lamp (green) in front of the Load Station is on.

Shutting Down the Instrument

When it is necessary to do a complete shutdown of the instrument, shut down the instrument and the computers in the following order:

1 Select **Go Off line**.

2 Select **Instrument** on the top right side of the main screen.

3 Select **Maintenance** located at the bottom of the Instrument screen.

4 Select **Shutdown**. The system will prompt: *Do you want to shut down the instrument?*

5 Select **Yes**. Windows will close and both computers (with two-computer system) will shut down or one computer (with single-computer system) will shut down.

6 Turn off the Microscopy Module by pressing the green button at the bottom right.

NOTE Restart the Microscopy Module as soon as possible. Do not allow the instrument to cool down or the focus will be affected. Do not turn off the chemistry system unless otherwise indicated.

7 If optional Load/Unload Stations are connected, turn off the power at the back of the Load/Unload Station.

Restarting the Instrument

1 Turn on and start the computer.

2 When the Instrument screen is displayed, start the DxU Microscopy Series by pressing the green button on the front of the instrument.

3 Log on to the system.

4 Select **Go On line**.

CHAPTER 9
Setup

Setup

This section describes the steps necessary to set-up and to customize the system definitions.

The DxU Microscopy Series must be initially turned on in the following order to achieve correct communication between the instrument and the computer:

1. Start the PC Module.

2. At initial start-up or if the instrument has been turned off completely, start the DxU Microscopy Series by pressing the ON switch on the back of the Microscopy Module. During routine use, this button will remain on.

3. If an automated chemistry system is connected, at initial start-up or if the instrument has been turned off completely, start the chemistry system by pressing the ON switch at the back of the Chemistry Module.

4. When the Instrument screen is displayed on the monitor, turn on the Microscopy Module by pressing the power switch on the front of the Microscopy Module. The button light will turn green.

5. If an automated chemistry system is attached, turn on the power by pressing the power switch located on the front of the chemistry system. The button light will turn green.

   If the optional Load/Unload Stations are attached, they should be empty during power up.

6. If the optional Load/Unload Stations are attached, turn on the power by pressing the power switch at the rear of the Load/Unload Station.

Settings Screen

NOTE Only a manager can modify the user-defined settings. Any operator can view the settings.The only exception is for switching from primary to back up settings, and vice versa.

1 To access the Settings menu, select **Instrument** located on the top right side of the main screen.

NOTE You must be logged in before you can select **Instrument**.

2 Select **Go Off line**. A confirm window pops up (with warnings).

3 Select **Yes**.

4 Select **Settings** located at the bottom of the Instrument screen.

Accessing a Setup Screen

To access a specific setup screen, select the appropriate button.

Only managers can make changes to the Settings, but both managers and technologists can always view the data.

The following options are available for user-defined settings:

- Operator Accounts
- Lab Information
- System Configuration
- LIS Interface
- Auto Lockout
- Duplicate Specimen
- Formed Particles
- Chemistry
- QC
- REF Override
- iWARE
- RMS Configuration
- Specimen
- Release
- Urine Gating
- Urine Auto-Release
- Urine Auto-Classify
- Load/Unload Station

Printing the Setup

To print the instrument settings, select **Print**.

View Log

Settings are saved in a log each time they are created, modified, or deleted. The log records the date/time and the operator who made the changes. This includes changes made to Chemistry QC such as expiration date made via the Instrument screen\Consumables\Chemistry QC screen.

To access the log, select **View Log**. The Settings Log screen is displayed.

The Settings Log screen includes: **Restore**, **Restore...**, and **Save As...**

NOTE Only one change at the time can be selected for **Restore**, **Restore...**, or **Save as...** options. After a setting has been restored, the operator must restart the system for the change to take effect. See Restart Button in CHAPTER 10, Troubleshooting for more information.

Restore Button

This option can be used to restore settings directly from the View Log.

1. From the list, select the change to restore.
2. Select **Restore**. The setting will be restored to its previous state. The system signals that a restart is necessary.

Restore... Button

This option can be used to restore setting from a source other than the Settings Log, for example a USB drive. See Save as... Button.

1. **Go Off line**.
2. Select **Settings > View Log...** The Settings Log screen is displayed.
3. Select **Restore...** A Windows screen is displayed.
4. Select the source where the setting change was saved.
5. Select the file with a *.slf* extension, and then select **Open**.

6 Select **OK**. The setting will be restored to its previous state. The system signals that a restart is necessary.

7 Perform a **Restart: Maintenance > Restart > Yes to confirm > OK**.

8 Log on to view restored settings.

Save as... Button

This option can be used to save setting change to a source other than the Settings Log, for example a USB drive.

1 Go **Off line.**

2 Select **Settings > View Log...** The Settings Log screen is displayed.

3 From the Settings Log list, select the setting change to save, and then select **Save as...** A Windows save screen is displayed.

4 Select the User (U:) drive where the setting change will be saved.

5 If necessary, change the name of the file, for example the setting parameter that was changed, and then select **Save** and **OK** to exit.

The setting change can be retrieved to restore the previous setting. See Restore... Button.

Viewing the Saved Settings

This function can be used to view the saved settings, and if necessary, transmit the settings to Beckman Coulter or your distributor.

1 Go **Off line**.

2 Select **Settings > View Log...** The Settings Log screen is displayed.

3 Perform a **Save as...** and select the User (U:) drive, and then select **Save**.

4 Press  and the **D** key. The User (U:) drive is displayed.

5 Select the User (U:) drive icon or external drive where the file was saved.

6 Find your file.

7 Right-click the file with the *.slf* extension, and then select **Rename**.

8 Replace the *.sfl* extension with **.xml** and then press **Enter**. A Warning is displayed.

9 Select **Yes**.

10 Double-click the **.xml** file.

11 Open the file with Internet Explorer (if prompted). Saved file contents with *.xml* settings is displayed.

Operator Accounts Settings

The Operator Accounts screen displays the list of authorized operators and their privilege level (*Technologist* or *Manager*). From this screen, operators can be added or deleted.

The Operator Accounts screen displays Operator Identifier and Privilege as well as **New** and **Delete** buttons.

Adding a New Operator

1 From the Operator Accounts screen, select **New**. The New Operator Account screen is displayed.

The New Operator Account includes: Operator Identifier, Tech, Manager, Password, and Confirm Password.

NOTE The *Operator Identifier*, *Password*, and *Confirm password* fields are case-sensitive.

2 Type the new operator identification in the *Operator Identifier* field (the following characters cannot be used: **[ ]** ‘ and no space insertion).

3 Select the corresponding button to select the operator level (**Technologist** or **Manager**).

4 Type the new operator password in the *Password* field.

5 Retype exactly the new operator password in the *Confirm password* field.

6 Select **OK** to add the new operator to the Operator Accounts screen.

7 Select **OK** to validate the new operator entry and close the screen.

Deleting an Operator

NOTE The currently logged operator cannot delete his/her own operator account.

1 From the Operator Accounts screen, select the operator to be deleted, and then select **Delete**.

The system prompts for confirmation: *Really delete the selected operator account?*

2 Select **Yes** to delete the selected operator from the operator list.

3 Select **OK** to validate the deletion and close the screen.

Modifying an Operator

To modify any information concerning an existing operator, first delete the operator from the list, and then add the operator with the new information (for example, changing a password).

Laboratory Information Settings

The Laboratory Information screen displays seven lines allowing the operator to enter specific laboratory information that will be displayed on reports. The screen instructs to enter laboratory information (such as laboratory name, telephone number, etc.) in the fields provided. The information will be included in reports produced by the instrument. Blank lines will be skipped. The screen also has a signature line label, which can be left blank to suppress.

1 Type the laboratory information in the order it will be displayed on reports.

2 To add a signature line to the last page of patient reports, enter the desired information into the Signature field. If no signature line is required, leave the field blank to suppress it.

3 Select **OK** to validate the entries and close the screen.

System Configuration Settings

The System Configuration Settings screen allows specifying the presence of microscopy and/or chemistry system, and activating the DxU Microscopy Series software chemistry gating options.

The chemistry settings can be saved for a primary and a backup chemistry system. The operator has the possibility to mix conventional and qualitative chemistry settings for the automated chemistry system. These values can be user-defined in the Chemistry Settings screen.

The System Configuration screen includes the following options:

- Microscopy System Present checkbox
- Chemistry System Present checkbox
- ID fields for both the microscopy analyzer and the chemistry analyzer
- Iris fully-automated chemistry system or other chemistry system
- Install settings
- Save as Primary
- Save as Backup
- Skip microscopy if chemistry available
- Gate on chemistry
- Consolidation Window (hours and/or minutes)

Select the appropriate checkbox depending on the laboratory configuration. Options are enabled if both the microscopy and chemistry systems are present.

Microscopy System Present

1 Select the checkbox to enable the microscopy system.

2 In the *ID* field, enter the microscopy system serial number. The serial number plate is located on the back of the instrument on the right bottom corner.

Chemistry System Present

1 Select the checkbox to enable the chemistry system.

2 In the *ID* field, enter the chemistry system serial number. The serial number plate is located on the back of the instrument.

Enter Primary Chemistry Settings

1 From the Instrument screen, select **Go Off line**. Select **Settings**. Select **System Configuration**.

2 From the System Configuration screen, select the analyzer to be used as primary system. Select **Install Settings**. The Select Chemistry Settings screen is displayed.

The Select Chemistry Settings screen includes the option to select the chemistry settings to install with a list of possible instrument setting choices. Settings may be designated as primary and/or backup.

3 Use the pull-down button to select the primary chemistry system and settings to install.

4 Select **OK** to install the chemistry settings and return to the System Configuration screen.

5 Select **OK**. The system will prompt to restart the software.

6 From the Instrument screen, select **Maintenance**, and then select **Restart**.

7 When the system restarts, from the Instrument screen, select **Go Off line**. Select **Settings**.

- If the chemistry settings need to be personalized: select **Chemistry** and edit the chemistry settings as necessary. When completed, select **OK**. The system will prompt to restart the software. From the Instrument screen, Select **Maintenance**, and then select **Restart**.
- If the chemistry settings do not need to be edited: select **System Configuration**.

8 From the System Configuration screen, make sure the proper primary settings are displayed.

9 Select **Save as Primary**.

10 Select **OK**. The system will prompt to restart the software. From the Instrument screen, select **Maintenance**, and then select **Restart**.

Enter Backup Chemistry Settings

1 From the Instrument screen, select **Go Off line**. Select **Settings**. Select **System Configuration**.

2 From the System Configuration screen, select the analyzer to be used as backup system – Other chemistry system. Select **Install Settings**. The Select Chemistry Settings screen is displayed.

The Select Chemistry Settings screen displays the option to select the chemistry settings to install with a list of possible choices.

3 Use the pull-down button to select the backup chemistry system and settings to install.

4 Select **OK** to install the chemistry settings and return to the System Configuration screen.

5 Select **OK**. The system will prompt to restart the software.

6 From the Instrument screen, select **Maintenance**, and then select **Restart**

7 When the system restarts, from the Instrument screen, select **Go Off line**. Select **Settings**.

- If the chemistry settings need to be personalized, select **Chemistry** and edit the chemistry settings as necessary. When completed, select **OK**. The system will prompt to restart the software. From the Instrument screen, select **Maintenance**, and then select **Restart**.
- If the chemistry settings do not need to be edited, select **System Configuration**.

8 From the System Configuration screen, make sure the proper settings are displayed.

9 Select **Save as Backup**.

10 Select **OK**. The system will prompt to restart the software. From the Instrument screen, select **Maintenance**, and then select **Restart**.

Consolidation Window

Enter the time frame during which chemistry and microscopy results will be associated when they are obtained from the reading of the same barcode label identification.

NOTE The time frame can be set between one hour and 48 hours. The default time frame is 24 hours.

Validating the Changes

1 Select **OK** to validate the entries and close the screen.

2 If any change is made to the System Configuration settings, restart the system for the changes to take effect. After rebooting, the Instrument screen will be displayed.

LIS Interface Settings

The LIS Interface screen is used to enable LIS communication and configure the LIS communication settings. It is used also to enter the patient demographics settings. You can send chemistry information before querying the LIS by selecting the **Send chemistry information before querying the LIS** check box on the LIS interface screen.

Enable LIS

Check the Enable LIS box to enable communication with the LIS.

Communication Settings

Use the drop-down arrow to select the specific communication settings for the LIS.

Specimen Information from LIS

Obtain Specimen Information from LIS

If this box is checked, the work orders (Run, Skip, Gate, Chem only, Micro only) and chemistry results will be obtained from the LIS. If this box is checked, the specimen gating criteria and chemistry results will be obtained from the LIS. This feature is not compatible with **Gate on**

Chemistry. When **Obtain Specimen Information from LIS** is selected in combination with **Gate on Chemistry**, a warning is displayed notifying the operator that this combination is incompatible. The operator will not be able to save these settings. See System Configuration Settings.

Skip Specimen if LIS Fails

If this box is checked, the specimen will not be sampled for microscopy if the communications with the LIS failed.

Obtain Chemistry Information from LIS

If this box is checked, chemistry results must be obtained from the LIS. The **Chemistry System Present** option must be disabled. See System Configuration Settings.

Obtain Patient Demographics Information from LIS

If this box is checked, the **Demographics** button is enabled.

Demographics

1 Select **Demographics** to open the Demographics screen.

The Demographics screen displays the following options under Check Required Fields: Last Name, First Name, Middle Name, Date of Birth, Location, Record Number, and Gender.

NOTE If a required field is missing, a Demographics Flag will be generated.

2 Select the demographics options required from the LIS after the barcode label on the patient specimen is read.

3 Select **OK** to validate the entries and return to the LIS Interface screen.

Suppress Usage of Generated Chemistry Results When Obtaining Specimen Information from the LIS

If this box is checked, the results will be released to the LIS when:

- Microscopy is not required - chemistry results are released.

OR

- Microscopy is required - consolidated chemistry and microscopy results are released.

If this box is not checked, the results will be released to the LIS when:

- Microscopy is not required - chemistry results are released.

AND

- If microscopy is required, chemistry results are released before microscopy is run; the consolidated chemistry and microscopy results are released. In this case, chemistry results will be released twice to the LIS.

Specimen Information to LIS

Suppress "[none]" Results

If this box is checked, any formed particle with a result of [none] will not be transmitted to the LIS.

Suppress Chemistry Result That Precedes Consolidation With Microscopy System

If this box is checked, chemistry results from the chemistry analyzer will be printed on the DxU Microscopy Series printer when:

- Microscopy is not required - chemistry results are printed.

OR

- Microscopy is required - consolidated chemistry and microscopy results are printed.

If this box is not checked, chemistry results from the chemistry analyzer will be printed on the DxU Microscopy Series printer when:

- Chemistry analysis is completed - chemistry results are printed.

AND

- Microscopy is required - consolidated chemistry and microscopy results are printed.

NOTE Chemistry results are always automatically printed on the chemistry analyzer printer when chemistry analysis is completed.

When all the settings have been entered, select **OK** to validate the entries and return to the Settings screen.

Auto Lockout Settings

The Auto Lockout Configuration settings allows you to define and set a time after which the software will automatically lockout the operator if the system has been idle for the specific user-defined amount of time. The time window can be set between 5 to 60 minutes. The enabled default time window is 15 minutes.

The automatic lockout can only be enabled or disabled by a Manager level operator. An auto lockout will occur if the instrument goes into Standby.

Follow these steps for Auto Lockout Settings:

1 Select**Auto Lockout.**

2 After Auto Lockout Configuration appears, select **Enable.**

3 Select the time window, which can be set between 5 to 60 minutes.

4 Select **OK.**

Duplicate Specimen ID Detection Configuration

This feature allows you to select the detection time window for possible duplicate specimen IDs in your laboratory between 12 and 72 hours. For example, a value of 12 indicates any specimens with the same ID run within the past 12 hours will be flagged as duplicate and held for your review. The default value is 12 and the value cannot be left empty.

Setting the Duplicate Specimen ID Detection Time:

To access and set the desired time frame:

1 Log on as a Manager.

2 From the Instrument Screen, select **Go Off line** > **Yes** to confirm.

3 Select **Settings** > **Duplicate Specimen**.

4 From the Duplicate Specimen ID Detection Configuration screen, enter a time between 12 and 72 hours.

5 Select **OK**.

6 Select **OK** again to return to the Instrument screen.

7 Select **Maintenance**.

8 Select **Restart**.

9 Select **Yes** to confirm.

10 When the system restarts, the Instrument screen will reappear.

11 Log back on to the system.

Formed Particles Settings

The Formed Particles screen allows you to enter specific information such as, short name, long name, reporting units, grading, and abnormal threshold. The **Dilutions** button allows you to define up to 10 dilutions.

The Formed Particles screen displays a list of all of the possible formed particle types.

NOTE The software uses the key names to classify the pictures. Short Names and Long Names are user-defined, but must match the software classification.

Table 9.1 Key Names for Picture Classification

Key	Category
RBC	Red blood Cell
DRBC	Dysmorphic Red Blood Cell*
WBC	White Blood Cell
WBCC	White Blood Cell Clump
BACT	Bacteria
BYST	Budding Yeast
HYST	Yeast with Pseudo Hyphae
SQEP	Squamous Epithelial
TREP	Transitional Epithelial
REEP	Renal Epithelial
OVFB	Oval Fat Body
FAT	Fat
MUCS	Mucous
RBCC	Red Blood Cell Clump
SPRM	Sperm
TRCH	Trichomonas

Table 9.1 Key Names for Picture Classification *(Continued)*

Key	Category
NSE	Non-Squamous Epithelial
UNCC	Unclassified Cast
HYAL	Hyaline Cast
EPIC	Epithelial Cast
WBCT	White Blood Cell Cast
RBCT	Red Blood Cell Cast
GRAN	Granular Cast
CELL	Cellular Cast
BROAD	Broad Cast
FATC	Fatty Cast
WAXY	Waxy Cast
UNCX	Unclassified Crystal
TP04	Triple Phosphate Crystal
CAOX	Calcium Oxalate Crystal
CAPH	Calcium Phosphate Crystal
CACB	Calcium Carbonate Crystal
URIC	Uric Acid Crystal
LEUC	Leucine Crystal
CYST	Cystine Crystal
TYRO	Tyrosine Crystal
AMOR	Amorphous Crystal
ART	Artifact
UNCL	Unclassified
ASP	All Small Particles

*Enabled under **Settings** > **Specimen**, then select box **Report Dysmorphic RBC's**.

Editing Dilution Codes

1 From the Formed Elements screen, select **Dilution Codes**.

Ten dilution ratios are available: default plus nine. The ratios will apply to all particles since they will be used on the sample.

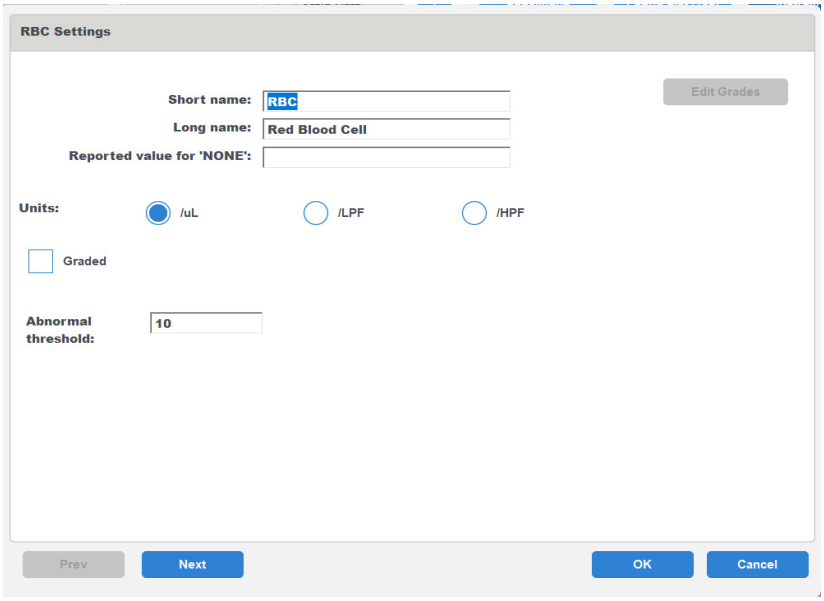
2 Select the dilution level to edit, enter the dilution ratio, and then select **OK** to close the Dilution screen.

A definition of 1:2 means 1 part specimen + 1 part Iris Diluent. All other dilutions are expressed similarly. A dilution of 1:4 is 1 part specimen plus 3 parts Iris Diluent with *4* as the total number of parts.

The Dilution Code screen displays a list of dilution codes labeled as 0-9 that are user definable (Exception: Dilution code labeled as 0 (a 1:1 dilution) cannot be changed).

Editing Particle Settings

1 Select the row corresponding to the particle to be edited, and then select **Edit** or double-click the row. The Particle Settings screen is displayed.



2 In the *Short Name* field, enter the particle abbreviation that will be displayed on the Specimen screen (alphanumeric).

3 In the *Long Name* field, enter the element name that will appear on the final reports (alphanumeric).

The *Reported value for the "NONE"* field is used to customize what is reported when both graded and counted particles are not detected.

- If the field is left blank, particle not detected will not be reported.
- If a value is entered, particle not detected will be reported to the LIS with the value entered in the field.

4 Select the Reporting Units by selecting the corresponding button: **µl**, **LPF**, or **HPF**.

5 Grading selection:

- If the elements are to be graded, select the **Graded** checkbox. The Abnormal threshold area will be displayed.
  - Select a grade for abnormal threshold. Microscopy results for this element with values greater than the selected value will be flagged with H (high).
- If the **Graded** checkbox is not selected, the *Abnormal threshold* edit box will be displayed.
  - Enter a specific value for abnormal threshold, such as 17/µL for RBC. Microscopy results for this particle with values greater than the entered value are flagged with H (high).

A new warning message appears when editing abnormal threshold and/or grade settings:

Risk of erroneous results. X units were changed. Please ensure to update the abnormal threshold and/or grade settings as applicable.

X refers to the analyte being modified.

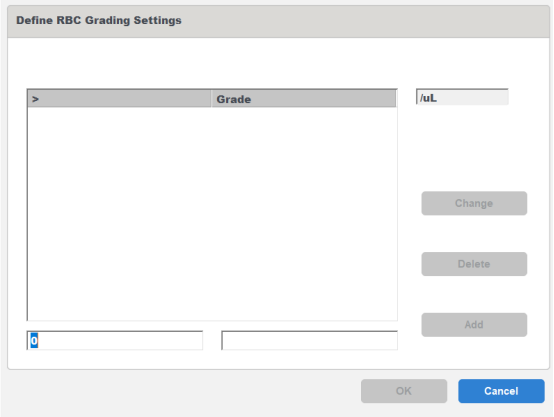
6 Select **OK** to close the Settings screen.

7 Select **OK** to confirm the changes and close the Formed Particle screen.

Editing Grades

1 Select the element to be edited, and then select **Edit** or double-click the row. The Seetings screen for the particle you selected is displayed.

2 Select **Graded**, then select **Edit Grades**. The Formed Particle Grading Settings screen is displayed.



The left box displays the instrument result while the right box represents the result that will be displayed on the Results screen, the report and the LIS. You can personalize the results that will be displayed by changing the Grade values. Commonly used grades are *Small, Moderate, Large +1, +2, etc. 0-2/LPF, 3-5/LPF, etc.*, or *Present*.

Changing a Grade

Select the desired row. The values are displayed in the edit boxes.

Enter the new grades in the edit boxes, and then select **Change**.

Deleting a Grade

Select the desired row, and then select **Delete**.

Adding a Grade

Enter the new grade in the edit boxes, and then select **Add**. The new grade is added to the list.

Validating the Changes

When all the changes are completed for a specific element, select **OK** to close the screen. The Formed Particle Settings screen is displayed reflecting the changes. Select **OK** to confirm the changes and close the screen.

Chemistry Settings

The Chemistry Settings screen allows you to enter chemistry specific information, such as short name, long name, reporting units, confirmation threshold, and abnormal threshold.

The chemistry system present and its reporting units are defined in the System Configuration Input Settings screen. See System Configuration Settings. Table 9.2, Chemistry Names for Chemistry Analytes lists the short and long names used for each chemistry analyte:

Table 9.2 Chemistry Names for Chemistry Analytes

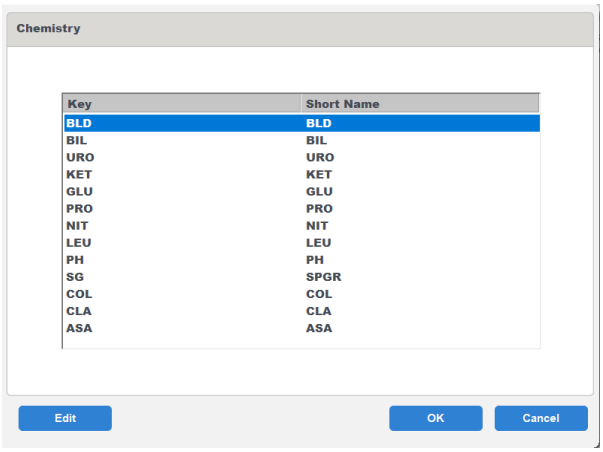
Chemistry Short Name	Chemistry Long Name
BLD	Blood
BIL	Bilirubin
URO	Urobilinogen
KET	Ketones
GLU	Glucose
PRO	Protein
NIT	Nitrite

Table 9.2 Chemistry Names for Chemistry Analytes *(Continued)*

Chemistry Short Name	Chemistry Long Name
LEU	Leukocytes
pH	pH
SPGR	Specific Gravity
COL	Color
CLA	Clarity
ASA	Ascorbic Acid

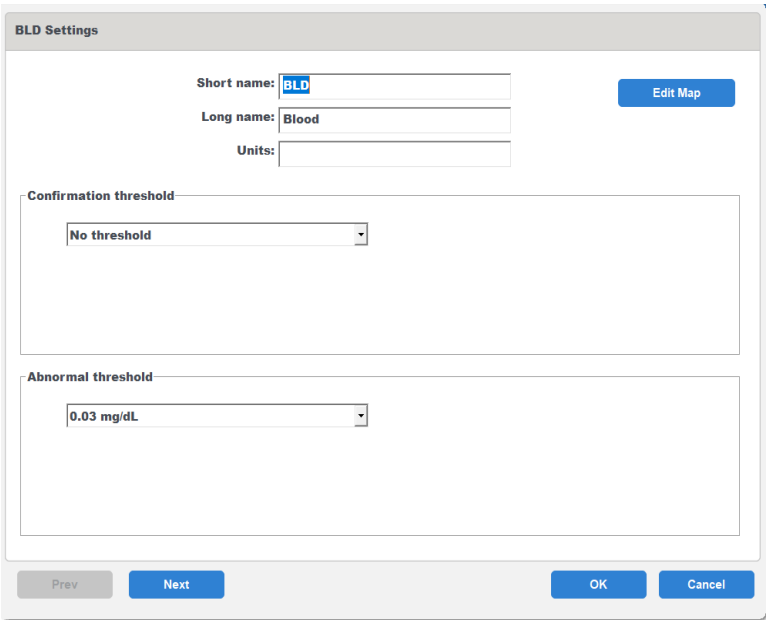
Do not change any Chemistry Input Settings without consultation with your Beckman Coulter Representative. Output may be changed as needed to reflect the usual reporting terminology of the laboratory.

Figure 9.1 Chemistry Key Names Screen



Editing Chemistry Settings

1 Select the row corresponding to the chemistry to be edited and select **Edit**, or double-click the row. The Chemistry Settings screen is displayed.



2 In the *Short Name* field, enter the chemistry abbreviation that will be displayed on the Specimen results screen (alphanumeric).

3 In the *Long Name* field, enter the chemistry name that will appear on the final reports (alphanumeric).

4 In the *Units* field, enter the reporting units.

5 Choose a **Confirmation threshold**, if applicable. A Confirmation threshold can be used to prevent Auto-release of specific chemistry results. If **No Threshold** is selected, chemistry results for that analyte will not be flagged for review.

- If a threshold value is selected, chemistry results with values equal to or higher than the confirmation threshold chosen will be flagged for review. This flag must be cleared before the results can be released. Abnormal chemistry results can thus be reviewed **before** clearing the flag.

NOTE The intent of the Confirmation Threshold is to remind the operator to perform a confirmatory test. In most laboratories, Bilirubin is the most commonly confirmed test. Most analytes will use *No Threshold*.

The Abnormal threshold defines the level at which a result is considered abnormal:

- If No Threshold is selected, no abnormal flags will appear with results.
- If a threshold value is selected, chemistry results with values equal to or higher than the abnormal threshold will be flagged H (high). The high result and the *H* flag will be displayed in red on the screen.

6 Edit the Chemistry Setting, if desired, by following the directions in the next section.

7 When all modifications for the chosen analyte are completed, select **Next** to move to the next analyte. When finished all changes, select **OK** to close the Settings screen. After the parameters are changed, a dialog box appears directing you to check and ensure that the Chemistry QC settings are still valid.

8 Select **OK** when the system prompts you to ensure that the Chemistry QC settings (located under *Consumables*) are still valid.

9 Select **OK** to confirm the changes and close the Chemistry screen.

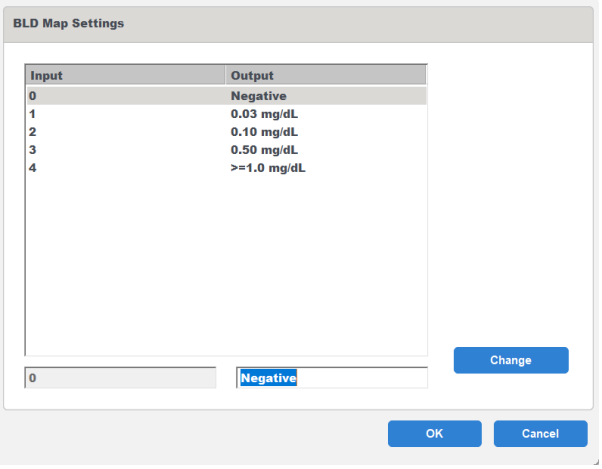
Editing Chemistry Values

1 Select the row corresponding to the chemistry to be edited and select **Edit**, or double-click the row. The Chemistry Settings screen for the chosen analyte is displayed.

2 From the Chemistry Settings screen, select **Edit Map**. The Chemistry Map Settings screen is displayed for the chosen analyte.

The Input Value is the value that comes from the chemistry analyzer to the Analysis Processor. The Output Value is the result that is displayed on the Monitor, the printed result, and the result transmitted to the LIS.

NOTE The outputs for the chemistry analyzer are originally selected within the System Configuration settings. If any further changes are desired, use the Edit Map Settings from the Chemistry Settings screen.



Changing a Value

NOTE Do this only with the assistance of your Beckman Coulter Representative.

Select the desired row. The value is displayed in the edit box.

Enter the new value in the edit box, and then select **Change**.

Validating the Changes

1 When all the changes are completed for a specific chemistry, select **Next** to move to the next analyte, or select **OK** to close the screen. The Chemistry Settings screen is displayed reflecting the changes.

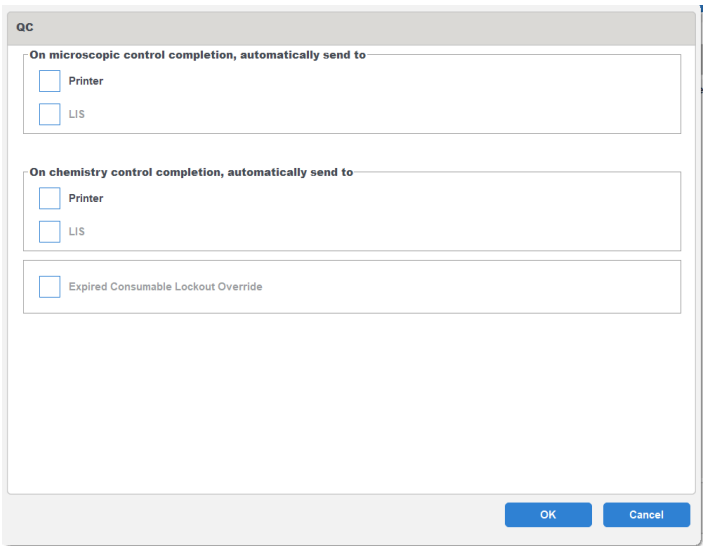
2 When all desired changes have been made, select **OK** to confirm the changes and close the screen.

QC Settings

QC Result Destination

The QC screen allows you to automatically send control results to the printer, the LIS, or both for Microscopy and Chemistry QC.

Figure 9.2 QC Screen



Select the destination for QC results to be sent automatically for Microscopy QC and Chemistry QC.

NOTE Both the Printer and LIS checkboxes can be selected as automatic release destinations for QC results.

Expired Consumable Lockout Override

See Expired Consumable Lockout Override in CHAPTER 17, Consumables Traceability.

Only a manager can enable the Expired Consumable Lockout Override function for a sample to be run on the instrument. This checkbox is enabled only if an expired consumable material is used.

⚠ WARNING

This feature is only there for training purposes. It is not to be used when reporting diagnostic results. Do not use for diagnostic purposes.

When a manager overrides the lockout, the Expired Consumable red alarm becomes a yellow alarm and the **Expired Consumable Lockout Override** checkbox is disabled again until an expired consumable material is used.

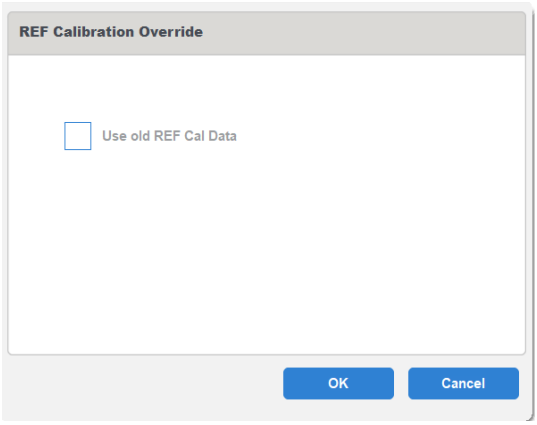
NOTE Use of expired consumable is not recommended by the manufacturer and may lead to reporting erroneous results.

REF Override Settings

The REF Calibration Override screen is used to override a failed calibration and to use the Run Equivalency Factor (REF) from the previously stored calibration data. This option can be used only by a manager-level operator.

NOTE This option becomes available only after a failed calibration attempt. It should only be used when the QC is within limits.

Figure 9.3 REF Calibration Override Screen



1 Check the **Use old REF Cal Data** box to use the previously stored calibration data.

2 Select **OK** to validate the selection and close the screen.

iWARE

See CHAPTER 14, iWARE Expert System for iWARE information.

RMS Configuration

This option allows you to enroll in the Remote Management System (RMS) program. The Remote Management screen is where your system's hardware is registered with Beckman Coulter's PROService. Registration creates an account that allows remote monitoring of your system. Remote Management, through PROService, can also be used as direct communication with your system with a Beckman Coulter Service Representative, for troubleshooting services. The Allow Control settings give you the ability to allow access for 15 minutes, access with lab authorization, or to automatically deny access.

Setting Up Remote Management

1. Select **Settings** > **RMS Configuration** > **RMS Registration**
2. Select **SubModel** from the drop-down menu.
3. Enter a number in the *Instance Number* text box. Service will supply you with the instance number.
4. Select **Enroll** (default is Unenroll). The Instrument Enrollment Status changes from Not Enrolled to Enrolled. A RMS ID, unique to the analyzer, is generated.
5. Set up Remote Desktop Sharing options by either selecting the **Lab Authorization** option or the **Always Deny** option.
6. Select **OK** to save settings.

Specimen Settings

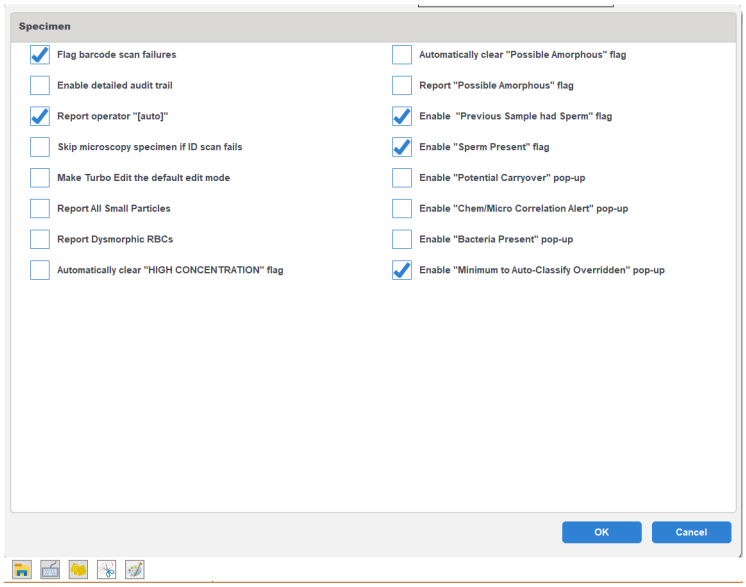
The Specimen screen allows you to:

- Flag barcode scan failures
- Enable a detailed audit trail
- Report the operator as [auto]
- Skip the specimen if the barcode reader fails to read the barcode label located on the sample tube
- Set the default edit mode
- Automatically clear or report specific flags
- Report all small particles and dysmorphic RBCs
- Enable/disable specific flags/pop-ups

Flags and/or pop-ups assist with the analysis of specimens. Pop-ups are a means of getting the technologist's attention for certain conditions when the operator has selected **Accept** on the Results screen.

Pop-ups do not impact the auto-release and are displayed in a dialog box requiring the operator response in order to proceed. Pop-ups are not recorded in the database or any reports (printer or LIS).

Figure 9.4 Specimen Screen



Flag Barcode Scan Failures

If checked, barcode scan failures will be flagged as ID_ERROR.

If unchecked, the condition will not be flagged and the specimen will be assigned an identifier consisting of underlines. If unchecked, **Skip specimen if ID scan fails** will be also unchecked. Leaving this box unchecked is not compatible with Manual Orders.

Enable Detail Audit Trail

If checked, this option will indicate, inside the Audit Trail field of the report, any changes that were made to the results, including the name of the operator who made these changes. This option must be selected in order to edit chemistry results. See Editing Chemistry Results in CHAPTER 6, Data Review.

Report Operator [Auto]

If checked, this option will set the username to [Auto] for results that are auto-released.

If unchecked, the results will display the name of the operator currently logged in when the results are auto-released.

Skip Microscopy Specimen if ID Scan Fails

If checked, the specimen will not be sampled for microscopy if the barcode reader cannot read the barcode label.

Make Turbo Edit the Default Edit Mode

If checked, the Turbo mode will be used to display the particle images. See Turbo Edit Button in CHAPTER 6, Data Review. If unchecked, all results will be shown in Full Edit mode.

Report All Small Particles

If checked, ASP will be included in the printout and transmitted reports.

Report Dysmorphic RBCs

If checked:

- DRBC settings can be defined. See Formed Particles Settings.
- DRBC verification button will be enabled in the Specimen resulting screen.
- DRBCs results will be transmitted to the DxU Microscopy Series printer and the LIS.

If unchecked, all fields and buttons associated with DRBCs will be disabled.

Automatically Clear “High Concentration” Flag

If checked, the High Concentration flag will be automatically cleared by the software.

If unchecked, the flagged specimen will remain on the Work List and the operator will be responsible for clearing the flag.

Automatically Clear “Possible Amorphous” Flag

If checked, Possible Amorphous flag will be automatically cleared by the software.

If unchecked, the flagged specimen will remain on the Work List and the operator will be responsible for clearing the flag. See Amorphous Flag in CHAPTER 16, Auto-Release (Edit-Free Release).

Report “Possible Amorphous” Flag

If checked, the Possible Amorphous flag will transmit to the LIS and/or printer.

If unchecked, the Possible Amorphous flag will not transmit to the LIS and/or printer.

Enable “Previous Sample Had Sperm” Flag

If checked, the specimen results will not transmit to the LIS and/or printer.

If unchecked, the specimen results will be automatically transmitted to the LIS and/or printer depending on user-defined criteria for auto-release.

Enable “Sperm Present” Flag

If checked, the specimen results will not transmit to the LIS and/or printer.

If unchecked, the specimen results will be automatically transmitted to the LIS and/or printer depending on user-defined criteria for auto-release.

Enable “Potential Carryover” Pop-Up

If checked, pop-ups are displayed in a dialog box requiring the operator response in order to proceed. See High Concentration in CHAPTER 6, Data Review.

If unchecked, the specimen results will be automatically transmitted to the LIS and/or printer depending on user-defined criteria for auto-release.

IMPORTANT If Auto-release is enabled, pop-ups will not stop result transmission to the LIS

Enable “Chem/Micro Correlation Alert” Pop-Up

If checked, pop-ups are displayed in a dialog box requiring the operator response in order to proceed. See Chem/Micro Correlation Alert in CHAPTER 6, Data Review.

If unchecked, the specimen results will be automatically transmitted to the LIS and/or printer depending on user-defined criteria for auto-release.

IMPORTANT If Auto-release is enabled, pop-ups will not stop result transmission to the LIS

Enable “Bacteria Present” Pop-Up

If checked, pop-ups are displayed in a dialog box requiring the operator response in order to proceed. See Bacteria Present in CHAPTER 6, Data Review.

If unchecked, the specimen results will be automatically transmitted to the LIS and/or printer depending on user-defined criteria for auto-release.

IMPORTANT If Auto-release is enabled, pop-ups will not stop result transmission to the LIS

Enable “Minimum to Auto-Classify Overridden” Pop-Up

If checked, pop-ups are displayed in a dialog box requiring the operator response in order to proceed. See Minimum to Auto-Classify Overridden in CHAPTER 6, Data Review.

If unchecked, the specimen results will be automatically transmitted to the LIS and/or printer depending on user-defined criteria for auto-release.

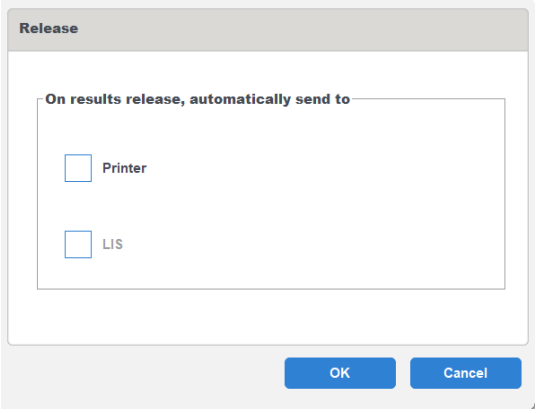
IMPORTANT If Auto-release is enabled, pop-ups will not stop result transmission to the LIS

When all the selections have been entered, select **OK** to validate the selections and close the screen.

Release Settings

The Release screen allows you to select the destination for the release of results.

Figure 9.5 Release Screen



1 Check the destination for the release of results.

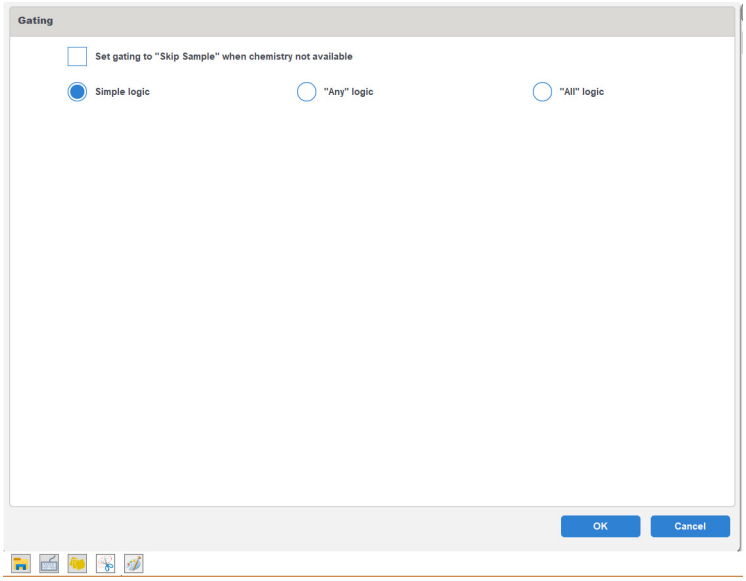
2 Select **OK** to validate the selection and close the screen.

NOTE Both the Printer and LIS checkboxes can be selected as the release destinations for results.

Urine Gating Settings

The Gating screen is used to define the skip/run criteria for microscopy based on the chemistry results. The settings do not take effect unless the **Gate on Chemistry** box is checked in the System Configuration section.

Figure 9.6 Gating Screen



Set Gating to “Skip Sample” When Chemistry Is Not Available

When this box is checked, and checked in System Configuration, microscopy testing will not be performed if the chemistry results are not available for the specimen.

Simple Logic

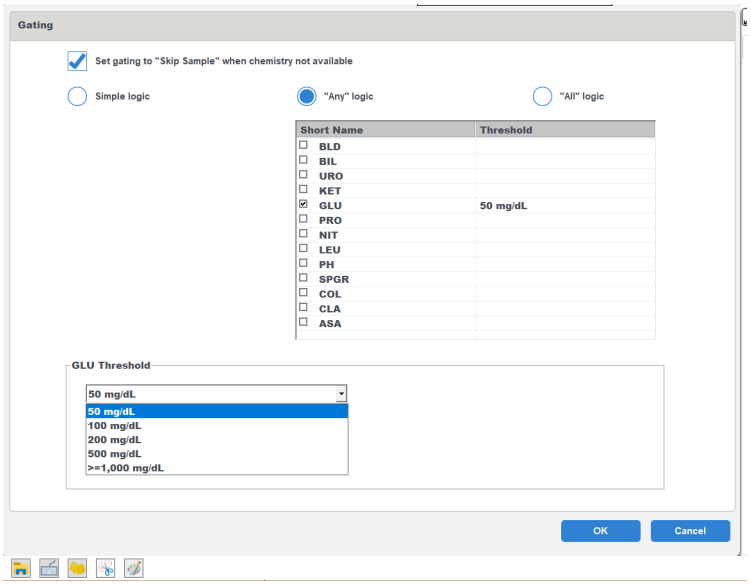
Specimens with any chemistry result(s) equal to or higher than the abnormal thresholds values entered in the Chemistry Settings screen will be sampled for microscopy.

Select **Simple Logic**, and then select **OK**.

“Any” Logic

Specimens with any selected chemistry results equal to or higher than the specific gating threshold will be sampled for microscopy.

1 Select **"Any" logic**. The Chemistry list is displayed.



2 Select the box next to chemistry short name.

3 Select a chemistry short name. The threshold values entered in *Settings* are displayed.

4 Edit the thresholds, if desired. Select the drop-down arrow. The available grades/values for the selected analyte are displayed.

5 To change the default threshold, select the line corresponding to the value at which the microscopy will be performed for the selected chemistry.

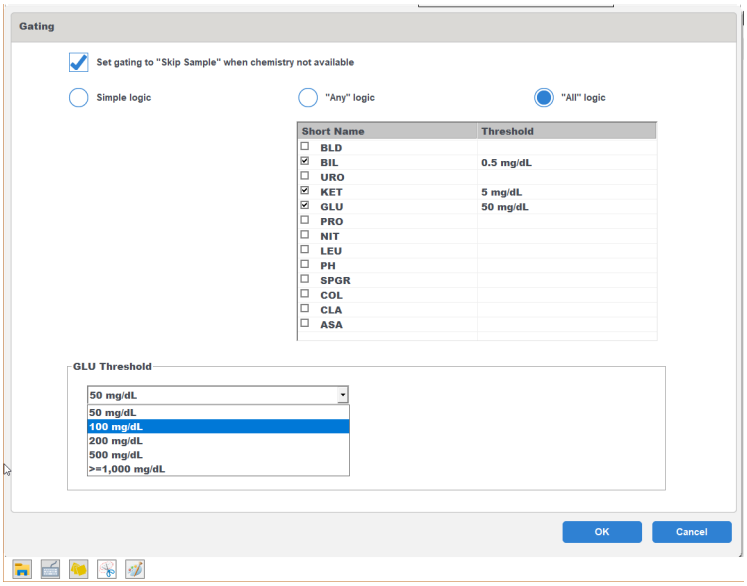
6 Repeat steps 2 and 5 for the each chemistry requiring entry.

7 Select **OK** to validate the entries and close the screen.

"All" Logic

Specimens with all selected chemistry results equal to or higher than the specific gating threshold will be sampled for microscopy

1 Select **"All" Logic**. The Chemistry list is displayed.



2 Select the box next to chemistry short name.

3 Select a chemistry short name. The threshold values entered in *Settings* are displayed.

4 Edit the thresholds, if desired. Select the drop-down arrow. The available grades/values for the selected analyte are displayed.

5 To change the default threshold, select the line corresponding to the value at which microscopy will be performed for the selected chemistry.

6 Repeat steps 2 and 5 for each chemistry requiring entry.

7 Select **OK** to validate the entries and close the screen.

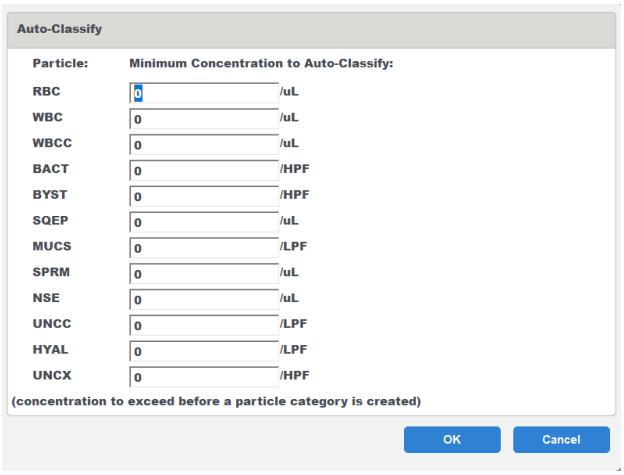
Urine Auto-Release

See CHAPTER 16, Access/Enable Auto-Release Screen.

Urine Auto-Classify Settings

The Auto-Classify screen allows you to define the concentration required for APR to create particle categories. This should be used to decrease the number of false positive results, such as WBCC and BYST.

Figure 9.7 Auto-Classify Screen



1 Enter the minimum concentration required for each category.

NOTE Particles that do not meet the minimum requirement for the category will be placed into the UNCL (Unclassified) category.

2 Select **OK** to validate the selection(s) and close the screen.

NOTE If the laboratory does not report one or more of the 12 particles identified by the APR, place a series of six or more nines (9) (99999999) in the minimum concentration field for the particle. This will cause all images for that particle to be placed in Unclassified [UNCL]. The particle result will not appear on the printed report or be transmitted to the LIS.

Load/Unload Station

1 Select the **Load/Unload Station** setting button. The *Load/Unload Available* option is unchecked by default.

2 Select **Load/Unload Station** if Load/Unload stations are available on this system. When a new operator logs in or 8 hours have passed since the Load/Unload warning has appeared, another Load/Unload warning message will display the following:

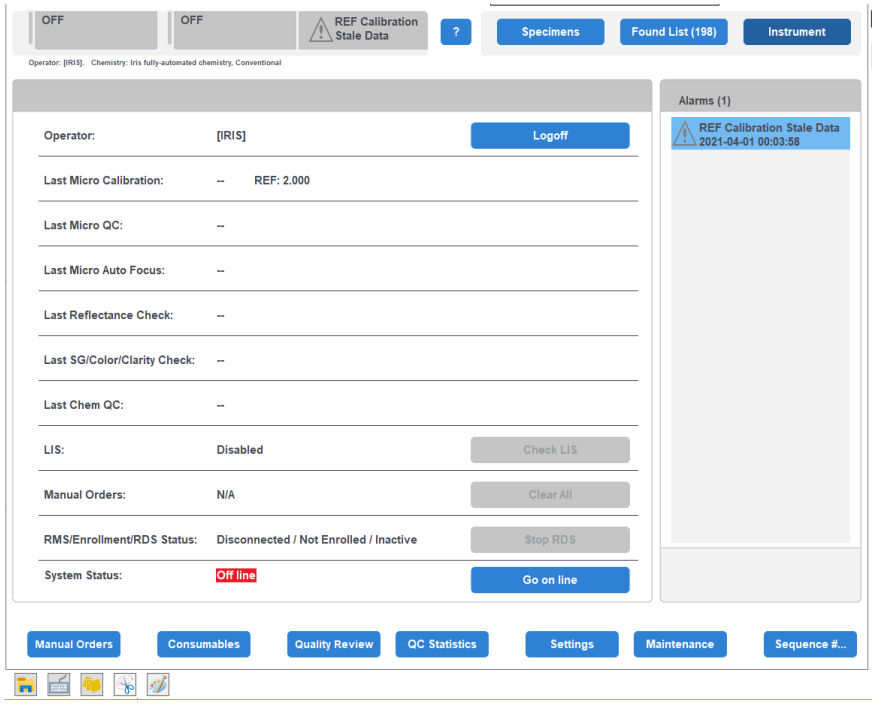
WARNING! Risk of Erroneous Results. Use validated preservative tubes. If using non-preservative tubes, do not reload the Load Station tray until all samples have left the chemistry system sampler.

3 Select when the message appears to acknowledge the specific sample and stability requirements associated with using the Load/Unload stations. See CHAPTER 1, Load/Unload Station (Optional). The acknowledgement will be captured and recorded.

Sequence Number

A sequence number is assigned to samples and functions as a counter of the number of samples that are run on the system. The sequence number is displayed on the Specimen Results screen, and is displayed and printed on the specimen report.

Figure 9.8 Instrument Screen with **Sequence** Button



The **Sequence** button, located on the bottom right of the Instrument screen, gives access to a Sequence number screen into which the next sequence number to be used can be entered. The initial sequence number that can be entered must be comprised between 0 and 2147483647.

CHAPTER 10

Troubleshooting

Maintenance

NOTE Refer to your chemistry operator's manual for chemistry system maintenance.

Precautions

⚠ WARNING

Wear protective gloves to prevent exposure to pathogens. Discard contaminated materials according to applicable regulations.

Daily Maintenance

Table 10.1 Daily Maintenance

Items	Suggested Interval
Run Control Rack	Daily

Periodic Maintenance

Table 10.2 Periodic Maintenance

Items	Suggested Intervals
Perform instrument calibration	Monthly
Perform System Back up	After setup or changes to settings

Daily Maintenance

Control Rack

The DxU Microscopy Series control rack is color-coded. The positions on the control rack are used for specific functions to the instrument. Position definitions and functions are indicated in Table 10.3, Control Rack Positions and Functions.

Table 10.3 Control Rack Positions and Functions

Position	Insert Color	Vol	Contents	Function	Barcode
1	None	3 mL	Iris System Cleanser	Cleans lines	No
2	Gray	3 mL	Iris Diluent	Rinses Cleanser from lines	No
3	Gray	3 mL	Iris Diluent	Rinses Cleanser from lines	No
4	None		**Empty**		
5	Dark Blue	6 mL	iQ Focus	Focuses camera	Yes
6	Orange	3 mL	iQ Positive Control	Primary lot positive control	Yes
7	Light Blue	3 mL	iQ Negative Control	Primary lot negative control	Yes

Primary control positions, 6 and 7, require that both Positive and Negative Controls be run together.

Secondary control positions, 8 and 9, are optional and intended to allow the laboratory to run controls in parallel for new lots. Either the Positive Control or the Negative Control may be run independently, as needed. Any control rack containing a tube in Position 8 and/or 9 must contain tubes in Positions 6 **and** 7.

This procedure should be performed at least once daily.

1 Prepare a control rack as defined in Table 10.3, Control Rack Positions and Functions.

2 Load the control rack on the right side of the Microscopy Module Sampler.

3 Press the Start button. The instrument will automatically perform a Self Test and any applicable messages will be displayed.

Wash Cycle

NOTE If Cleanser is run as part of the Control rack, this procedure does not need to be performed separately.

A wash cycle should be performed at the beginning of each work day to prevent accumulation of residue in the fluidic system. Iris System Cleanser must be used to clean the sample lines and the flowcell.

⚠ WARNING

Use only Iris System Cleanser for the Wash Cycle. Other similar solutions of hypochlorite should not be used because of the risk of particulate contaminants, trace oils or releasing compounds that could cause blockage or damage to the optical window.

1. Pour at least 3 mL of Iris System Cleanser into a test tube.
2. Place the tube in Position 1 of the iQ Control Rack.
3. Pour 3 mL of Iris Diluent into two test tubes.
4. Place the tubes in Positions 2 and 3 of the iQ Control Rack.
5. Place the rack on the DxU Microscopy Series and then press Start.

During a Wash cycle, the Cleanser is aspirated through the lines and the flowcell, and then Iris Diluent is aspirated to rinse and prime the system, and to remove any residue or air bubbles.

NOTE If an error message appears, copy it down for reference when troubleshooting or when contacting your Beckman Coulter Representative.

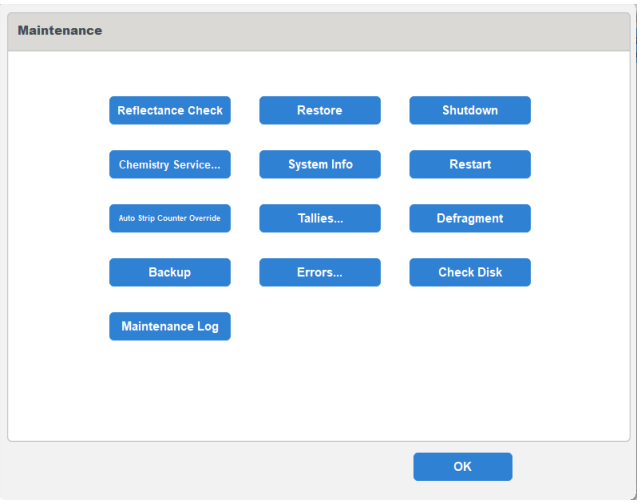
Monthly Maintenance

Perform an DxU Microscopy Series calibration. See Running Calibration in CHAPTER 11, Quality Assurance.

Accessing the Maintenance Menu

From the Instrument screen, select **Maintenance**.

Figure 10.1 Maintenance Screen - DxU Microscopy Series



Maintenance Options

- **Reflectance check**: This option is enabled only if an DxU 810c Iris chemistry system is connected to the microscopy module. See the DxU 810c Iris Operator's Manual for more information concerning this function.
- **Chemistry Service**: This option is enabled only if a DxU 810c Iris chemistry system is connected to the microscopy module. See the DxU 810c Iris Operator's Manual for more information concerning this function.
- **Auto Strip Counter Override**: This option is enabled only if an DxU 810c Iris chemistry is connected to the microscopy module. See the DxU 810c Iris Operator's Manual for more information concerning this function.
- **Backup**: Instrument configuration, results without images, and QC data are transferred to CD.
- **Maintenance Log:** Allows the operator to log maintenance activities.
- **Restore**: Allows a manager-level operator to restore instrument configuration and results from a backup.
- **System Info**: Describes the version of software currently loaded on the instrument.
- **Tallies**: Allows the operator to select a data range for the tally. The default is the last full month. Provides a record of tests performed.
- **Errors**: Operator-accessible Error Log of Microscopy Module Errors.
- **Shutdown**: After going offline, allows the operator to shutdown the Analysis/Results Processor.
- **Restart**: This function is used to shutdown and to restart only the user interface software, without any effect on the systems.
- **Defragment**: This function can be used when the computer performance is slow.
- **Check Disk**: Some computer problems can be solved and the performance of the computer can be improved by making sure that the hard disk has no errors.

System Backup

The System Backup should be performed after the initial Setup, when settings are changed, and/or when software is upgraded. The backup can only be performed to a CD-R disk.

1 **Log on**.

2 The system must be offline to perform a backup. If the system is online, select **Go Off line**.

3 Confirm going Off line (if prompted).

4 From the Instrument screen, select **Maintenance > Backup**.

5 Insert a blank CD-R disc when the system directs you.

NOTE The computer CD-R drive does not extend out to insert a disk. Insert the disk directly into the CD-R opening.

6 Select **OK**. The Backup dialog box displays the progress of the backup procedure.

When the backup is complete, the system displays: *The backup completed successfully.*

The CD will be ejected.

7 Remove the CD-R disc from the drive. Store the backup CD-Rs in a safe place.

8 Select **OK** to close the dialog box. The Maintenance screen appears. Select **OK**.

NOTE The system will indicate that a USB can be used for a backup. Only use a CD-R for backup. Do not press the power button on the PC during any step of the system backup.

Maintenance Log

The on-board maintenance log captures maintenance activities. An audit trail log captures all interactions and entries within the feature.

1 The system must be offline to enter data. If the system is online, select **Go off line**.

2 From the instrument screen, select **Maintenance** > **Maintenance Log**. *Instrument Selection* is displayed.

3 Select the appropriate instrument to document maintenance: **DxU Microscopy Series** OR **DxU 810c Iris** OR **AX-4030**. *On-Board Maintenance Log* is displayed. The default for the log is the current month and year. The current date is displayed on the screen.

4 After performing the required maintenance activity, select **Save**.

NOTE Select **Save** or entries will be lost if you exit the screen prior to saving data.

5 Select the following options as needed:

- **Cancel** to cancel the operation.
- **View Audit Trail** to view all maintenance activities.
- **Print** to print the screen to the default print or save to a PDF.
- **Save** to save the current screen contents.
- **Comments** to enter relevant comments. Select **Save** to save the entered comments.

6 To search for previous data or to update entries from the past (up to 12 months), you may retrospectively edit (per the laboratory protocol) or review entries up to one year as follows:

a. From the On-Board Maintenance Log screen, select the appropriate month and year from the drop down menu.

b. Change the relevant entry (per the laboratory protocol).

c. Add a comment to justify the revision.

d. Select **Save** to save the revision.

NOTE All changes are recorded in the *View Audit Log*.

Restore Procedure

⚠ CAUTION

Restoring data will overwrite current data and settings. Only a manager-level operator can perform this procedure

1 The system must be offline to perform a restore. If the system is online, select **Go Off line**.

2 From the Instrument screen, select **Maintenance > Restore**. Insert the CD with the data to be restored. Select **OK**.

NOTE The computer CD-R drive does not extend out to insert a disk. Insert the disk directly into the CD-R opening.

3 The system displays the Restore dialog box (after a few minutes). The following information will be displayed:

- Date and time of backup
- Options for restore (Restore everything, Restore instrument data only or Restore instrument configuration only)

4 Select the option to restore, and then select **OK**. The Confirm Options for Restore dialog box is displayed.

NOTE The most common use of Restore is to load Settings. For this purpose, select **Restore instrument configuration only**. If **Restore everything** or **Restore instrument data only** is selected, remember that the results restored will not contain images. Any specimens run between the time the backup was made and the restore was performed will be erased.

5 Select **OK** to continue the procedure.

The Restoring dialog box is displayed. It shows the progress of the restore procedure and prompts you to insert the next CD-R disc.

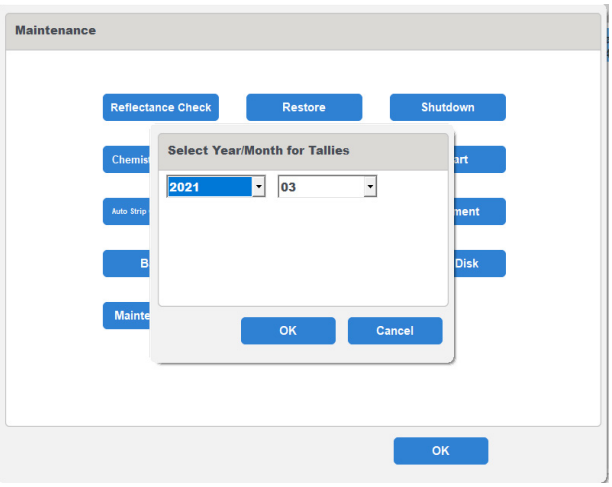
6 When the procedure is successfully completed, select **OK** to reboot the system. It may take a few minutes for the system to reboot.

Tallies

This option lets you obtain detailed information concerning the number of tests and controls run on the DxU Microscopy Series for a specific period of time.

1 From the Instrument screen, select **Maintenance**.

2 From the Maintenance screen, select **Tallies**.



3 Select the year and the month, and then select **OK**.

Restart Button

This function must be used after software settings have been modified, communication settings, or error message requiring a restart of the instrument. This option shuts down and restarts only the system software.

1 Select **Go Off line**.

2 From the Instrument screen, select **Maintenance**.

3 From the Maintenance screen, select **Restart**.

Defragment Button

This function optimizes the performance of the drive. The defragmentation process may take a few minutes to a few hours to complete based on the amount of data on the hard drive.

1 If the system is online, from the Instrument screen, select **Go Off line**. The system must be offline to perform a defragmentation.

NOTE Before running a defragmentation, it is recommended to run a Check Disk. See Check Disk.

2 From the Instrument screen, select **Maintenance**.

3 From the Maintenance screen, select **Defragment**. Multiple drives will appear.

4 Highlight a drive and select **Optimize**.

5 Repeat for each drive.

6 Do not perform Defragment if the drive displays 0% fragmented or less than 50% fragmented, unless the computer operation response appears to be slow.

Check Disk

This function scans the disk; and lists and corrects errors found on the disk. Depending upon the size of the hard drive, this may take several minutes.

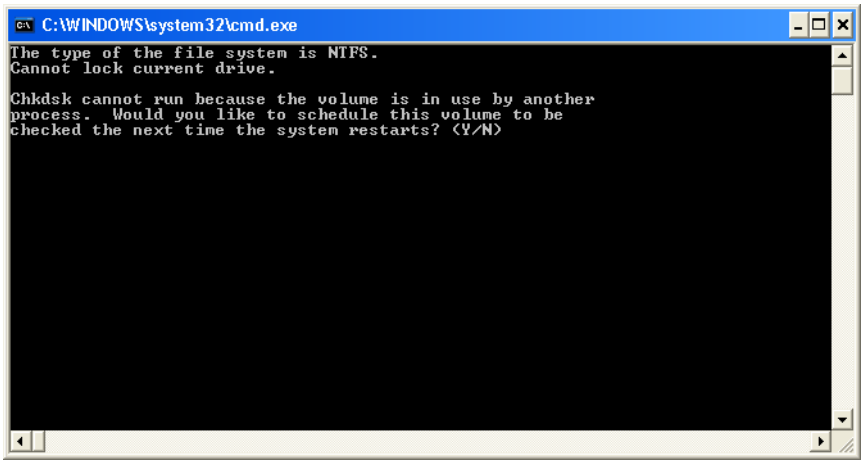
NOTE The Check Disk function will start only when the computer is restarted.

1 **Go Off line**.

2 From the Instrument screen, select **Maintenance**.

3 From the Maintenance screen, select **Check Disk**. A screen is displayed, *Would you like to schedule this volume to be checked the next time the system restarts? (Y/N).*

4 Press **Y**, then **Enter** on the keyboard to enable the Check Disk function. Press **N**, then **Enter** on the keyboard to cancel.



5 Log back on the system.

6 Go **Off line**.

7 Select **Maintenance**.

8 Select **Restart** > **Yes** > **OK**.

Troubleshooting

Before Calling for Service

- Refer to the troubleshooting section at the end of this chapter.
- Visually verify Lamina container levels.

NOTE Before calling for Service, please make a note of any error messages displayed.

After completing the above, contact your Beckman Coulter Representative for assistance. Stay close to the system and be prepared to explain the nature of the problem.

Provide:

- Your name

- Account name
- Telephone number with area code
- DxU Microscopy Series serial number

Describe:

- Error messages
- Operation in process
- Problem

Alarms

Control Rack Positions

Table 10.4 Control Rack Positions

Position	Control
1	Iris System Cleanser (optional)
2	Iris Diluent (optional)
3	Iris Diluent (optional)
4	Empty
5*	iQ Focus 6 mL (optional)
6*	iQ Primary Positive Control
7*	iQ Primary Negative Control
8*	iQ Secondary Positive Control (optional)
9*	iQ Secondary Negative Control (optional)
10	Iris Diluent (optional)

* Requires a barcode label

Alarm #1

CAUSES	REMEDIES
Normal operation of the instrument depletes the Lamina. Eventually, the amount of Lamina remaining is so low it triggers this alarm.	This condition should be remedied before the Lamina becomes empty. Replace the Lamina container.

NOTE Do not top off the Lamina bottle contents in any way, this may cause the instrument to shut down. Good laboratory practices recommend to not mix existing reagents with new reagents, even if they have the same lot number.

Alarm #3

CAUSES	REMEDIES
Normal operation of the instrument depletes the Lamina. Eventually, the amount of Lamina remaining is so low it triggers this alarm.	This condition must be remedied for the instrument to run more specimens or controls. Replace the Lamina container.

Alarm #5

CAUSES	REMEDIES
• The Focus failed. • A tube other than Focus was found in the Focus position. • The fluidic sub-system is dirty.	This condition must be remedied for the instrument to run more specimens. Run another Control Rack, making sure properly labeled and oriented control tubes are in the proper positions in the rack, along with Iris System Cleanser and Iris Diluent in the appropriate positions. If the control still fails: • If the Control Rack did not include a Focus, run another Control Rack with a Focus. • Open and run a new bottle of Control. If the failure persists, restart the instrument and try again. If the failure still persists, turn off the power and contact your distributor.

Alarm #6

CAUSES	REMEDIES
• The primary positive control results were not within the limits necessary to pass the control. • A primary positive control was not found in the primary positive count control position. See Preparing DxU Microscopy Series Quality Control Rack in CHAPTER 4, Quality Control. • The Focus failed. • The fluidic sub-system is dirty.	This condition must be remedied for the instrument to run more specimens. Run another Control Rack, making sure properly labeled and oriented control tubes are in the proper positions in the rack, along with Iris System Cleanser and Iris Diluent in the appropriate positions. If the control still fails: • If the Control Rack did not include a Focus, run another Control Rack with a Focus. • Open and run a new bottle of Control. If the failure persists, restart the instrument and try again. If the failure still persists, turn off the power and contact your distributor.

Alarm #7

CAUSES	REMEDIES
• The primary negative control results were not within the limits necessary to pass the control. • A primary negative control was not found in the primary negative count control position. • The Focus failed. • The fluidic sub-system is dirty.	This condition must be remedied for the instrument to run more specimens. Run another Control Rack, making sure properly labeled and oriented control tubes are in the proper positions in the rack, along with Iris System Cleanser and Iris Diluent in the appropriate positions. If the control still fails: • If the Control Rack did not include a Focus, run another Control Rack with a Focus. • Open and run a new bottle of Control. If the failure persists, restart the instrument and try again. If the failure still persists, turn off the power and contact your distributor.

Alarm #8

CAUSES	REMEDIES
• The secondary (Parallel) positive control results were not within the limits necessary to Pass the control. • A tube other than the secondary (Parallel) positive control was found in the secondary (Parallel) positive control position. See Preparing DxU Microscopy Series Quality Control Rack in CHAPTER 4, Quality Control. • The secondary (Parallel) positive control was not preceded by primary positive and negative controls on the same Control Rack. • The fluidic sub-system may be dirty.	It is not necessary for the secondary/Parallel control to Pass to run patient specimens; however, the secondary/Parallel control must establish a track record of Passing runs in order to switch lots. Run another Control Rack, making sure properly labeled and oriented control tubes are in the proper positions in the rack. If the previous Focus failed, include a Focus in the control rack, along with Iris System Cleanser and Iris Diluent in the appropriate positions. If the control still fails: • If the Control Rack did not include a Focus, run another Control Rack with a Focus. • Open and run a new bottle of Control. If the failure persists, restart the instrument and try again. If the failure still persists, turn off the power and contact your distributor.

Alarm #9

CAUSES	REMEDIES
• The secondary (Parallel) negative control results were not within the limits necessary to Pass the control. • A tube other than the secondary (Parallel) negative control was found in the secondary (Parallel) negative control position. See Preparing DxU Microscopy Series Quality Control Rack in CHAPTER 4, Quality Control. • The secondary (Parallel) negative control was not preceded by primary positive and negative controls on the same Control Rack. • The fluidic sub-system is dirty.	It is not necessary for the secondary/Parallel control to Pass to run patient specimens; however, the secondary/Parallel control must establish a track record of Passing runs in order to switch lots. Run another Control Rack, making sure properly labeled and oriented control tubes are in the proper positions in the rack. If the previous Focus failed, include a Focus in the control rack, along with Iris System Cleanser and Iris Diluent in the appropriate positions. If the control still fails: If the Control Rack did not include a Focus, run another Control Rack with a Focus. Open and run a new bottle of Control. If the failure persists, restart the instrument and try again. If the failure still persists, turn off the power and contact your distributor.

Alarm #10

CAUSES	REMEDIES
The instrument failed to scan the Focus ID, triggering this alarm.	This condition must be remedied for the instrument to run more specimens. Make sure the tube is oriented so the label is facing the scanner. Run a Control Rack again. If the failure persists, restart the instrument and try again. If the failure still persists, turn off the power and contact your distributor.

Alarm #11

CAUSES	REMEDIES
The instrument failed to scan the primary positive control ID.	This condition must be remedied for the instrument to run more specimens. Replace bad barcode with a good one, or properly orient tube, then run a Control Rack again. If the failure persists, restart the instrument and try again. If the failure still persists, turn off the power and contact your distributor.

Alarm #12

CAUSES	REMEDIES
The instrument failed to scan the primary negative control ID.	This condition must be remedied for the instrument to run more specimens. Replace bad barcode with a good one, or properly orient tube, then run a Control Rack again. If the failure persists, restart the instrument and try again. If the failure still persists, turn off the power and contact your distributor.

Alarm #13

CAUSES	REMEDIES
The instrument failed to scan the secondary positive control ID.	The instrument still operates under this failed condition. Replace bad barcode with a good one, or properly orient tube, then run a Control Rack again.

Alarm #14

CAUSES	REMEDIES
The instrument failed to scan the secondary negative control ID.	The instrument still operates under this failed condition. Replace bad barcode with a good one, or properly orient tube, then run a Control Rack again.

Alarm #17

CAUSES	REMEDIES
The instrument is getting close to having too many unreleased results in memory.	Handle specimens on the Work List, which will free some memory.

Alarm #18

CAUSES	REMEDIES
The instrument has too many unreleased results in memory.	This condition must be remedied for the instrument to run more specimens. Handle specimens on the Work List, which will free some memory.

Alarm #19

CAUSES	REMEDIES
The system could not communicate with the LIS. The LIS cable has been disconnected. The LIS is down. The LIS is too busy to respond (overloaded).	Possible remedies: • Reconnect the LIS cable. • Check with your LIS Manager to see when the LIS will be back up. • Request increased LIS capacity from your LIS Manager.

Alarm #21

CAUSES	REMEDIES
• A setting has been changed which requires restarting the system for the change to take effect. • A microscopy or chemistry system has experienced an error.	Restart the system.

Alarm #22

CAUSES	REMEDIES
The Microscopy System encountered an error, triggering this alarm.	This condition must be remedied for the instrument to run more specimens. Restart necessary: **1.** Power off DxU **2.** Restart PC **3.** Power on DxU Should problem persist, a Shutdown is necessary: **1.** Power off DxU **2.** Shut down PC **3.** Power on PC **4.** Power on DxU when the instrument screen appears If the failure persists, turn off the power and contact your distributor.

Alarm #25

CAUSES	REMEDIES
The instrument checks for ongoing problems by monitoring certain flags. If any of the monitored flags occurs in all three of the last samples run on the instrument this alarm is raised. See the **Remedy** section for the list of flags monitored.	This condition must be remedied for the instrument to run more specimens. Note that more than one may apply. Check the Work List to determine which flags have been present for the last three runs. • FLOW – Run a Control Rack with Iris System Cleanser, Iris Diluent, and Focus. • IMAGE ACQ – Check the connections on the large cable connecting the Microscopy Module to the Frame Grabber in the Results Processor. Run a Control Rack with Iris System Cleanser, Iris Diluent, and Focus. • LIGHT FLUCTUATION– Run a Control Rack with Iris System Cleanser, Iris Diluent, and Focus. • SHORT SAMPLE – Run a Control Rack with Iris System Cleanser, Iris Diluent, and Focus. In all cases, it will be necessary to run a Control Rack with Iris System Cleanser, Iris Diluent, and Focus to re-enable the instrument to run specimens. If the problem persists, contact your distributor.

Alarm #26

CAUSES	REMEDIES
Calibration Failure. The calculated Run Equivalency Factor value is not within range for running the instrument.	Refill a Calibration Rack with Calibrator and rerun.

Alarm #27

CAUSES	REMEDIES
A Calibrator label is missing or unreadable in the Calibration Rack.	Replace tube with a tube that has a valid barcode. Refill the Calibration Rack with Calibrator and rerun it.

Alarm #28

CAUSES	REMEDIES
A Calibration Rack is missing one or more tubes.	Add tubes with valid barcodes in order to fill the entire (10 position) Calibration Rack. Refill a Calibration Rack with Calibrator and rerun.

Alarm #29

CAUSES	REMEDIES
It has been more than 30 days since the last Run Equivalency Factor Calibration.	Run a Calibration Rack.

Alarm #30

CAUSES	REMEDIES
An attempt to run a Calibration Rack occurred but Focus has not been run or Focus has failed.	Run a Control Rack with an Focus tube, and then run a Calibration Rack.

Alarm #31

CAUSES	REMEDIES
The last calibration failed. An account with manager privilege is presently running the system using old calibration data.	Rerun a Calibration Rack.

Troubleshooting By Symptom

Rack Transport Problem

CAUSES	REMEDIES
The Sample Transport needs cleaning.	Clean the Sample Transport thoroughly. Blow the area with compressed air.
The racks are dirty.	Clean all racks by soaking them in soapy warm water using a mild detergent. Rinse

Waste Well Overflow

CAUSES	REMEDIES

The drain tubing is pinched.	Make sure that the drain tubing (located on the right side towards the back of the instrument) is not pinched.
The waste well is clogged.	Select **Go Off line**. Turn the power off on the back of the system. Pour Iris System Cleanser into the Waste Well and let soak for 15 to 30 minutes. Turn the system back on, the waste pump will aspirate the liquid from the waste well. If the problem persists, call Technical Service.

CHAPTER 11

Quality Assurance

Calibration Material

iQ Calibrator is used to automatically calibrate the instrument. Each bottle is intended for a single calibration. Do not save leftover material or mix calibration material from different bottles.

NOTE Discard QC, focus, and calibration barcode labels between lot numbers. The barcodes contain specific lot number information.

Storage and Use

iQ Calibrator is a suspension of fixed human red blood cells in a particulate-free solution. An accurate count is certified and the expected value is printed on each label.

Barcodes are provided that contain lot number, expiration date, and expected value.

Store iQ Calibrator at 2 to 8° C (35.6 C to 46.4° F) and bring to room temperature before use. **Shake the bottle as described below before use.**

iQ Focus solution should be stored at 2 to 8° C (35.6 C to 46.4° F) before and after opening. See the package insert for more information.

Calibration Frequency

Calibration should be performed monthly on the DxU Microscopy Series.

Running Calibration

NOTE Do not use plastic tubes (other than those listed in the Sample Tube Specifications section) or pipetting devices. Any use of plastic tubes (other than those listed in the Sample Tube Specifications section) with QC/Focus/Cal must be validated by your laboratory.

The best practice is to clean and focus the instrument, calibrate, and then run QC. At minimum, a Focus must be run before calibration.

Shake the bottle as described below before use. Hold the bottle upside down and give FIVE HARD SHARP SHAKES followed by five gentle inversions. Let sit about one minute until the air bubbles are dispersed.

Running a Focus

1 Shake a bottle of iQ Focus material as described below before use:

- Hold the bottle upside down and give FIVE HARD SHARP SHAKES followed by five gentle inversions.
- Let sit about one minute until the air bubbles are dispersed.

2 Place the provided barcode label on a sample tube. Fill the tube with 6 mL of iQ Focus material and place in position 5 of the Control rack.

Beckman Coulter recommends running Iris System Cleanser in position 1, Iris Diluent in positions 2 and 3 (see the table below) before running the Focus.

Position	Insert Color	Volume	Contents	Barcode
1	None	3 mL	Iris System Cleanser	No
2	Gray	3 mL	Iris Diluent	No
3	Gray	3 mL	Iris Diluent	No
4	None		Empty	
5	Blue	6 mL	iQ Focus	Yes

3 Load the Control rack onto the right side of the DxU Microscopy Series sampler.

4 Press Start. The rack will be processed.

Running a Calibration

1 Shake a bottle of iQ Calibrator as described below before use:

- Hold the bottle upside down and give FIVE HARD SHARP SHAKES followed by five gentle inversions.
- Let sit about one minute until the air bubbles are dispersed.

2 Transfer at least 4 mL of iQ Calibrator into 10 round-bottom 16 x 100 mm glass test tubes.

3 Place one provided barcode label on the tube that will be placed in the first position, and then load the tubes into the Calibration rack.

4 Load the Calibration rack onto the right side of the DxU Microscopy Series sampler.

5 Press Start. The rack will be processed and all calculations will be performed automatically.

If an expired material was used, the system will display a red alarm, and sample processing cannot be performed.

A manager-level operator can enable the Expired Consumable Lockout Override function in order to run samples on the instrument. See Expired Consumable Lockout Override in CHAPTER 17, Consumables Traceability.

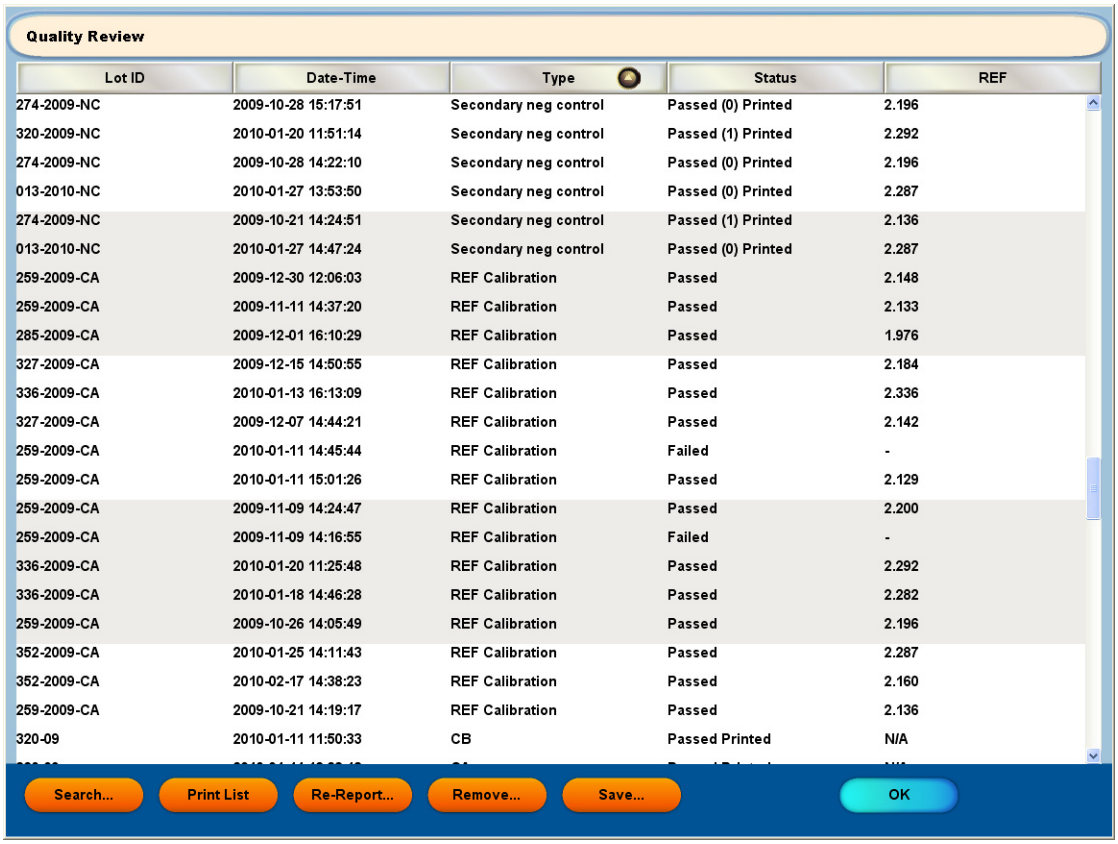
When the calibration is successful, the date/time and new REF value will be displayed in the Last Calibration field on the Instrument screen.

6 Run a QC by running primary positive and negative controls after Calibration is successful.

Calibration Results

At least 24 months of calibration results history can be reviewed by accessing the Quality Review screen.

Figure 11.1 Quality Review Screen with Calibration Results



In addition to the results available in the Quality Review window, the screen displays the date and time of the calibration, the type of calibration (REF for the microscopy module), the status (pass/fail), and the REF value (Run Equivalency Factor).

QC/CAL Result Flags

QC/CAL Label Mismatch

CAUSES	REMEDIES
If this error occurs during a calibration, the barcode reader did not read the label on the first tube from a Calibration rack, the barcode label was missing, or it was a patient barcode label. The rack was ejected and the system taken offline.	If running Calibration Entering a manual ID is not possible. Make sure barcode label is present and correctly oriented. Select **Go On line.** Refill and re-run the Calibration rack. If running QC Entering a manual ID is not possible. Make sure barcode labels are present and correctly oriented. Select **Go On line**. Re-run the QC rack from the misread tube on. Example: If the Focus ID was not read, remove the Cleanser and Diluent tubes and re-run Focus, Positive and Negative. If, however, the Negative Control fails, both Positive and Negative Controls must be re-run.

QC/CAL Out of Order

CAUSES	REMEDIES
Focus has not been run or passed within 24 hours of running the calibration. QC/Focus tubes are not in the correct order on the QC rack.	Control rack Make sure the tubes are in the correct positions. Refill and repeat the run for the control rack. Calibration rack Run a control rack with 6mL of Focus in tube at position 5. Repeat the run for the calibration rack.

CHAPTER 12

Cleaning Procedures

Maintenance

NOTE Refer to your chemistry operator's manual for chemistry system maintenance.

Precautions

⚠ WARNING

Wear protective gloves to prevent exposure to pathogens. Discard contaminated materials according to applicable regulations.

On-Board Maintenance Log

The system provides an on-board maintenance log. Select **Access Maintenance** > **Maintenance Log**.

See Figure 12.2, Maintenance Log.

Daily Maintenance

Table 12.1 Daily Maintenance

Item	Suggested Interval
Cleaning Instrument Surfaces	Daily
Cleaning the Sampler	Daily
Cleaning the Load/Unload Stations	Daily

Periodic Maintenance

Table 12.2 Periodic Maintenance

Item	Suggested Interval
Cleaning the Sample Tube Detector	As needed
Cleaning the Barcode Reader Window	As needed
Cleaning the Optical Sensors on the Sampler	As needed
Cleaning the iQclear Adapter and Rinse/Waste Tube	Monthly

Cleaning Instrument Surfaces

Items Required: Iris System Cleanser diluted 1:10, paper towels, and protective gloves

Clean the instrument using a paper towel moistened in Iris System Cleanser diluted 1:10. Wipe again using distilled water and then dry.

NOTE To prevent sample transport problems, immediately clean any spills.

Cleaning the Sampler

Items Required: Iris System Cleanser, lint-free tissue, and protective gloves

1. Dilute the Cleanser 1:10 with distilled or deionized water.
2. Moisten a tissue with the solution and wipe the sampler to remove any deposits. Check under the belts and the pulleys.
3. Wipe again using distilled water.
4. Dry.

Cleaning the Load/Unload Stations

Items Required: Iris System Cleanser, cloth, and protective gloves

1. Power off the Load/Unload Stations by switching the power button on the rear of the Load/Unload Module.
2. Dilute the Cleanser 1:10 with distilled or deionized water.
3. Moisten a cloth or towel with the solution and wipe the surface of the tray. Then, wipe the surface of the tray with a cloth or towel soaked with deionized water.
4. Wipe again using distilled or deionized water.

5 Dry.

Cleaning the iQclear Adapter and Rinse/Waste Tube

The iQclear is an enhanced cleaning aspiration module.

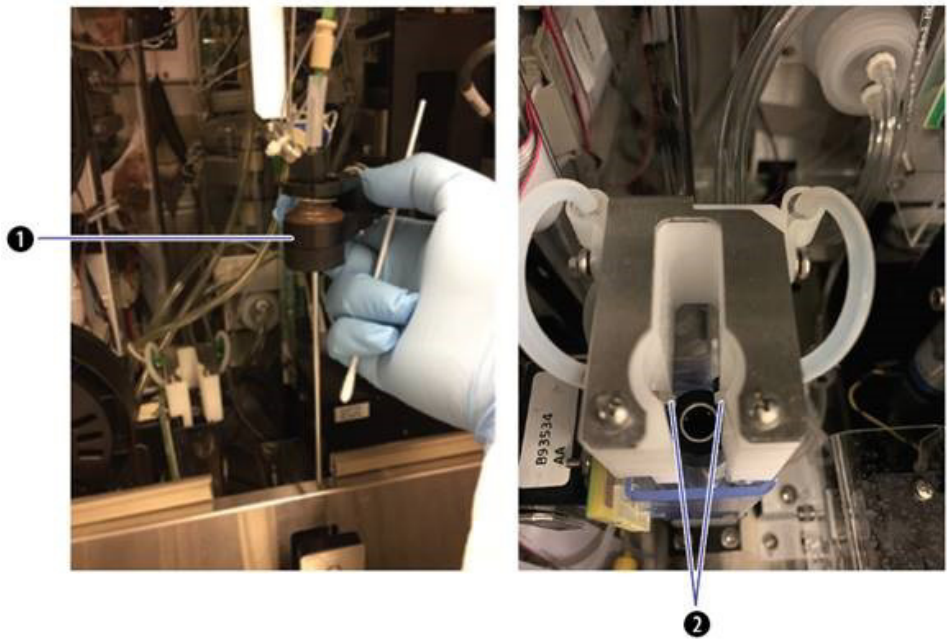
Items required: Deionized water, cotton swabs, and protective gloves.

1 Make sure the system is in Standby mode as indicated on the top left side of the instrument screen, as follows:

- **a.** Log on to the instrument. Select **Instrument** on the top right side of the main screen.
- **b.** Select **Go Off line**. The system status will change to *Off line*.
- **c.** The DxU Microscopy Series Status area located on the top left side of the Instrument screen will display *Standby*.

2 Turn the power off by pressing the button located on the bottom left of the Microscopy Module.

3 Open the front cover and manually rotate the Sample Probe Assembly (SPA) away from the Rinse/Waste Bath to access the Rinse/Waste Bath.

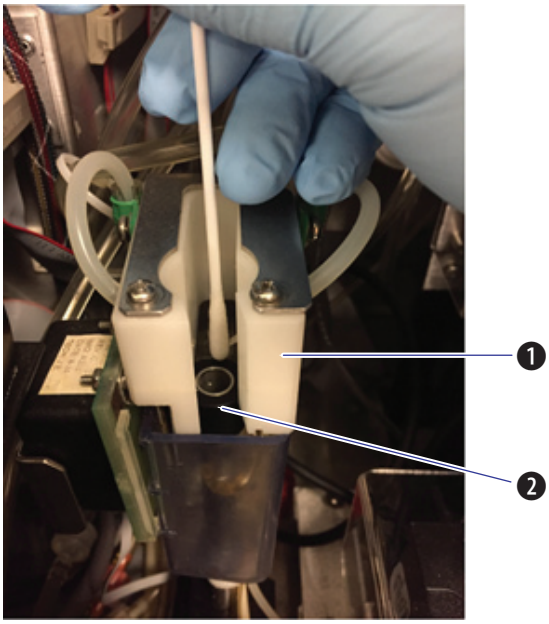


Number	Description
1	Sample Probe Assembly
2	Rinse Jets

4 Using a cotton swab moistened with deionized water, remove salt deposits present on the iQclear Adapter and Rinse/Waste Tube.

⚠ CAUTION

Do not insert the cotton swab inside the Rinse/Waste Tube. Cotton particles may clog the tubing connectors.

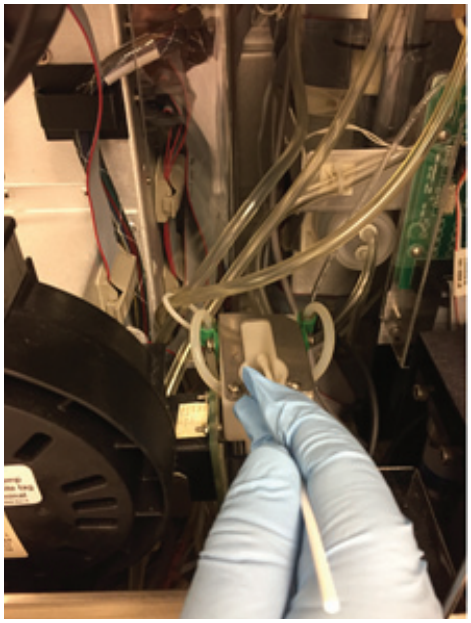


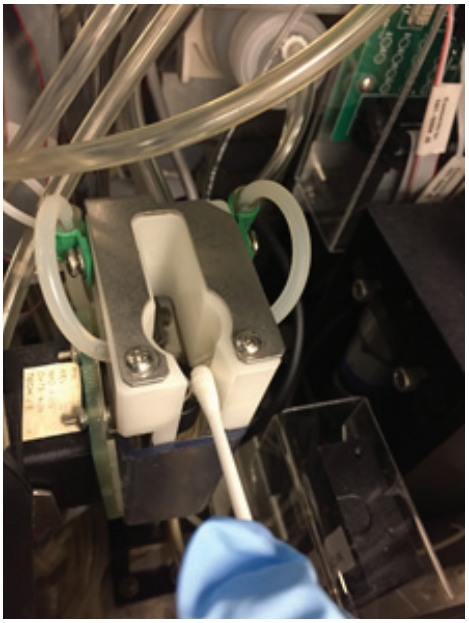
Number	Description
1	iQclear Adapter
2	Rinse/Waste Tube

5 Using cotton swabs moistened with deionized water, clean the inside walls of the iQclear Adapter.

⚠ CAUTION

Do not remove the iQclear Adapter or apply too much pressure on the iQclear Adapter and Rinse jets. This may impact the alignment and/or damage the Rinse Jets.





6 Close the front door.

7 Turn the power on by pressing the green button located at the bottom left of the Microscopy module.

NOTE The SPA will home automatically once the system goes back online.

8 Select **Go On line.** The system status will change to *On line.*

9 Perform daily QC and verify QC results are within limits before resuming patient analysis.

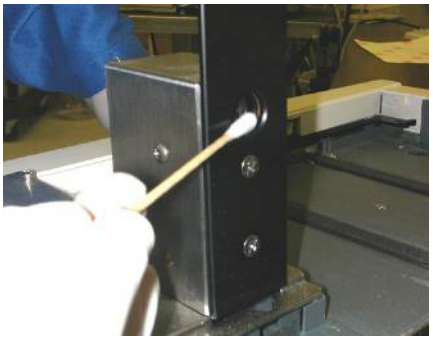
Cleaning the Sample Tube Detector

Items Required: Deionized water, cotton swabs, and protective gloves

This should be performed only if the detector is missing tubes.

1 Make sure the instrument is in Standby mode as indicated on the top left side of the instrument screen.

2 The tube detector window is located on the instrument side of the tube detector. Pass your hand across that surface to locate the window.



3 Using a cotton swab moistened with deionized water, wipe the sample tube detector. Break the swab to about 1 1/2 inches to facilitate reaching the detector window. Dry using a clean cotton swab.

Cleaning the Barcode Reader Window

Items Required: Deionized water, lint-free tissue, and protective gloves

1 Make sure the system is in Standby mode as indicated on the top left side of the instrument screen.

2 Select **Instrument** on the top right side of the main screen.

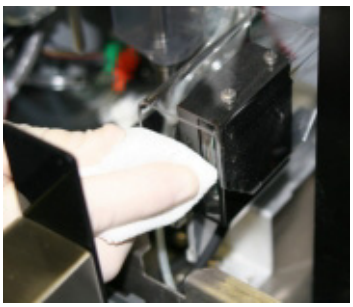
3 Select **Go Off line.** The system status will change to *Off line*.

4 Turn the power off by pressing the green button located on the bottom left of the Microscopy Module.

5 Open the front door to access the barcode reader.

6 Remove the splashguard/strikeplate.

7 Using tissue moistened with deionized water, wipe the barcode reader window. Dry using a clean tissue.



8 Install the splashguard.

9 Close the front door.

10 Turn the power on by pressing the green button located at the bottom left of the Microscopy module.

11 Select **Go On line**. The system status will change to *On line*.

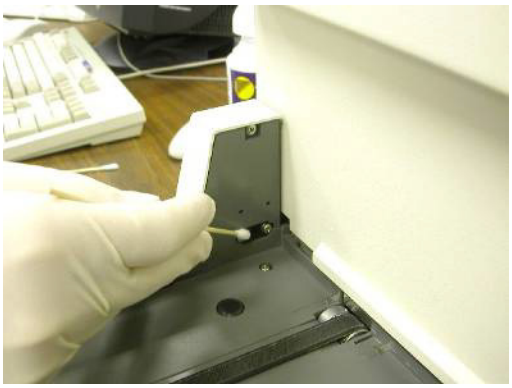
Cleaning the Optical Sensors on the Sampler

Items Required: Deionized water, cotton swabs, and protective gloves

1 Make sure the instrument is in Standby mode as indicated on the top left side of the instrument screen.

2 Using a cotton swab moistened with deionized water, wipe the optical sensors located on the front right and back left corners of the sampler.

3 Dry using a clean swab.



Clean the Sample Filter (Type 1)

Items Required: Deionized water, protective gloves, hemostats, protective eye gear/goggles, sample flush kit, and needleless syringe

⚠ WARNING

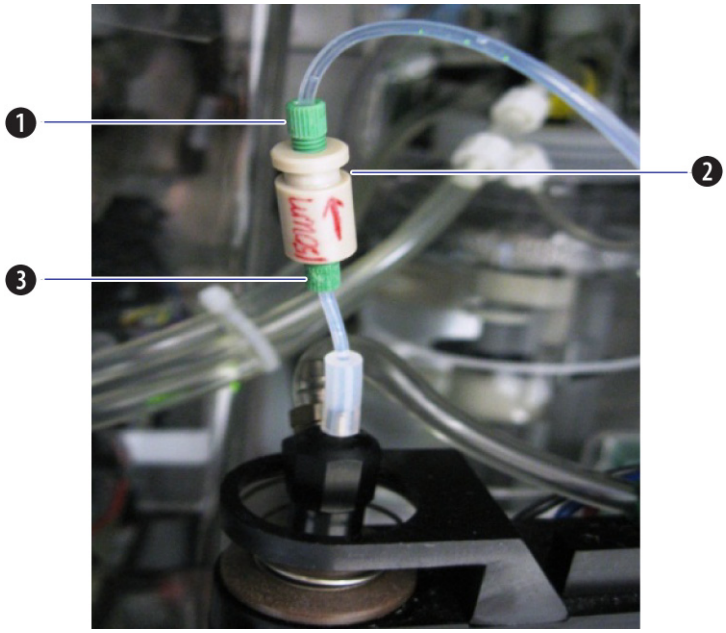
Wear goggles.

This procedure can be performed to resolve the following problems:

- Flow error
- Control failure
- Focus failure/Autofocus failure

- Count problem carryover

Figure 12.1 Sample Filter (Type 1)



Number	Description
1	Top Green Fitting
2	Notched Side of Filter
3	Bottom Green Fitting

Procedure 1:

1 With one hand, hold the sample filter firmly in place.

2 With the other hand, carefully unscrew the top green fitting (counterclockwise).

⚠ CAUTION

Do not pull the tubing out of the green fitting.

3 Holding the sample filter in place, carefully unscrew the bottom green fitting.

4 Place the Sample Filter in a test tube filled with Iris Cleanser.

5 Let the filter soak for 15 to 30 minutes.

6 After the filter has been soaked in the cleanser, remove the filter from the test tube, take a plastic transfer pipette and perform the following:

- Fill the plastic pipette with deionized water. Using the plastic pipette, push the water through the sample filter going first in the opposite direction of the arrow located on the sample filter.
- Fill the plastic pipette with deionized water. Using the plastic pipette, push the water through the sample filter going in the direction of the arrow located on the sample filter in order to accomplish a complete back flush and flush. After cleaning/flushing the sample filter, reinstall the filter on the instrument.

Procedure 2:

Part Required: Sample filter flush kit

Items Required: Iris System Cleanser, test tube, deionized water, protective gloves, 5 to 20 ml plastic syringe/no needle, and protective eye gear/goggles

⚠ WARNING

Wear goggles.

1 With one hand, hold the sample filter firmly in place.

2 With the other hand, carefully unscrew the top green fitting (counterclockwise).

⚠ CAUTION

Do not pull the tubing out of the green fitting.

3 Holding the filter in place, carefully unscrew the bottom green fitting.

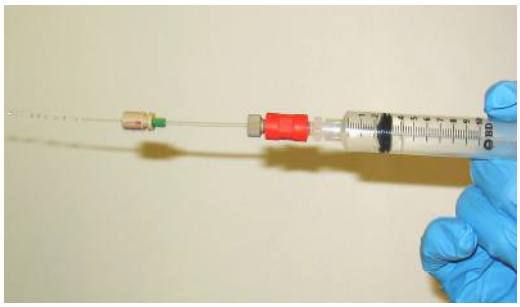
4 Place the Sample Filter in a test tube filled with Iris Cleanser. Let the filter soak for 15 to 30 minutes.

5 After the filter has been soaked in the cleanser, remove the filter from the test tube, take a syringe and perform the following:

- Using the clear fitting of the flush kit set; attach the syringe to the flush kit set by pushing the clear fitting onto the syringe.
- Fill the syringe with deionized water. Connect the syringe to the notched end of the filter by using the green fitting of the flush kit set. Push the water through the sample filter going in the opposite direction of the arrow. See the picture at the end of this step.

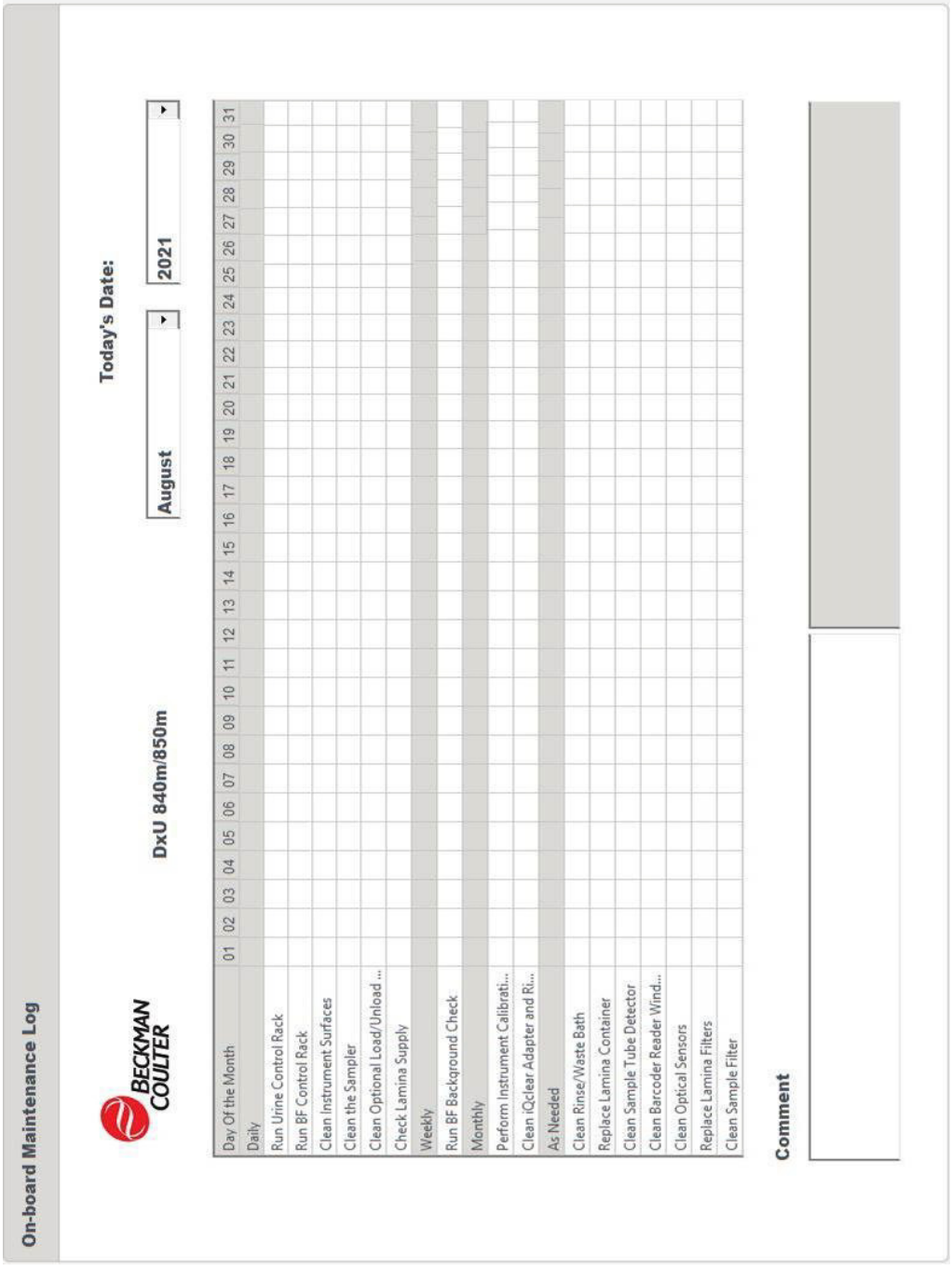
- Fill the syringe with deionized water. Connect the syringe to the smooth end of the filter by using the green fitting of the flush kit set. Push the water through the sample filter going in the direction of the arrow located on the sample filter in order to accomplish a complete back flush and flush. After cleaning/flushing the sample filter, reinstall the filter on the instrument.

  This picture shows deionized water being pushed through the sample filter:



Maintenance Log

Figure 12.2 Maintenance Log



CHAPTER 13

Replacement/Adjustment Procedures

Maintenance

NOTE Refer to your chemistry operator's manual for chemistry system maintenance.

Precautions

⚠ WARNING

Wear protective gloves to prevent exposure to pathogens. Discard contaminated materials according to applicable regulations.

Periodic Maintenance

Table 13.1 Periodic Maintenance

Item	Suggested Interval
Run a Calibration	Monthly. See Running a Calibration in CHAPTER 11, Quality Assurance.
Replace the Lamina Filter	Every 4th container. See Replacing Lamina Container.

Consumable Replenishment

Table 13.2 Consumable Replenishment

Item	Suggested Interval
Replacing Lamina Container	As needed. See Replacing Lamina Container.

Replacing Lamina Container

Items Required: Paper towels and protective gloves

⚠ CAUTION

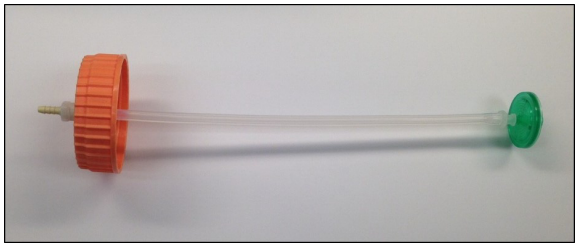
Wear fresh gloves when changing the Lamina filter. Have a supply of paper towels to catch spills and drips.

When the *Lamina Container is low* message appears:

1 Remove the cap from the new container.

2 Remove the cap from the old container.

3 The green filter located at the end of the tubing needs to be replaced every 4th bottle. A new filter comes with each box of Lamina containers. Best practice is to change the filter when loading the first bottle of a new case.



4 Remove the old filter by grasping the tube above the filter and pulling the filter straight off.

5 Remove the new filter from its package and push straight onto the tube. The filter only goes on one way, with the narrow section going into the tube.

6 Do not mix the contents of the bottles.

7 Attach the cap connected to the instrument to the new container.

NOTE Diluting or substituting Lamina bottle contents may cause the instrument to shut down until you install a valid Lamina. For further assistance, contact your Beckman Coulter Representative.

CHAPTER 14

iWARE Expert System

iWARE

The iWARE function uses specific filtering rules set up by the laboratory. When microscopy and/or chemistry results become available, the filtering rules are applied. Any result matching a rule can be used to signal for review by the operator.

The iWARE applies the rules on each sample at the end of each run and takes appropriate action:

- Set a Validation flag and prevent auto-release
- Output additional data to LIS
- Signal the operator in the Information pane during sample review to review the sample
- Utilize reporting tags for screen and printer based reports

This function allows you:

- To create, edit, and save logic statements for filtering results based upon multiple Urine Chemistry parameters, multiple Microscopy parameters, and patient demographics (gender, age, location)
- To apply to each parameter, a user-defined value and a logic sign
- To recreate pre-populated logic statements
- To display results on-screen and generate printable work lists based on logic statements
- To easily activate/disable every saved logic statement without deleting

The iWARE function has three components:

- Rule Generator
- Results/Rules Tagging
- Report Generator

Rule Generator

This feature is used to create customized rules for management of results.

The Rule Generator function allows you:

- To create, edit, and save logic statements for filtering results based upon multiple Urine Chemistry parameters, multiple Microscopy parameters, and patient demographics (gender, age, location).
- To apply to each parameter, a user-defined value and a logic sign.

- To recreate pre-populated logic statements.

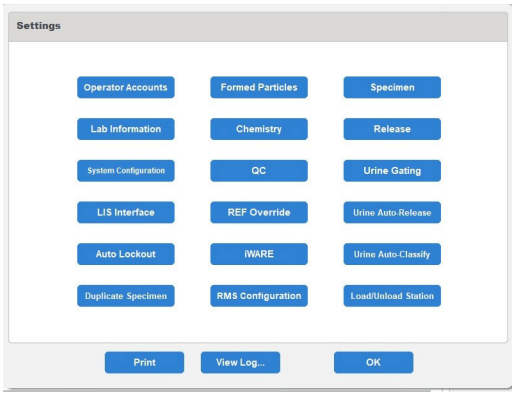
NOTE Only a manager can modify the user-defined settings. Only a manager can view the settings.

1 To access the Settings menu, select **Instrument** located on the top right side of the main screen.

2 Select **Go Off line**. A confirm window pops up (with warnings).

3 Select **Yes**.

4 Select **Settings** located at the bottom of the Instrument screen. The Settings screen is displayed.



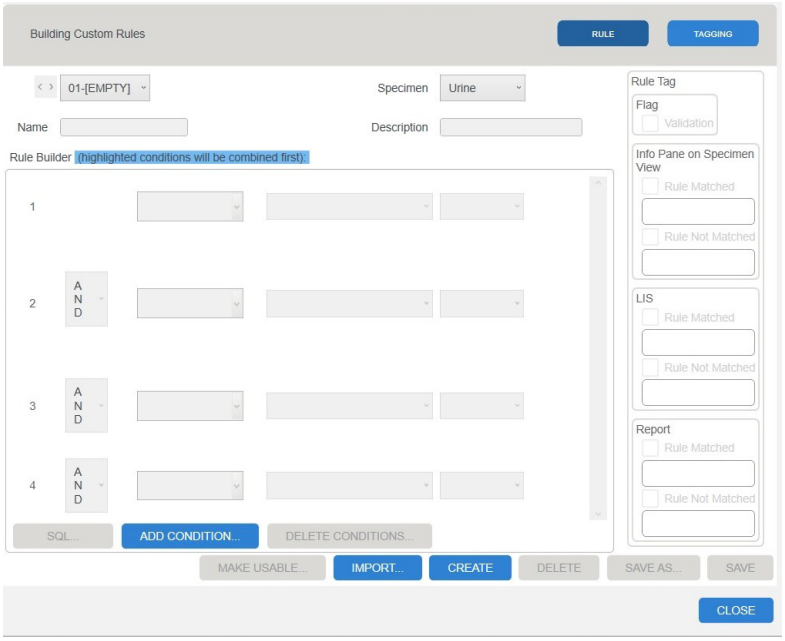
5 Select **iWARE**.

6 Select **OK**. The Building Custom Rules screen is displayed.

Building Custom Rules Screen

Up to 64 numbered rules and an unlimited number of unnumbered rules can be defined using this screen. Numbered rules can be tagged. See Tagging Options. Unnumbered rules cannot be tagged and can be created to provide additional criteria to perform a customized Search.

Figure 14.1 Building Custom Rules Screen



Rule Button

Select this button to display the last selected rule, the conditions, and the tags associated with the rule.

Tagging Button

Select this button to display the Configuring Rules Tags screen.

SQL Button

This button is intended for IT personnel only. It allows programmers to view any rule that was created in terms of computer programming language.

Add Condition Button

Select this button to add and specify the position of a filtering condition to the selected rule.

Delete Conditions Button

Select this button to specify the set of conditions to be deleted from the selected rule.

Make Usable Button

This button is enabled when the conditions imported for the selected rule are not compatible with the system setup. Select **Make Usable** to confirm the filtering conditions.

Import Button

Select this button to import a pre-populated rule.

Create Button

Select this button to create an unnumbered rule where all fields and conditions can be user-defined. Unnumbered rule cannot be defined for tagging.

Delete Button

Select this button to delete the selected rule. A warning will be displayed before the deletion. A deleted rule cannot be un-deleted.

Save As Button

Select this button to save the parameters of the selected rule in an empty selection, or to overwrite an existing rule. Saving to a numbered rule will automatically reset/clear the tagging selection.

Save Button

Select this button after changes have been made to save the selected rule. After saving, the button is disabled until new changes are made.

Import Pre-Populated Rules

The iWARE contains rules already created by Beckman Coulter.

To utilize any of these rules, you must first import them into the system.

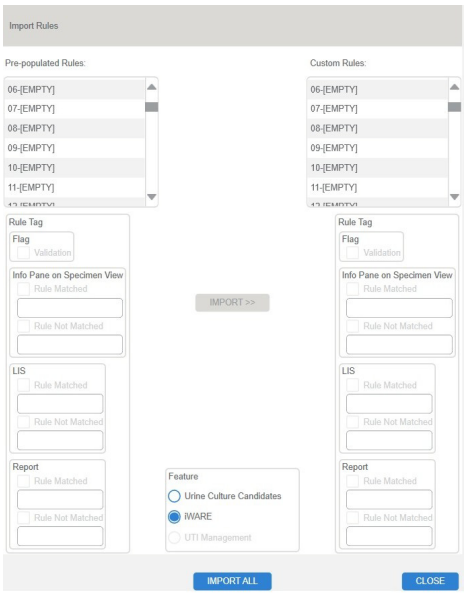
---

1 From the Building Custom Rules screen, select **Import**.

---

2 Before importing rules for the first time, a chemistry module must be selected if the system is configured to be Microscopy stand-alone. Select the drop-down arrow, and then select the appropriate chemistry module. Select **OK**.

The Import Rules screen is displayed.



3 To import a specific rule, select the rule from the *Pre-populated Rules* field, and then select **Import**. Only one rule at the time can be selected to import.

4 To import all the available rules, select **Import All**. The system will prompt: *Are you sure you want to import one or all of the pre-populated rules?*

5 Select **Yes** to import the rule(s). The imported rules are displayed in the Custom Rules field. The number associated with the rule from the *Pre-Populated Rules* remains with the custom rule.

6 When importing is completed, select **Close** to return to the Building Custom Rules screen.

7 Configure the related rule tags. See Results/Rules Tagging.

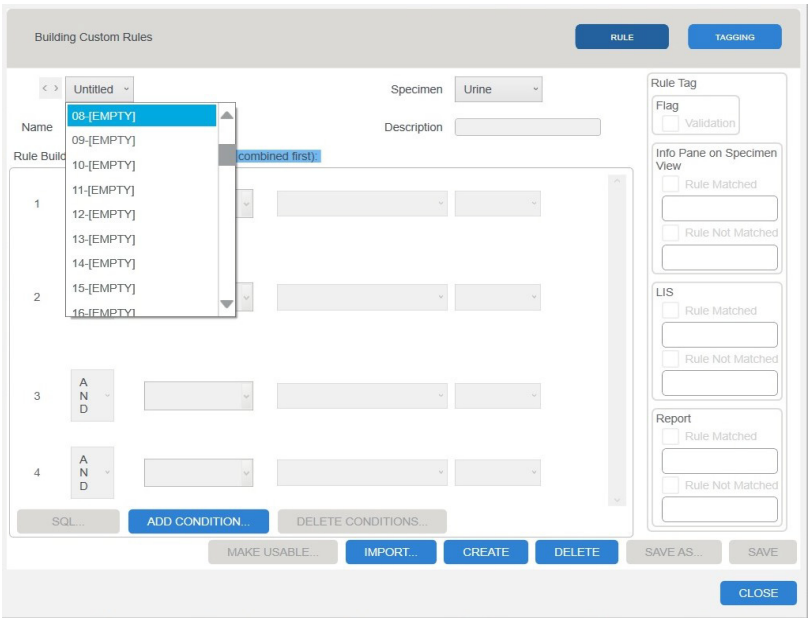
Creating Customized Rules

From the Building Custom Rules screen, customized rules specific to the laboratory can be manually created.

Creating a New Numbered Custom Rule

NOTE Tagging can be added to any numbered rule.

1 From the Building Custom Rules screen, use the drop-down arrow to display and then select the first available [Empty] field. See the following screen.



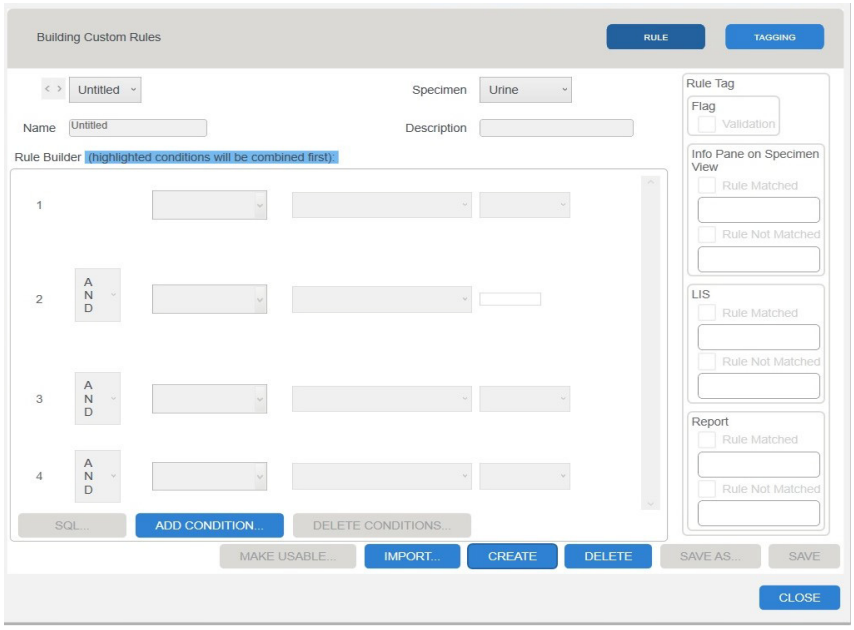
2 Use the drop-down arrow to display and then select the Specimen type.

3 Proceed to the condition configuration. See Adding One Condition.

Creating a New Unnumbered Rule

NOTE Unnumbered rules cannot be tagged and can be created to provide additional criteria to perform a customized Search.

Figure 14.2 Building Custom Rules Screen



1 From the Building Custom Rules screen, select **Create**.

2 Use the drop-down arrow to select **Untitled**.

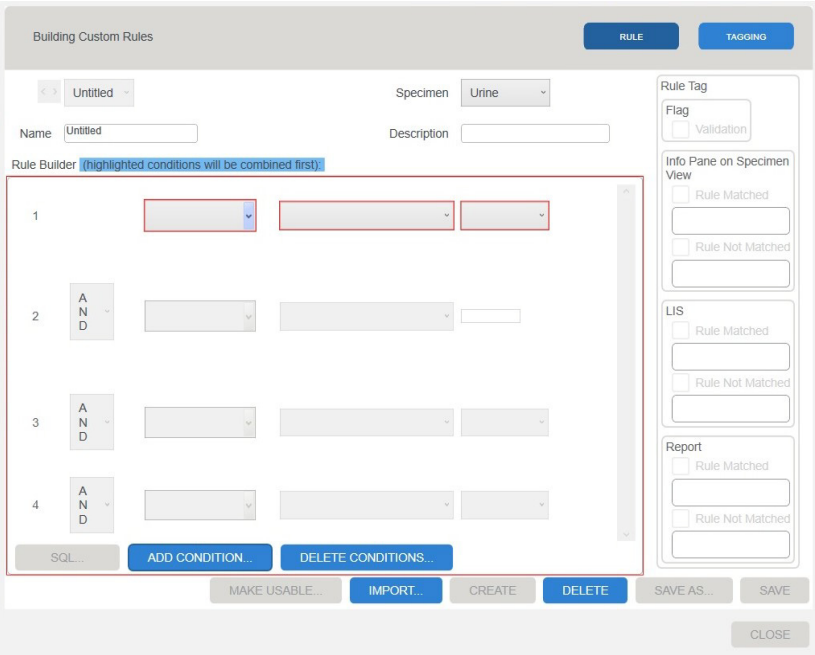
3 Use the drop-down arrow to display and then select the Specimen type.

4 Proceed to the condition configuration. See Adding One Condition.

Adding One Condition

1 Select **Add Condition**. The following screen is displayed.

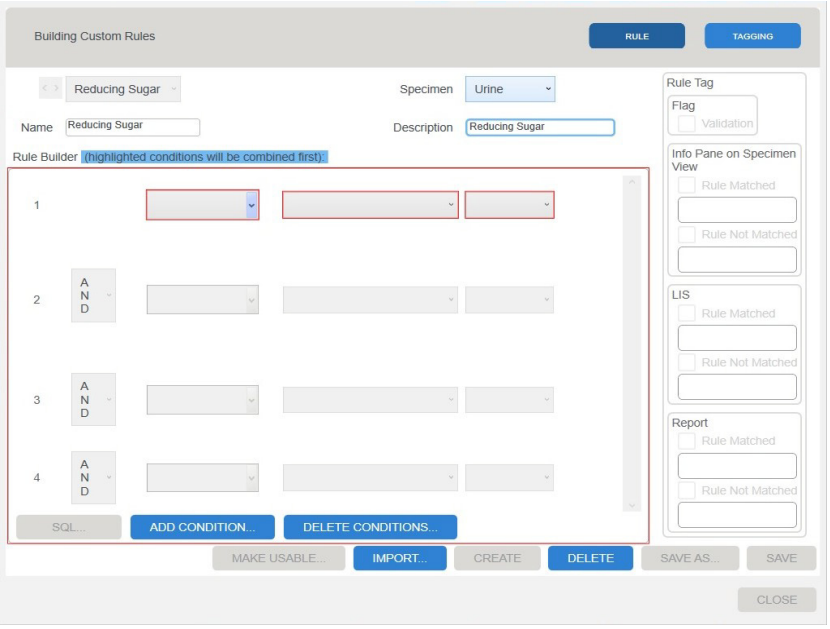
2 Complete the fields indicated by a red border.



3 In the *Name* field, type the rule identification.

4 In the *Description* field, type a brief description of the rule.

5 Enter the first condition for the rule. See the example below.



Use the drop-down arrow to select the first criteria for the rule:

- Formed particles for microscopy
- Analytes for chemistry
- Last name, first name, age, gender, or location for demographics

Use the drop-down arrow to select the logic sign. The following are available:

= (Equal to)	< (Less than)	> (Greater than)
<= (Less than or equal to)	>= (Greater than or equal to)	!= (Not equal to)

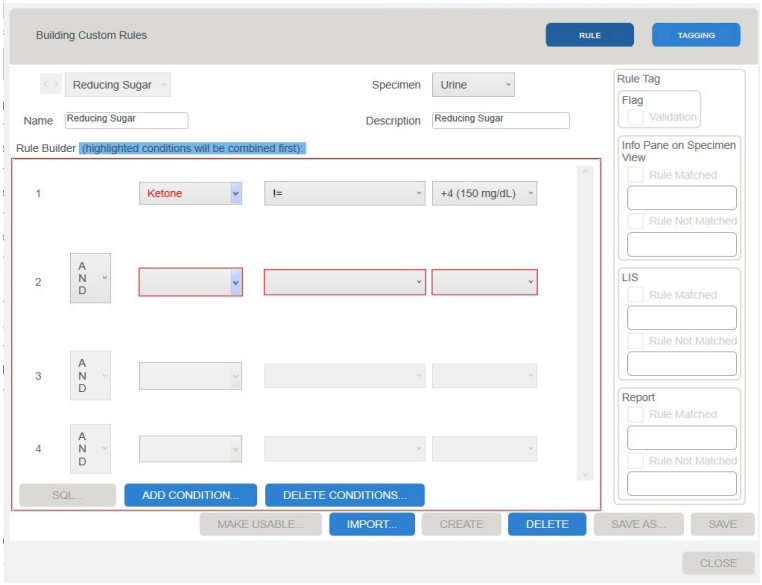
Use the drop-down arrow to select the specific value. Values are pre-populated from the user-defined settings. See Formed Particles Settings in CHAPTER 9, Setup. If the drop-down option is not available, use the keyboard to enter a specific value.

Adding More Conditions to a Rule

1 To enter more conditions, select **Add Condition**. The Add Condition screen is displayed.

2 Select the condition number before which a new condition will be inserted. Only one condition can be selected. Select **OK**.

3 Using the drop-down arrow, select the first criteria for the new condition: AND/OR; and then repeat step 5 from Adding One Condition. Below is an example of a Rule Condition.



Deleting a Condition from a Rule

1 To delete a condition, select **Delete Conditions**. The Delete Conditions screen is displayed.

2 Select the condition(s) to suppress, and then select **OK**.

NOTE There is no confirmation box when deleting conditions unless all conditions will be deleted. Selecting **OK** will delete the selected conditions.

Saving a Rule

Select **Save** to save the selected rule after changes have been made.

Select **Save As** to save the parameters of the selected rule in an empty selection or to overwrite an existing rule. The name of the rule cannot be changed.

Results/Rules Tagging

This feature applies the filtering rules on each specimen results at the end of each run and takes appropriate action according to the operator selection for tagging. Only numbered rules can be tagged. See Creating a New Numbered Custom Rule.

The following tags are available for selection:

- Validation flag
- Info Pane Rule Matched tagging and/or Info Pane Rule Not Matched tagging
- LIS Rule Matched tagging and/or LIS Rule Not Matched tagging
- Report Rule Matched tagging and/or Report Rule Not Matched tagging

NOTE This is an example only; you must define the tagging according to the conditions for the currently selected rule.

Table 14.1 Rule Tagging - Examples

Rule Condition	Specimen Result	Tagging	Action
Urine color yellow	Yellow	Info Pane Rule matched	Display associated text on the specimen screen
Urine color colorless, straw, yellow, amber, red	Purple	Info Pane Rule not matched	Display associated text on the specimen screen

Tagging Options

Validation Flag

If the validation flag is selected for a rule and the results match the filtering conditions, the specimen results will not be auto-released.

Info Pane Tagging

This selection signals in the Information pane for the operator to review the sample.

Rule Matched and/or Rule Not Matched

LIS Tagging

This selection provides specific messages to be sent to the LIS.

Rule Matched and/or Rule Not Matched

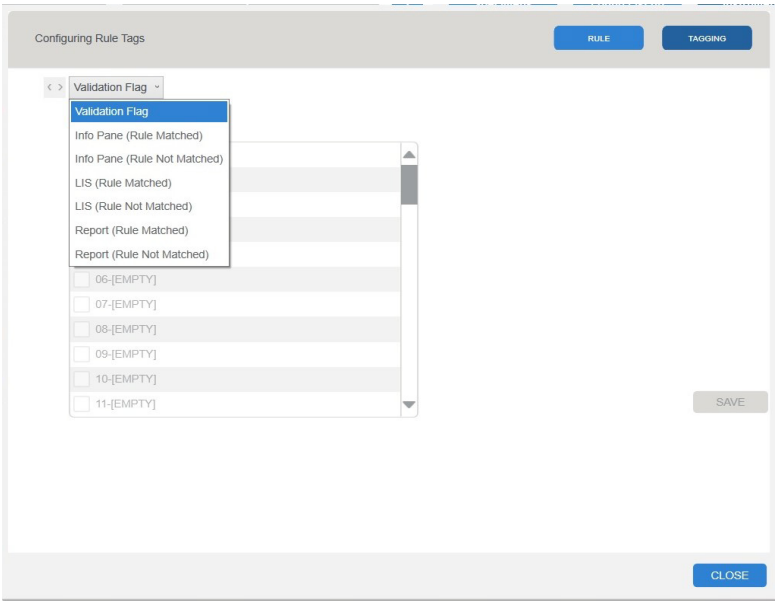
Report Tagging

This function incorporates reporting tags for displayed and printed reports.

Rule Matched and/or Rule Not Matched

Tagging Using the Tagging Button

1 From the Building Custom Rules screen, select **Tagging**. The Configuring Rule Tags screen is displayed.



2 Using the drop-down arrow, select the tagging to apply to the rules.

NOTE Comment associated with the tagging can only be inserted from the Rule screen.

3 Check the rules for which the selected tagging will apply.

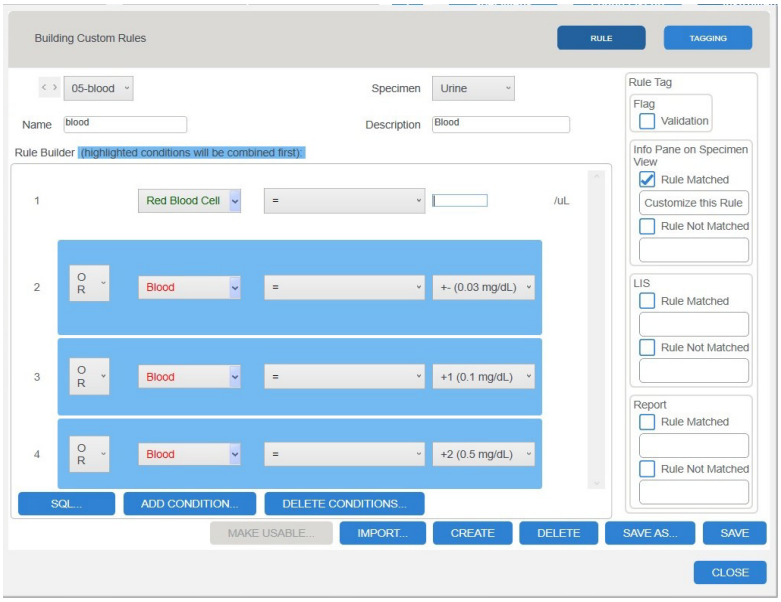
4 When tagging is completed, select **Save**.

5 Select **Rule** to return to the Building Custom Rules screen.

6 Select **Close** to return to the Settings screen.

Tagging from the Building Custom Rules Screen

1 From the Building Custom Rules screen, select the rule to be tagged.



2 Select the checkbox for the tagging selection. See Tagging Options for more information.

3 Type a comment in the associated comment field. The comment will be added to the selected tagging.

4 When tagging is completed, select **Save**.

5 Select **Close** to return to the Settings screen.

Report Generator

This feature adds capability to create detailed, customized reports using searches from the Search screen. Additional selection criteria derived from the iWARE rules have been added to the Search screen.

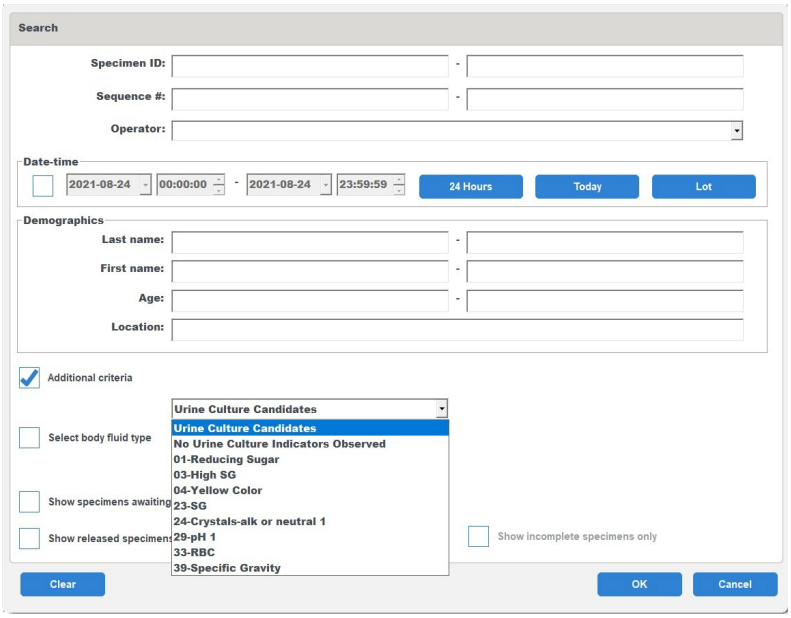
Search with Additional Criteria

1 From the Work List screen, select **Search**. The Search screen is displayed.

2 Select the **Additional criteria** checkbox.

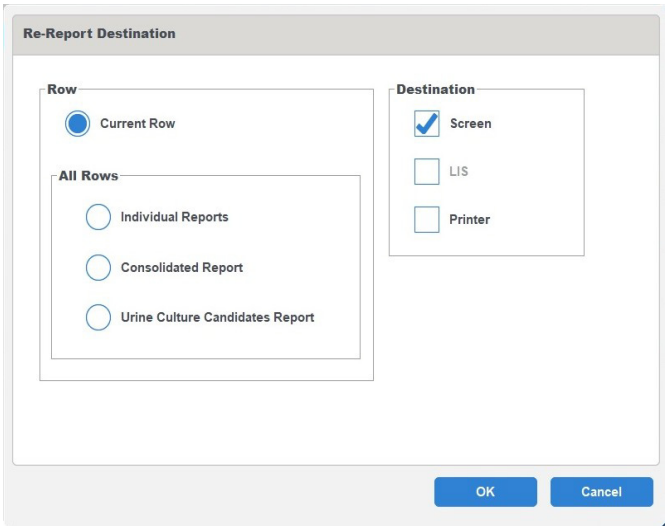
3 Use the drop-down arrow to display the available options.

4 Select the desired option from the additional criteria list. Select any other field as necessary, and then select **OK**. Results matching the search criteria are displayed in the Found List screen.



5 Select a result from the Found List screen.

6 Select **Re-Report**. The Re-report screen is displayed. Results can be re-reported as individual report or consolidated report.



7 Select the Re-Report options and the destination, and then select **OK**.

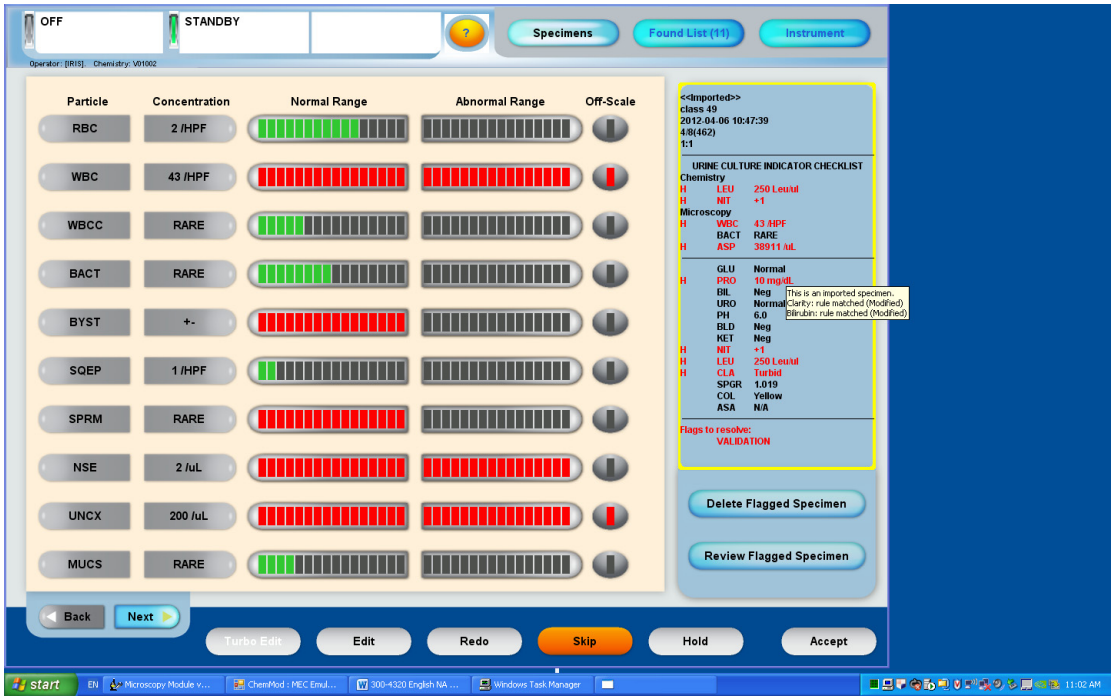
Below is an example of a consolidated report obtained from iWARE criteria. The second line of the report indicates which rule was selected. The date in red for the Analysis time stamp indicates that the rule was modified after this run completed.

iWARE Results

Specimen Screen with Tag

Below is an example of an Info pane tag. Place the mouse cursor over the Info Pane area to display more information regarding the result.

Figure 14.3 Specimen Screen with Tag

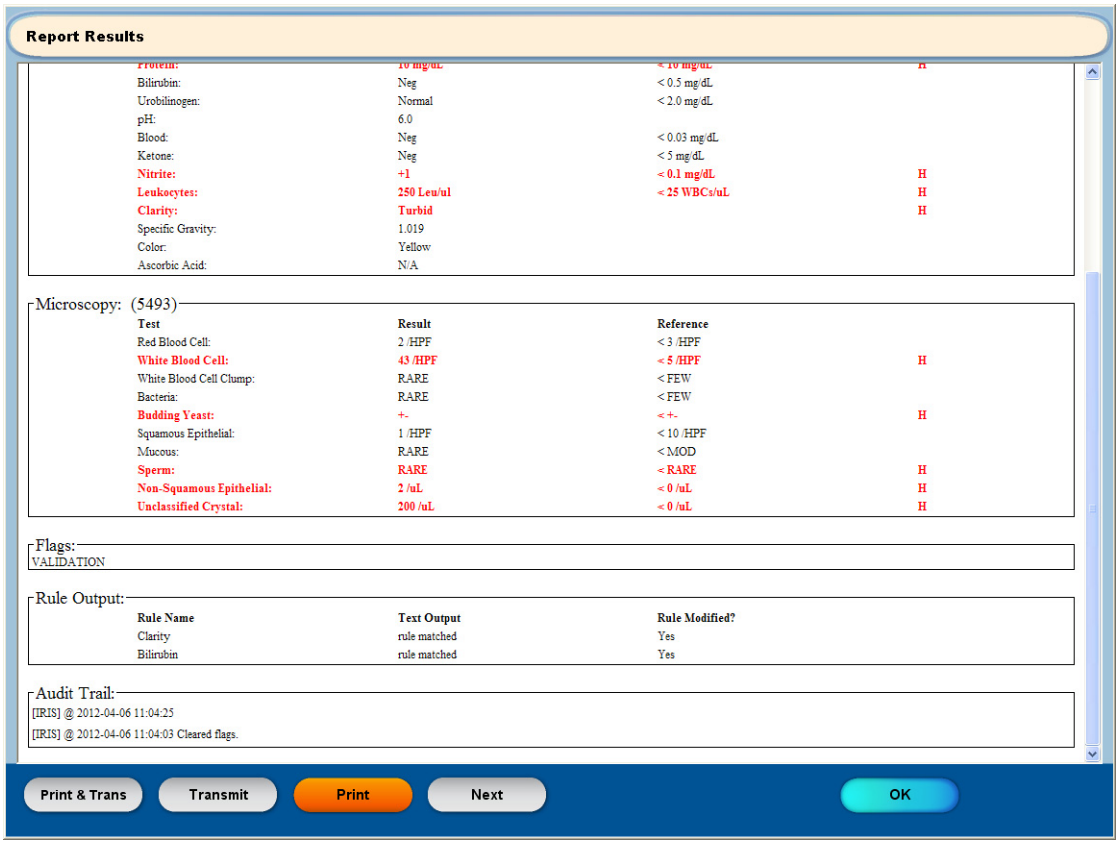


A fuchsia box outline indicates that iWARE rules were reapplied.

Patient Report with Tag

Below is an example of a patient report with a message tagged. The Rule Output field indicates the Rule Name that was applied to the results, the comment that was entered during rule tagging. The system will also indicate if the rule has been modified after the sample was run.

Figure 14.4 Patient Report with Tag



CHAPTER 15

iQ Body Fluids Module

Introduction

Intended Use

The iQ Body Fluids Module is an *in-vitro* diagnostic device used by a trained human observer to examine and count red blood cells and nucleated cells in cerebrospinal fluid, serous fluids, and synovial fluids.

NOTE Seminal Fluid is not an FDA cleared source.

Installation

The Body Fluids Module Key Disc must be inserted in the DxU Microscopy Series CD-ROM drive at start up for the DxU Microscopy Series to process body fluids.

NOTE The Key Disc must remain in the CD-ROM for the Body Fluids Module to run QC and specimens.

The iQ Body Fluids Module Key Disc cannot be copied and lost Key Disc can only be replaced by purchasing a new one. If a Body Fluids Key Disc is scratched or broken and the disc or pieces are returned to Beckman Coulter, the Body Fluids Key Disc will be replaced at no charge.

DxU Microscopy Series systems with body fluids functionality are identified by a Body Fluids Module door sticker that is included in the starter kit and affixed to the front door of the DxU Microscopy Series upon installation.

Synovial Fluid Application Installation

The synovial fluid application is activated by installing the Synovial Fluid Installation CD. The Synovial Fluid Installation CD is installed by your Beckman Coulter representative.

1 Store the Synovial Fluid Installation disc in a secure location after activation. The Synovial Fluid Installtion disc may need to be retrieved if your Beckman Coulter representative determines that the application must be reinstalled (For example, if a new software version dictates reinstallation, if the existing DxU Microscopy Series PC is replaced, or if the operating system must be reimaged as part of troubleshooting.)

2 To determine if the synovial fluid application has been activated, select **Settings** > **Fluid Type**.

- If Synovial Fluid displays after selecting Fluid Type, the application has been activated.

- If Synovial Fluid settings are not active on your system after the iQ Body Fluids Module Key Disc has been installed, check to see that the Body Fluids Key Disc is inserted in the CD-ROM and that the Body Fluids Module was activated properly.
- Contact your local Beckman Coulter representative if the Body Fluids Key Disc was properly inserted, but Synovial Fluid still does not display when selecting **Settings** > **Fluid Type**.

Body Fluids Startup Instructions

IMPORTANT: Do not lose the Body Fluids key disc as it is needed to run all body fluids specimens.

1 Power ON the instrument computer.

2 Insert the Body Fluids Module key disc into the CD drive in the PC.

3 RESTART the instrument using the software following the steps below:

a. Access the instrument screen.

b. Select **Log on > Off line > Maintenance > RESTART > Log on**

NOTE The Body Fluids Module key disc must be in the CD drive in the PC while restarting the computer in order to access all Body Fluids Module settings.

4 Leave the Body Fluids Module key disc in the CD drive when running the Body Fluids and/or urine samples. The key disc does not need to be removed to run urine specimens.

5 If the key disc is removed to perform activities which use the CD drive (example: backup/restore, import/export, etc.), place the Body Fluids Module key disc back into the CD drive after any of these functions are performed. The Body Fluids Module function will only be active if the Body Fluids Module key disc is in the PC during RESTART and when running Body Fluids samples.

Synovial Installation Instructions for the iQ Body Fluids Module

NOTE Installation of the Synovial Installation disc is typically performed by a Beckman Coulter Representative, but may need to be performed by the laboratory as needed. The Synovial Fluid Installation disc only needs to be installed one time, unless the computer is replaced or a software upgrade necessitates re-installation.

Software Installation

1 Before installing the Synovial Fluid installation disc, be sure that the Body Fluids Module is enabled as follows:

- **a.** Select the **Work List** screen.
- **b.** View the column headers on the **Work List.**
- **c.** If the Body Fluids Module is enabled, there will be a header for **Type** above the list in the column headers.
  - **1)** You may proceed with installation of Synovial Fluid installation disc.
- **d.** If the Body Fluids Module is not enabled, install the Body Fluids key disc.
  - **1)** See Body Fluids startup instructions.

2 Find the Synovial Fluid Installation disc.

3 Remove the Body Fluids Module key disc from the instrument CD-R or DVD-R drive and place it in a safe location where it will not be damaged.

4 Insert the Synovial Fluid Installation disc into the instrument CD-R or DVD-R drive. The software will automatically run and install the Synovial Fluid Installation disc. The **EnableSynovial** window will appear for a few seconds, and then close.

5 After the **EnableSynovial** window closes, restart the instrument software as follows:

- **a.** Select **Go off line** on the Instrument screen and wait for the **Off line** message to appear.
- **b.** Select **Maintenance** on the Instrument screen and the Maintenance dialog will appear.
- **c.** Remove the Synovial Fluid Installation disc from the drive and reinsert the Body Fluids Module key disc.
- **d.** Next select the **Restart** button to restart the instrument software. You are logged off the system.

6 Select **Log on**.

7 Select **Off line** again.

8 Select **Settings**. The Settings dialog appears.

9 Make sure the **Fluid Type** is displayed.

a. If **Formed Particles** is displayed, the Body Fluids key disc was not read correctly. You need to verify the Body Fluids key disc is inserted correctly, then **Restart** again.

10 Select **Fluid Type**.

11 Review the list to see if **Synovial** displays. If **Synovial** displays, the Synovial Fluid Installation was successful.

System Description

The iQ Body Fluids Module is a software program that runs on the DxU Microscopy Series and automates body fluid sample handling, capturing particle images in a manner very similar to that of the urinalysis application. The DxU Microscopy Series uses a CCD camera to capture images from each sample. The software needs to be at version 4.0 or higher in order to be able to run the iQ Body Fluids Module.

For more details, see Theory of Operation in CHAPTER 2, Operation Principles.

Theory of Operation

The DxU Microscopy Series auto-identifies, processes, and identifies images from specimens that are loaded into specific body fluid racks.

Body Fluids specimens are prepared by splitting the specimens into two aliquots. One aliquot is mixed with iQ Body Fluids Lysing Reagent and the other is mixed with Iris Diluent.

The two aliquots are prepared differently because successful analysis relies on subjecting one aliquot to selective cell lysis. Selective lysis is a chemical process that destroys red blood cells' membrane, causing the membrane to burst and releasing its contents into the solution.

The iQ Body Fluids Module reports the total number of cells in each of the two aliquots, the cells from the diluted aliquot are called *Total Cells* and the cells from the lysed aliquot *Nucleated Cells* because the RBCs have been destroyed. Therefore, the difference between the *Total Cells* and the *Nucleated Cells* represents the number of RBCs in the specimen.

System Components

The iQ Body Fluids Module consists of a Key Disc that contains the software required to process body fluids, the designated 10-position body fluids racks, and Body Fluids QC rack.

In addition, the following consumables are required:

- Iris Diluent
- iQ Body Fluids Lysing Reagent

- 10mL plastic conical bottom tubes
- Patient ID barcode labels
- Body Fluid/Dilution specific barcode labels
- Synovial fluid activator disc (enabled by a Beckman Coulter Representative)
- Any commercially available hyaluronidase
- Any commercially available wooden stick

Body Fluids Startup

1 Verify that the Body Fluids module CD is in the CD-ROM disc drive.

2 If the Body Fluids module is not in the disc drive, then perform a shutdown.

3 Power ON the PC and allow the software to load.

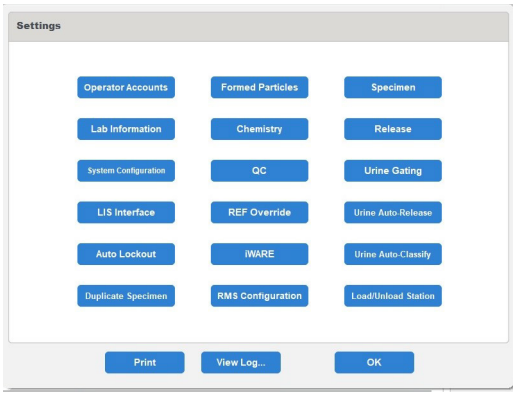
4 When the main screen appears, log on using your User ID and Password.

Settings

NOTE The operator must be offline to change settings.

When the Body Fluids Module is enabled on the DxU Microscopy Series, one button on the Settings menu is changed: the **Fluid Type** button (formerly the **Formed Particles** button) allows access to the setting screens for each fluid type.

Figure 15.1 Settings Screen



The **Urine Auto-Release** button and the **Urine Auto-Classify** button only relate to urinalysis, and have no function when processing other body fluids.

To access the Formed Particles screen for urine analysis when the Body Fluids Module is enabled:

1. Select **Settings** located at the bottom of the Instrument screen.
2. From the Settings screen, select **Fluid Type**, and then select **Urine**.
3. Proceed as for the Urine module. See Formed Particles Settings in CHAPTER 9, Setup.

Body Fluids Source/Type

The following Body Fluid Sources were FDA-cleared:

- CSF
- Pleural
- Peritoneal
- Peritoneal Dialysate
- Peritoneal Lavage
- Pericardial
- Serous
- Synovial Fluid

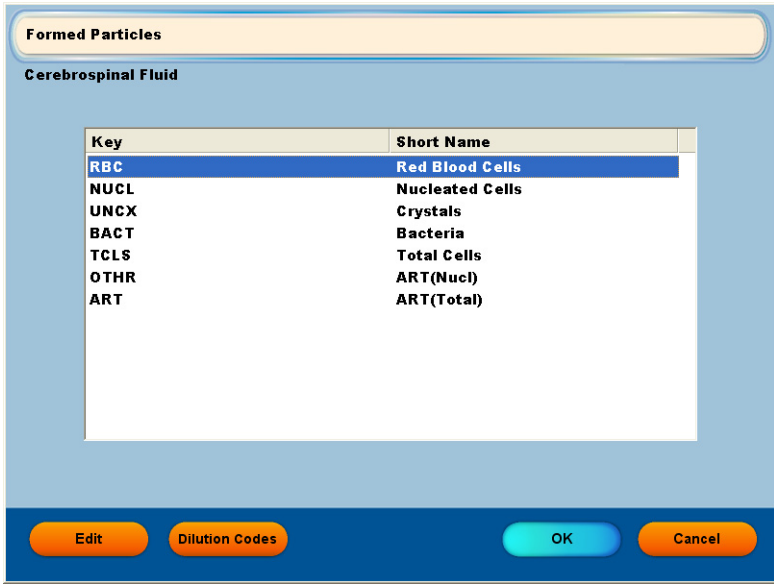
NOTE The iQ Body Fluids Module was not FDA-cleared for seminal fluid.

Fluid Types

To access the Formed Particles screen for Body Fluid analysis when the Body Fluids Module is enabled:

1. Select **Settings** located at the bottom of the Instrument screen.
2. From the Settings screen, select **Fluid Type**.

3 Select the body fluid type (e.g., selecting Cerebrospinal for CSF) to display a Formed Particles screen for that specific body fluid.



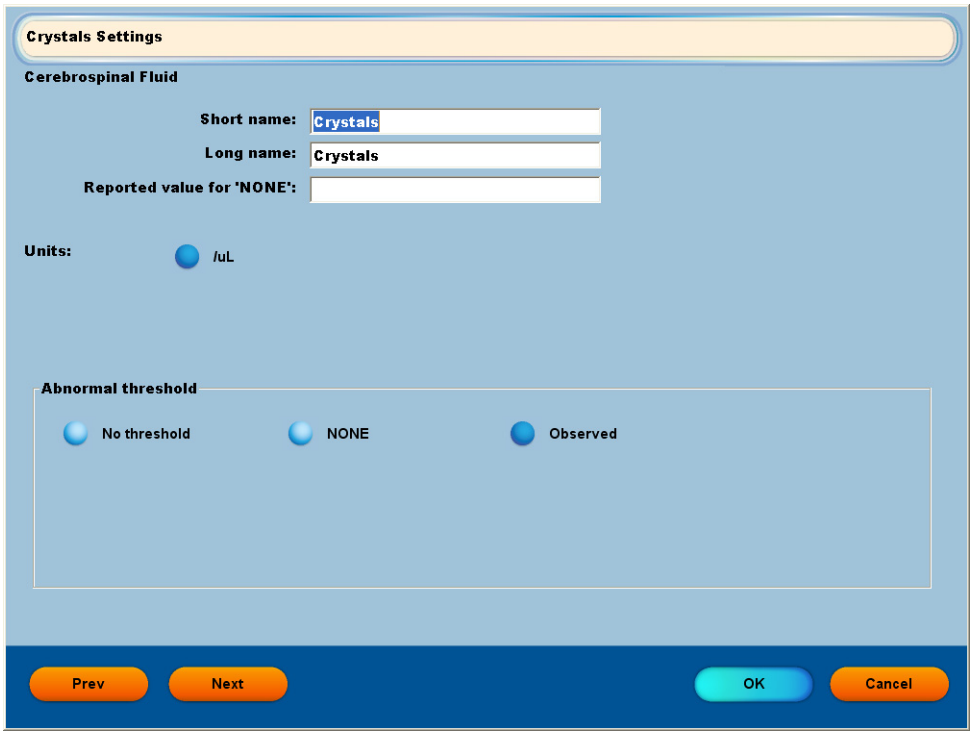
Seven formed particle classifications are available:

- RBC – Red Blood Cells
- NUCL – Nucleated cells
- UNCX – Crystals
- BACT – Bacteria
- TCLS – Total Cells
- OTHR – Artifacts (Nucl)
- ART – Artifacts (Total)

NOTE The particle key (capitalized abbreviation) cannot be changed.

4 Select a formed particle type, and select **Edit** to access a Settings screen where it is possible to change the parameters associated with each particle type, including the short name, long name, and abnormal threshold.

In the Crystals Settings and Bacteria Settings screens, the abnormal threshold can only be set as No Threshold, Not Observed, or Observed. This is because the Body Fluids Module does not quantify these particles, and the abnormal threshold is only used to flag the specimen for confirmatory testing by another method, such as polarized microscopy analysis. Setting the abnormal threshold as Not Observed will give an abnormal result for any Crystals or Bacteria observed.



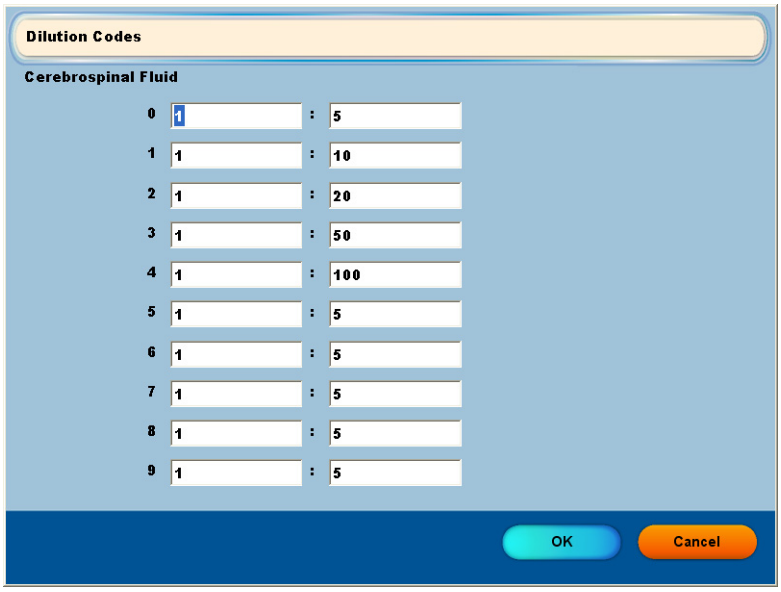
Dilutions Settings

The **Dilutions** button on the Formed Particles screen displays the same screen as in the Urine Module, although the settings are different for each body fluid type.

NOTE The defaults for each fluid type should not be changed. It is the minimum dilution tested and approved for use with the instrument and the reagents. There is a minimum specimen requirement of 15 µL and a maximum of 250 µL per specimen tube.

Cerebrospinal Fluid

Figure 15.2 Dilution Codes Screen - Cerebrospinal Fluid



NOTE Synovial fluid has the same default dilution format as Cerebrospinal fluid.

Specimen Processing

Tubes

Unlike urine, the volume of other body fluid specimens is typically limited. The low volume of body fluids that are often required to process necessitates the use of specific tubes that have been proven to resist interactions with body fluids and particles.

The only tubes recommended for use with the iQ Body Fluids Module are 10mL plastic conical bottom tubes supplied by Beckman Coulter. Do not attempt to run body fluids using other tubes. Improper tubes could cause the system to create a *short sample* flag. In addition, it is possible that your specimen could adhere to the walls of tubes that have not been approved by Beckman Coulter.

Specimen Preparation

Body Fluids specimens are prepared by splitting the specimens into two aliquots. For each body fluids specimen, prepare two sample tubes: one tube in which the specimen will be diluted with iQ Body Fluids Lysing Reagent and one tube in which the specimen will be diluted with Iris Diluent. This process prepares each specimen for analysis and brings the volume up to a workable level.

Figure 15.3 Specimen Preparation - Barcode Labels

Number	Description
1	Patient Identification Barcode Label
2	Body Fluids Barcode Label

Place an identical Patient ID barcode label on both tubes. The barcode labels should be oriented with the numbers reading down, the barcode label beginning approximately 1/2 inch from the top of the tube. If no Patient ID barcode labels are available, the operator can use the Manual Orders Work List to run the Body fluids samples.

Synovial Fluids

Pre-Analytical Processing of Specimens Required

Synovial specimens may be collected using K_2EDTA as an anti-coagulant. Synovial Fluid specimens require pre-analytical treatment with hyaluronidase prior to preparing Total Count and Lyse dilutions. The purpose of this pre-analytical step is to reduce the viscosity and thereby increase fluidity and homogeneity of the specimen. In addition, it prevents the formation of a blue coagulate when the specimen is dispensed into the iQ Body Fluids Lysing Reagent.

Materials Required

Hyaluronidase

Any commercially available Hyaluronidase crystals.

Specimen Processing for Synovial Fluid

Prior to following the steps above in iQ Body Fluids Module, *Specimen Processing,* all synovial fluid specimens **must be pre-treated with hyaluronidase** to reduce the viscosity, increasing fluidity and homogeneity of the specimen and preventing the formation of a blue coagulate when the specimen is dispensed into the iQ Body Fluids Lysing Reagent.

1. Add 400 units of hyaluronidase to ~1 mL of synovial fluid specimen.

2. Mix thoroughly on a hematology tube rocker and incubate for 10 minutes at 20 to 28° C (64 to 82° F).

3. After 10 minutes, mix the specimen and follow the processing steps located above in iQ Body Fluids Module, *Specimen Processing*.

Precautions

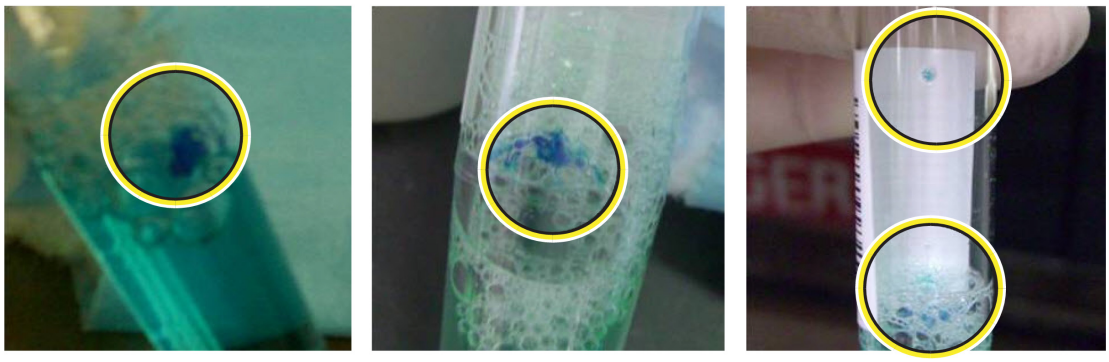
The following conditions may result in the formation of a blue coagulate when the specimen is dispensed into the iQ Body Fluids Lysing Reagent:

- No hyaluronidase added to the synovial fluid specimen.
- Expired or loss of activity of the hyaluronidase reagent.
- Inadequate mixing of the hyaluronidase with the synovial fluid specimen.
- Inadequate incubation time of the hyaluronidase with the synovial fluid specimen.

If any of the above four conditions are present, they may be detected by examination of the blue colored Lysing Reagent tube. Following the dispensing of the synovial fluid into the tube, a blue coagulate immediately forms and floats to the top of the solution and/or adheres to the wall of the tube.

Examples of the blue coagulate are illustrated in Figure 15.4, Blue Coagulate - Examples.

Figure 15.4 Blue Coagulate - Examples



Dilutions

NOTE The dilution step in analyzing Body Fluids is extremely important. If the dilution is too low, the result may exceed the reportable range of the DxU Microscopy Series (10,000 /µL) and will require an additional dilution. If the dilution is too high, too few cells may be available for counting.

Determine the appropriate dilution for the specimen based on the body fluid type and the condition of the specimen. Choose the Body Fluid barcode labels corresponding to the appropriate Body Fluid and Dilution, and place these barcode labels on both sample tubes immediately below the Patient ID barcode label. (The text on the barcode label for the lysed sample is blue; the text on the barcode label for the diluted sample is black.)

Recommended Body Fluids Specimen Dilutions

Table 15.1 Recommended Body Fluids Specimen Dilutions

Specimen Type Appearance	CSF/Synovial			Serous		
	Dilution	Sample Volume	Diluent/Lyse Volume	Dilution	Sample Volume	Diluent/Lyse Volume
Clear/Colorless	1:5	250 µL	1000 µL	1:20	100 µL	1900 µL
Slightly Pink/Hazy	1:10	150 µL	1350 µL	1:20	100 µL	1900 µL
Pink/Slightly Cloudy	1:20	100 µL	1900 µL	1:20	100 µL	1900 µL
Red/Cloudy	1:50	30 µL	1470 µL	1:50	30 µL	1470 µL
Extremely Bloody/Extremely Turbid	1:100	15 µL	1485 µL	1:100	15 µL	1485 µL

Barcode Labels

Because every body fluid specimen is diluted, every specimen needs a dilution-specific barcode label. There is a specific set of barcode labels for each body fluid type. The abbreviations on the labels are indicated in Table 15.2, Barcode Labels for Body Fluid Types.

Table 15.2 Barcode Labels for Body Fluid Types

Body Fluid Type Abbreviations	Body Fluid Type
CSF	Cerebrospinal fluid
PLE	Pleural
PER	Peritoneal
PED	Peritoneal Dialysate
PEL	Peritoneal Lavage
PCA	Pericardial
SER	Serous
SYN	Synovial

As an example, Table 15.3, Cerebrospinal Fluid (CSF) Dilution Codes and Barcode Labels - Example displays the cerebrospinal fluid (CSF) dilution codes and corresponding barcode labels.

Table 15.3 Cerebrospinal Fluid (CSF) Dilution Codes and Barcode Labels - Example

Number	Dilution	Barcode Label (Lysis Tube)	Barcode Label (Diluted Tube)
0	1:5	CSF LYS 0	CSF TOT 0
1	1:10	CSF LYS 1	CSF TOT 1
2	1:20	CSF LYS 2	CSF TOT 2
3	1:50	CSF LYS 3	CSF TOT 3
4	1:100	CSF LYS 4	CSF TOT 4
5	1:5	CSF LYS 5	CSF TOT 5
6	1:5	CSF LYS 6	CSF TOT 6
7	1:5	CSF LYS 7	CSF TOT 7
8	1:5	CSF LYS 8	CSF TOT 8
9	1:5	CSF LYS 9	CSF TOT 9

Body Fluid Rack

Each specimen is run on its own Body Fluids rack, while operating in the iQ Body Fluids Module mode. Use rack 25, 26, and 27 for running samples. Body Fluids Controls and Background are run in a BFQC rack.

Figure 15.5 Body Fluid Rack

Positions 1 through 5 in the body fluid rack can accept tubes for processing by the Body Fluids Module. Positions 2 through 4 are required. The instrument will read the tubes in each position as follows:

Position	Required/ Optional	Contents	When to use it
1	Optional	Iris Diluent min 1.25 mL	After bloody or turbid urine sample
2	Required	Iris Diluent min 1.25 mL	
3	Required	Lysed sample 1.25 mL	
4	Required	Diluted sample 1.25 mL	
5	Optional	Iris Diluent min 1.25 mL	After bloody, turbid, or extremely bloody body fluid sample

NOTE In the case of a bloody, turbid or extremely bloody body fluid specimen, an additional tube of Iris Diluent may be processed in position 5 of the Body Fluids Rack. This tube is added to ensure that there is no carryover in the next sample tube.

NOTE When testing a body fluid specimen after urine samples, especially a bloody or turbid urine sample, it is advisable to run an additional tube of Iris Diluent in position 1 of the Body Fluids Rack for the first body fluid specimen processed.

Loading the Rack

1 Place the tube that will contain just Iris Diluent (1.25 mL) in position 2 of the body fluids rack.

2 Place the tube that will contain the lysed specimen in position 3 of the body fluids rack.

3 Place the tube that will contain the diluted specimen in position 4 of the body fluids rack.

Barcode labels should face the openings in the back of the rack and are only required on tubes 3 and 4.

4 Using a pipettor, aliquot an appropriate amount of solution to make the required dilution into each of the two tubes (3 and 4). For example, when making a 1:20 dilution, pipette 1900 µL of Body Fluids Lysing Reagent (blue) into the tube in position 3, and 1900 µL of Iris Diluent into the tube in position 4.

5 Immediately before loading the rack onto the DxU Microscopy Series system, add the appropriate amount of specimen to the solutions. For example, when making a 1:20 dilution, pipette 100 µL of specimen into the tubes in positions 3 and 4 and thoroughly mix the tube.

NOTE Always add the correct amount of lysing reagent or diluent to the tube first. It is very important to add the specimen to the lysing reagent or diluent, and not vice versa. Specimens that are added directly to empty tubes can adhere to the wall of the tube, which can impede them from mixing properly into solution. For the same reason it is important **not** to apply the specimen to the wall of the tube above the solution.

Body Fluid patient racks and Urine patient racks can be loaded and run one after the other without separation.

Analyzing the Specimen

NOTE Beckman Coulter recommends running the Body Fluids mixed specimens IMMEDIATELY after performing the dilution.

Position the rack on the DxU Microscopy Series system the same way you would when using the Urine Module.

If you accidentally place the body fluid rack on the automated urine chemistry analyzer, the urine chemistry analyzer recognizes the rack and immediately shuttles it over to the DxU Microscopy Series analyzer for microscopy analysis. The DxU 810c Iris analyzer is preprogrammed to skip these racks.

NOTE Samples must always be run in both **position 3 AND position 4**, and both **tubes** must be included in the same run. If the tube in position 4 is missing, your sample will be lost. (If you forget to include the tube in position 4, you cannot run it by itself later.)

Turbo edit is the only verification mode used for the body fluid analysis.

Quality Control

The iQ Body Fluids Module protocols assume that as operators of the Urine Module, you will already be running the focus and urine controls at least every 24 hours. Daily DxU Microscopy Series start-up and urinalysis controls must be performed before Body Fluid Controls are run. For more details, see Quality Control in CHAPTER 4, Quality Control.

The iQ Body Fluids Module allows for two additional controls that should be processed every 24 hours (when body fluids analyses are performed): two levels of positive control with defined values to confirm system accuracy. These controls are run with two tubes, just as a run of patient specimen. Results are stored and Levey-Jennings charts are created.

A background check must be performed weekly, using the reagents straight and the same process of barcoding as the QC. Results are logged in QC Review and Statistics.

Positive Controls

Running positive controls every 24 hours with known quantities of specific cells types ensures that the system is accurately measuring the cells in each specimen.

The iQ Body Fluids Level I and Level II Controls contain two known levels of red blood cells and nucleated cells. This controls need to be run separately (i.e., one rack for each concentration) because there are two concentrations of the positive control that must be prepared the same as BF patients specimens.

Barcode Labels

Barcode labels are provided for both levels of controls and Background check. The labels include the lot identification, number, expiration date, and cell counts for the controls.

Body Fluid Control Rack

Body Fluid QC rack (BFQC rack) must be used for running body fluid controls.

Body Fluid Control Material:

1. Let the controls return to room temperature for about 30 minutes.
2. Hold the vial horizontally between the palms of the hands and roll the vial back and forth for 20 to 30 seconds.
3. Mix by rapid inversion. If the vial was stored for an extended time, gently invert the vial 8 to 10 times.
4. After opening, control materials are stable for 30 (thirty) days when stored at 2 to 8^{o}C.

Loading the Body Fluid Rack with Body Fluid Tubes:

1. Place a tube that contains just Iris Diluent (1.25 mL) in position 2 of the body fluids rack without barcode label.
2. Place a tube that will contain the lysed control in position 3 of the body fluids rack. Label the tube with the corresponding QC label for the specific body fluids control level.

3 Place a tube that will contain the diluted control in position 4 of the body fluids rack. Label the tube with the corresponding QC label for the specific body fluids control level.

4 Barcode labels should face the openings in the back of the rack and are only required on tubes 3 and 4.

5 Using a pipettor, pipette 1000 µL of Body Fluids Lysing Reagent (blue) into the tube in position 3, and 1000 µL of Iris Diluent into the tube in position 4.

6 Immediately before loading the rack onto the DxU Microscopy Series, pipette 250 µL of positive control into the tubes in positions 3 and 4 and gently mix the tube.

7 Place the control rack onto the DxU Microscopy Series and then press the Start button.

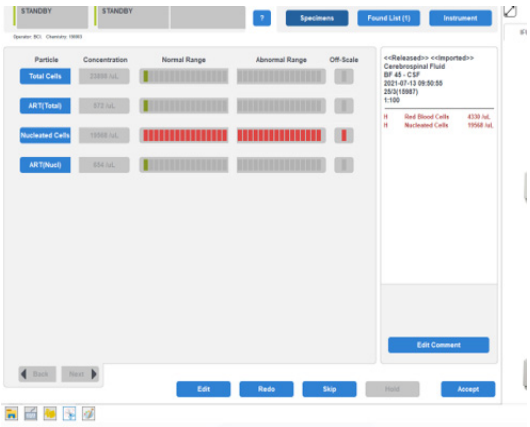
8 Repeat steps 1 to 7 with the second control material and Background Check.

NOTE Beckman Coulter recommends running the well mixed Body Fluids control materials IMMEDIATELY after performing the dilution.

Reviewing QC Results

1 After running the control rack, the control results are displayed on the Work List.

2 Select the control to be reviewed and select **Specimens**. The specimen screen will display the results for the selected control.



3 Review and edit the results in the same manner as a patient specimen. Ensure that all artifacts are moved into the designated ART classification.

4 Select **Accept**. The results will be transmitted to the QC Review, QC Statistics and LIS (optional).

Figure 15.6, RBCs and Nucleated Cells from the iQ Body Fluids Level II Control - Example 1 and Figure 15.7, RBCs and Nucleated Cells from the iQ Body Fluids Level II Control - Example 2 show examples of RBCs and nucleated cells from the iQ Body Fluids Level II Control.

Figure 15.6 RBCs and Nucleated Cells from the iQ Body Fluids Level II Control - Example 1

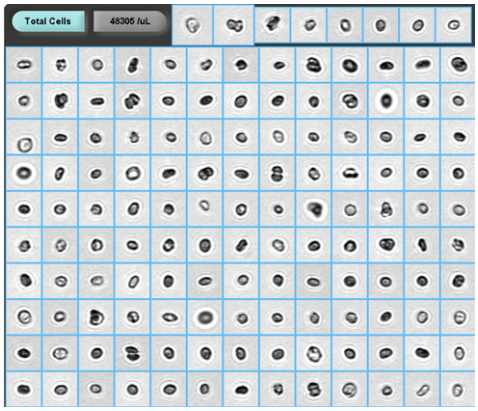
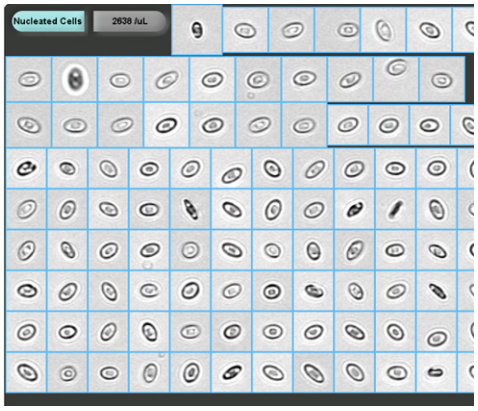


Figure 15.7 RBCs and Nucleated Cells from the iQ Body Fluids Level II Control - Example 2



Failed Body Fluid Controls

If the control fails, a yellow flag will be displayed on the Instrument screen. If this flag is displayed, body fluid specimens will not be allowed to run but urine specimens will not be affected. The operator has the option to re-run the control or a manager can re-edit the results. If the logged-on operator is not a manager, the **Accept** button will be disabled on released BF QC samples.

1 From the Work List screen, select the control to be reviewed and select **Specimens**. The specimen screen will display the results for the selected control.

2 Review and edit the results in the same manner as a body fluid patient specimen by moving all artifacts into the designated ART classification.

3 Select **Accept**. The results will be transmitted to the QC Review, QC Statistics and LIS (optional).

NOTE A manager can re-edit and release a previously run/edited body fluid QC result. To review these released QC results, access the Work List and perform a search the same way as a patient specimen.

Reagent Background Check

The reagent background check is run to ensure that the system reagents (iQ Body Fluids Lysing Reagent and Iris Diluent) have not been contaminated. This should be done once a week.

Load the Body Fluid control rack (#24) with the following body fluid tubes:

1 Place the tube that contains only Iris Diluent (1.25 mL) in position 2 of the body fluids rack.

2 Place the tube that will contain the iQ Body Fluids Lysing Reagent in position 3 of the body fluids rack.

3 Place the tube that will contain the iQ Iris Diluent in position 4 of the body fluids rack.

4 Using a pipettor, pipette 1.25 mL of Body Fluids Lysing Reagent (blue) into the tube in position 3, and 1.25 mL of Iris Diluent into the tube in position 4.

5 Place the control rack onto the DxU Microscopy Series and then press the Start button.

Beckman Coulter provides a barcode label for background check; it is required on tube positions 3 and 4.

After running the rack, review and edit the results in the same manner as a patient specimen. See Reviewing QC Results. Edited background count passes if there are ≤3 particles/µL.

QC Review and QC Statistics

See Quality Control Review in CHAPTER 4, Quality Control for more information.

Results

The iQ Body Fluids Module initially classifies particles based on their size, which streamlines the editing process. After editing is complete, a report quantifying the number of RBCs and the number of Nucleated Cells in the fluid specimen is created.

NOTE Even though the iQ Body Fluids Module initially counts the number of Nucleated Cells and Total Cells, the module calculates and reports the number of RBCs by subtracting the number of cells in the lysed aliquot (in which the RBCs are destroyed) from the number of cells in the diluted aliquot.

Table 15.4 Image Reports

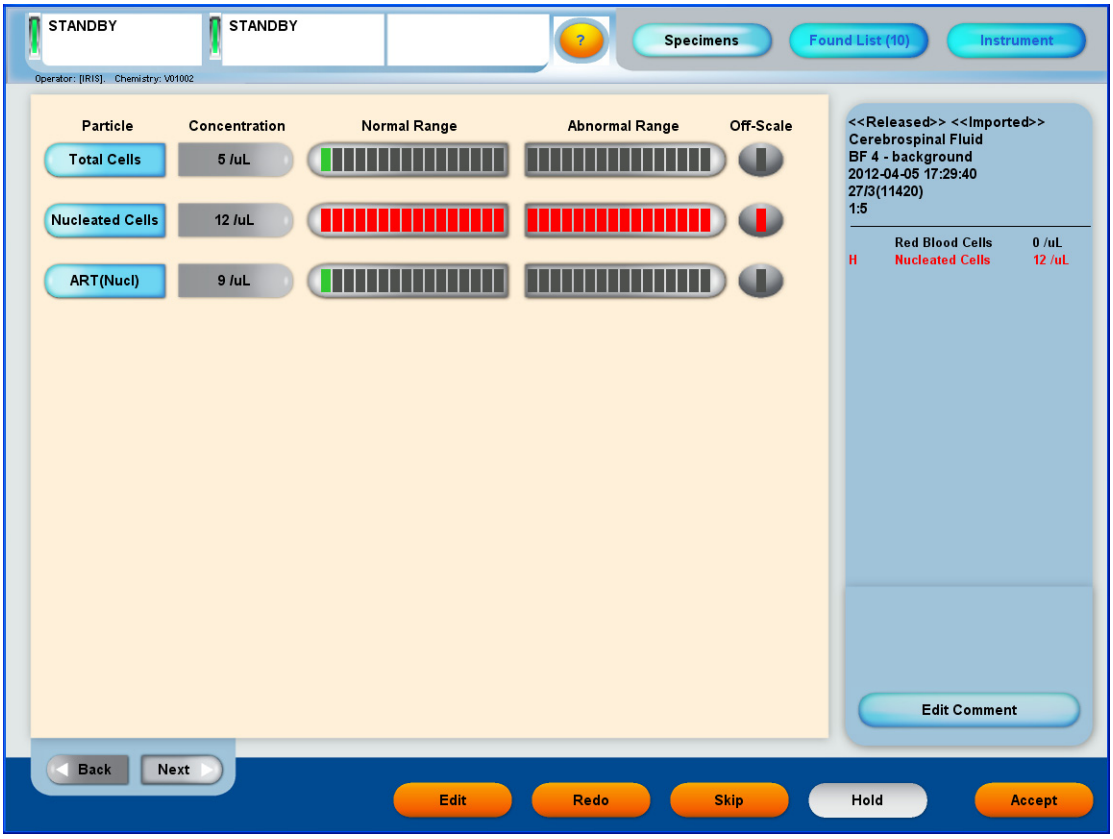
System Displays	Operator Edits	System Reports
Images from diluted aliquot -- Total Cells	Images that do not appear to be cells are reclassified as ART (Total)	RBCs (Total Cells minus Nucleated Cells)
Images from lysed aliquot -- Nucleated Cells	Images that do not appear to be nucleated cells are reclassified as ART (Nucl) **NOTE**: Lymphocytes may *appear* to be unnucleated when viewed. Do not remove such cells from this category.	Nucleated Cells

Reviewing and Re-Classifying Images

When the Body Fluid is enabled, the Work List automatically displays an extra column labeled *Type* which identifies the type of fluid sample. The rack ID/barcode label for tubes analyzed with the Body Fluids Module will always be racks 24, 25, 26, or 27, and the tube position will always read 3 (the position of the lysed sample).

Figure 15.8 Work List with *Type*

1 Select the specimen results on the Work List and then select **Specimens**. The Specimen screen in the body fluids module displays the aggregate results from the two sample tubes (i.e., lysed and diluted) within one BF rack.



2 To review the images, select the particle name, for example Total Cells. The initial cell counts are presented on this screen.

In the above screen, the operator is able to reclassify images that do not belong in that category. For example, in the Total Cells screen, the operator can move images to the Bacteria or Crystals categories to indicate that these particles may be present and tag the sample for confirmatory testing, or the operator can select **ART (Total)** to reclassify images as artifacts.

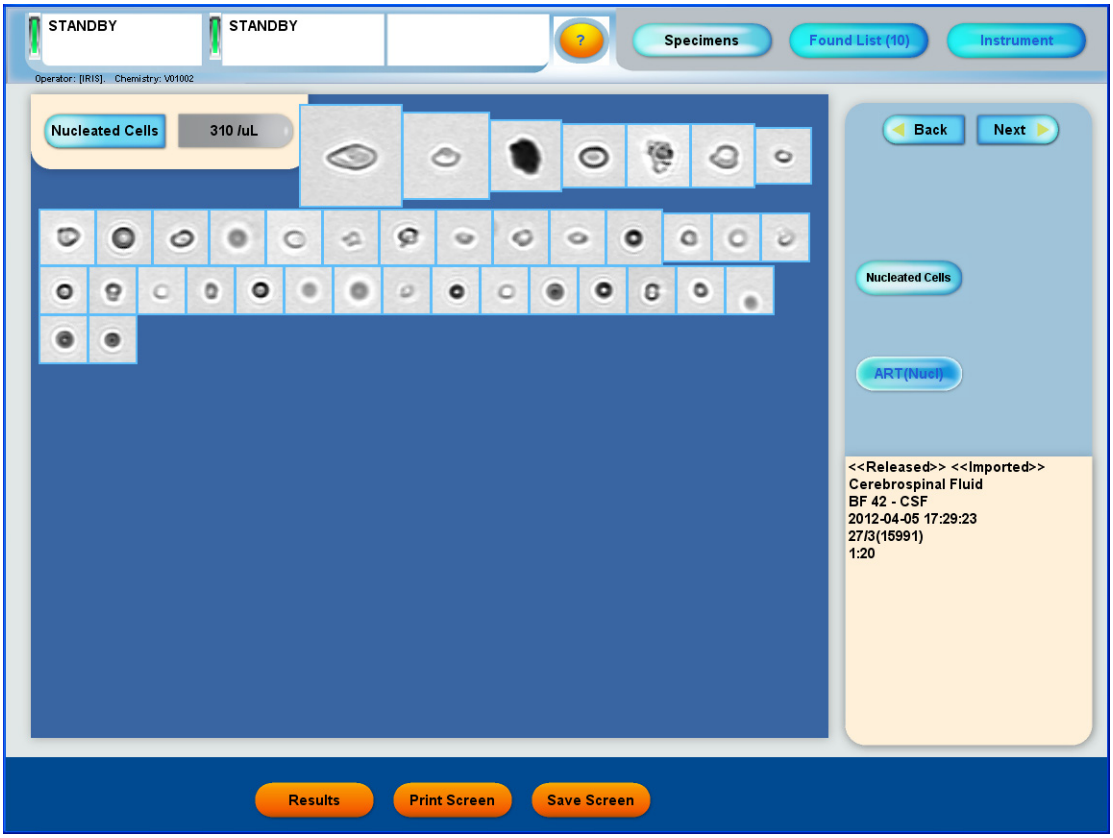
NOTE All bacteria and crystals isolated without cells must be reclassified into their respective sub-classification or ART.

The steps involved in the editing process are the same as in the Urine Module. See Verification of Results in CHAPTER 6, Data Review.

Bacteria and Crystals

During the editing process, the operator is also able to flag the specimen for further testing to determine if bacteria or crystals are present. Although the operator may classify images as bacteria or crystals, the iQ Body Fluids Module will not quantify bacteria or crystals present; however, by reclassifying these particles into Bacteria or Crystals, the operator can report Bacteria and/or Crystals observed. These specimens should be identified for further testing if necessary depending on the laboratory's protocol.

Figure 15.9 Bacteria and Crystals



Body Fluid Verification Summary

The following is a quick summary of verifying Body Fluid results:

1. Starting with the review for Total Cells, verify that only red and nucleated cells are in *Total Cells*, placing artifacts into the Artifact category. Review the Artifact category for cells to be reclassified to *Total Cells*.

2. To review Nucleated Cells, verify that only nucleated cells are in *Nucleated Cells*, placing artifacts into the Aritifact category. Review the Artifact category for cells to be reclassified to *Nucleated Cells*.

3. If Bacteria is seen, move into the appropriate category. Bateria will be reported as *Observed*. If bacteria and crystals are not present, these parameters will not be mentioned on the patient report.

Differentiating Cell Types

NOTE In all cases, if a nucleated cell differential is required it should be determined from a stained, cytocentrifuged slide.

When editing cell types, it is important to remember that the selective lysis process can dramatically alter the appearance of cells.

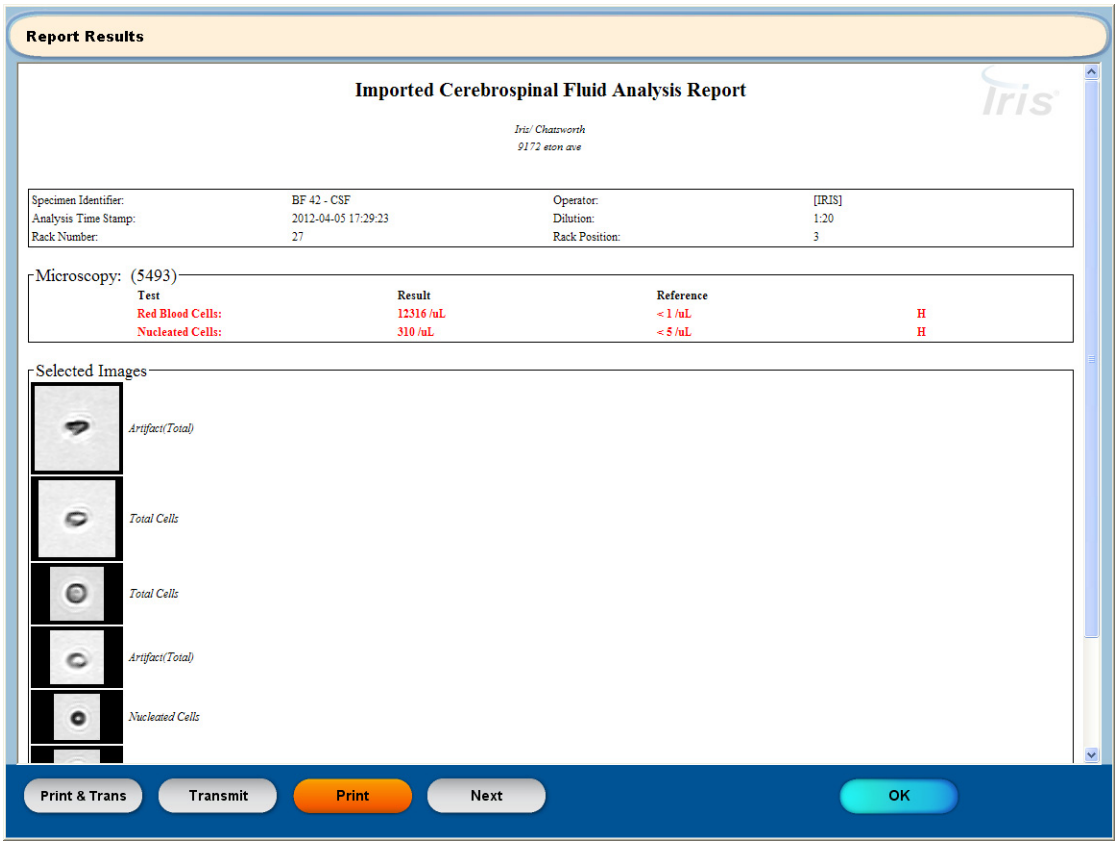
The output available from the iQ Body Fluids Module is the total number of nucleated cells and the total number of RBCs. For example, although you may believe that you see white blood cells in a specimen, there is no method for classifying these cells with the iQ Body Fluids Module. Their presence must be confirmed using a stained, spun smear.

Reporting

After completing the review and reclassification process, generate the final report by returning to the Results screen and selecting **Accept**. The report can be printed, sent to the LIS, or both. See Release Settings in CHAPTER 9, Setup.

The report indicates the tested body fluid type, the specimen identifier, the operator, the processing information, the laboratory notes, and the microscopy results.

Figure 15.10 Report Results Screen

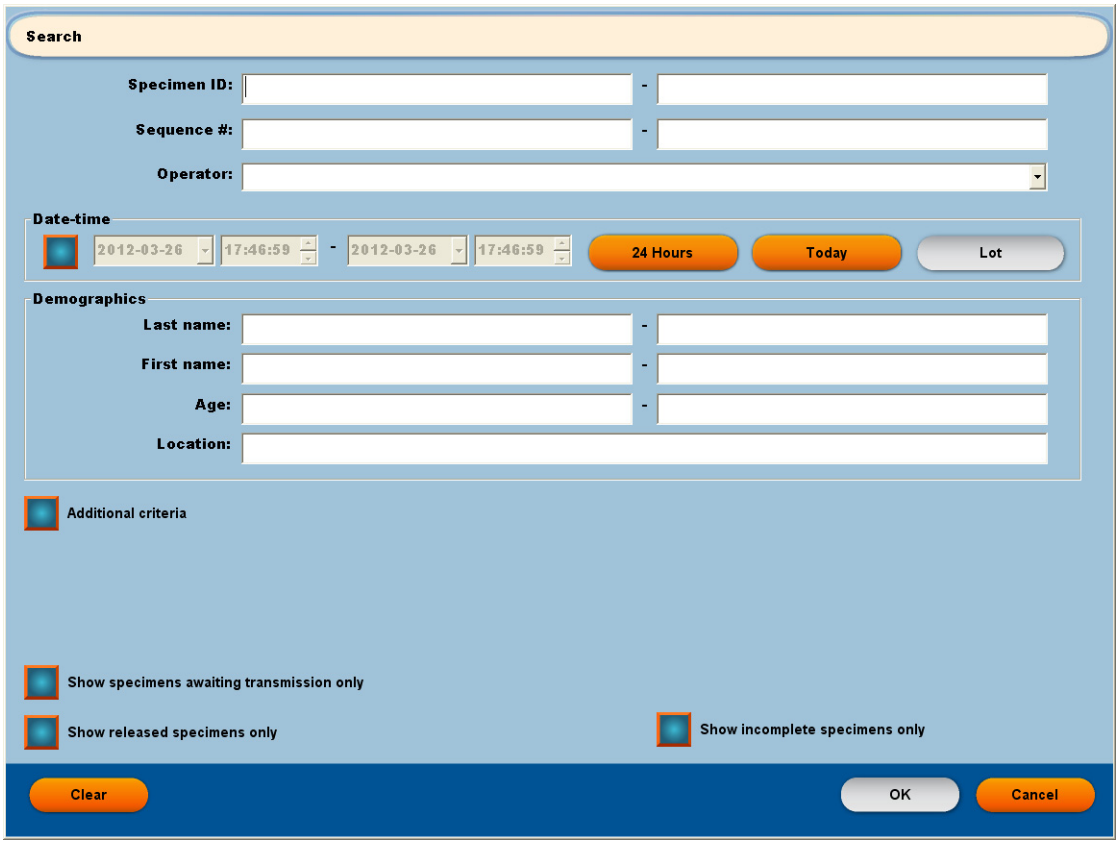


Search Features

The **Search** button located on the Work List screen, allows you to search the archived specimen results for specific data.

1 From the Work List screen, select **Search**. The Search screen will be displayed.

The Search criteria are the same as the urinalysis. See Search in CHAPTER 6, Data Review.



2 An extra checkbox is displayed limiting research results for Body Fluid Type. Select the checkbox to restrict the search to body fluid specimen.

3 Select **OK**.

Alarms

Alarm #32

CAUSES	REMEDIES
The fluidic sub-system is dirty or contaminated by a high-concentration specimen.	This condition must be remedied for the instrument to run more body fluid specimens (it does not prevent running urine specimens). • Run a BFA rack with a Prime tube in position 1 and a Prime Check tube in position 2. • Run a BFA rack with a Prime tube in position 1 and a Prime Check tube in position 2. — Run a BFA rack with a Prime tube in position 1 and a Prime Check tube in position 2. — Run a Control Rack with Iris System Cleanser, Iris Diluent, and Focus. — Open a new bottle of diluent and repeat. • If the failure persists, restart the instrument and try again. • If the failure still persists, turn off the power and contact your distributor.

Alarm #33

CAUSES	REMEDIES
• Control not edited by the operator • Control not warmed to room temperature before use • Control not properly mixed before use • Control not stored properly • Control dilution not made properly • Control mislabeled • Contaminated Reagents, Lamina, and/or System • Dirty specimen filter	This condition must be remedied in order to run patient body fluids samples; urine samples can still be run. Rerun Control making sure it is warmed to room temperature and properly diluted and mixed before placing on the instrument If Control Level I still fails: • Cleanse the system using the Control Rack, 3 mL of Iris System Cleanser in Position 1 and 3 mL of Iris Diluent in Positions 2 and 3; then rerun • Open new vial of Control Level I and rerun • Open new bottles of Body Fluids Lysing Reagent and Iris Diluent and rerun the Background Check • Replace specimen filter If failure persists, restart the instrument and try again. If failure persists, contact distributor.

Alarm 34

CAUSES	REMEDIES
• Control not edited by the operator • Control not warmed to room temperature before use • Control not properly mixed before use • Control not stored properly • Control dilution not made properly • Control mislabeled • Contaminated Reagents, Lamina, and/or System • Dirty specimen filter	This condition must be remedied in order to run patient body fluids samples; urine samples can still be run. • Rerun Control making sure it is warmed to room temperature and properly mixed before aspirated If Control Level II still fails: • Cleanse the system using the Control Rack, 3 mL of Iris System Cleanser in Position 1 and 3 mL of Iris Diluent in Positions 2 and 3; then rerun • Open new vial of Control Level II and rerun • Open new bottles of Body Fluids Lysing Reagent and Iris Diluent and rerun the Background Check Replace specimen filter If failure persists, restart the instrument and try again. If failure persists, contact distributor.

Alarm #35

CAUSES	REMEDIES
The following things can trigger this alarm: • Background Check not edited by the operator • Body Fluids Lysing Reagent and/or Iris Diluent mixed before use • Contaminated Reagents, Lamina, and/or System • Dirty specimen filter	This condition must be remedied in order to run patient body fluids samples; urine samples can still be run. • Rerun and edit the Background Check making sure that the reagents are not mixed before being used If the Background Check still fails: • Cleanse the system using the Control Rack, 3 mL of Iris System Cleanser in Position 1 and 3 mL of Iris Diluent in Positions 2 and 3; then rerun • Replace specimen filter • Open new bottles of Body Fluids Lysing Reagent and Iris Diluent and rerun the Background Check • Replace specimen filter If failure persists, restart the instrument and try again. If failure persists, contact distributor.

Troubleshooting

BFA Not Enabled

CAUSES	REMEDIES
There is no iQ Body Fluids Module Key Disc in the CD-ROM of the PC.	The Body Fluids Module Key Disc must be inserted in the DxU Microscopy Series system CD-ROM drive at start up for the DxU Microscopy Series system to process body fluids. (In a two-computer configuration, the Key Disc is inserted into the computer designated as the Analysis Processor.) The Key Disc must remain in the CD-ROM for body fluid QC and patient samples to be analyzed.

BFA Skipped

CAUSES	REMEDIES
There is no tube in position 3 and/or position 4 of the body fluids rack.	Select **Delete Flagged Specimen** in the Results Screen and then select **Accept**. Rerun the specimen with a tube containing the specimen diluted in iQ Body Fluids Lysing Reagent in position 3 of the body fluid rack, and the specimen diluted with Iris Diluent in position 4 of the body fluid rack.

NOTE If there is a sample tube in position 3 and not in position 4 the DxU Microscopy Series system will take up the sample from the tube in position 3 but will not process it because of the vacancy in position 4. The lysed and diluted samples must be run together or the specimen will be lost.

ID Error

CAUSES	REMEDIES
There is no patient identification barcode label and or body fluids barcode label detected on the tube in position 3 and/or position 4 of the body fluids rack. This error can also occur if the patient identification barcode labels and or the body fluids labels on the tubes in position 3 and position 4 do not match.	Select **Delete Flagged Specimen** in the Results Screen and then select **Accept**. Rerun the specimen with a tube containing the specimen diluted in iQ Body Fluids Lysing Reagent in position 3 of the body fluid rack, and the specimen diluted with Iris Diluent in position 4 of the body fluid rack.

Incomplete Selective Lysis

CAUSES	REMEDIES
Selective lysis causes RBCs to burst completely; but incomplete lysis due to high concentration of RBCs can leave the outer cell membrane partially intact and create *ghost cell* images that could be misinterpreted if the operator is not careful. iQ Body Fluids Lysing Reagent is supplied by Beckman Coulter for the purpose of lysing RBCs, and is designed to minimize incomplete selective lysis and the appearance of ghost cells. IQ Body Fluids Lysing Reagent is the only recommended lysing solution for the iQ Body Fluids Application.	

BF Performance Characteristics

Analytical performance of the iQ Body Fluids Module is measured in terms of linearity range, concentration agreement (accuracy), and sample-to-sample precision.

Linearity Range

The linear range of the iQ Body Fluids Module is measured according to the NCCLS EP6A protocol.

Concentration Agreement

Linear regression analysis is performed to compare the specimen-by-specimen counts of RBC and Nucleated Cells (NUCL) from the iQ Body Fluids Module against manual counts of the same particles using a standard hemacytometer chamber.

The following criteria are used to evaluate the quality of the regression line:

- **R^2 (R Square)**: This is the square of the correlation between the counts obtained by the iQ Body Fluids Module and the counts obtained by the hemacytometer method. A correlation coefficient of 1 would signify perfect correlation resulting from identical values for both methods.[1]
- **The slope of the regression line**: A value close to 1 indicates that the two methods produce identical numerical results.
- **The intercept of the regression line**: Ideally the intercept of the regression line should be zero.

All regression analyses are carefully evaluated for the presence of outliers and recomputed if necessary with the exclusion of outliers to provide a truer assessment of the inter-method comparison.

[1] High R2 correlation coefficient can result from a single point with a large value and many low value points. On the other hand, a low R2 correlation coefficient can be obtained when comparing only low values even though they are within statistical limits of each other.

Sample-to-Sample Precision

Paired t-test is performed to compare counts of RBC and Nucleated cells (NUCL) from the iQ Body Fluids Module for two samples of the same specimen. The paired-t tests the hypothesis that the average of the sample-to-sample (paired) differences for RBC or Nucleated cells is zero.

The following statistical parameters are used to evaluate the sample-to-sample precision:

- **T-value**: Value of the t-statistic computed for paired replicates. A lower absolute t value indicates closer agreement of the replicate results.
- **Significance**: Value above 0.05 will indicate that the group composed of all first samples and the group composed of the second samples are statistically similar.
- **Pmean**: Average difference between paired values.

Analytical Performance Summary

Linearity Range (Except Synovial Fluids)

To demonstrate that the iQ Body Fluids Module reports linear counts estimates of undiluted specimen between 0 and 10,000/microliter a study was conducted following the NCCLS EP6A protocol.

Freshly drawn whole blood is diluted with Iris Diluent to create an evenly distributed sequence of 5 pool dilutions ranging from 0/µL to 10,000/µL. Additionally, iQ Control is diluted with Iris Diluent to create an evenly distributed sequence of 5 pool dilutions ranging from 0/µL to 1000/µL. Five replicates of each pool dilution are processed randomly.

A Summary of the NCCLS EP6A linearity analysis for blood dilutions in the range of 0 to 10,000/µL showing that the higher order coefficients of the quadratic and cubic fit are not statistically significant is shown in Table 15.5, Linearity Analysis for Blood Dilutions in the 0 to 10,000/µL Range.

Table 15.5 Linearity Analysis for Blood Dilutions in the 0 to 10,000/µL Range

Parameter	Linear	Quadratic	Cubic
Intercept	124.84	-26.902	2.717
Intercept Significance	0.420	0.715	0.923
Slope	2483.46	2786.95	2574.67
Slope Significance	0.000	0.007	0.014
Quadratic		-75.87	72.23
Quadratic Significance		0.053	0.297

Table 15.5 Linearity Analysis for Blood Dilutions in the 0 to 10,000/µL Range *(Continued)*

Parameter	Linear	Quadratic	Cubic
Cubic			-24.68
Cubic Significance			0.152

Table 15.5, Linearity Analysis for Blood Dilutions in the 0 to 10,000/µL Range demonstrates that the only parameter significant in the linear, quadratic, and cubic regressions is the **slope** parameter whose significance is always well below 0.05, indicating that the DxU Microscopy Series Body Fluids Module estimates particulate concentrations linearly in the 0 to 10,000/µL.

Summary of the NCCLS EP6A linearity analysis for blood dilutions in the range of 0 to 1000/µL showing that the higher order coefficients of the quadratic and cubic fit are not statistically significant.

Table 15.6 Linearity Analysis for Blood Dilutions in the 0 to 1,000/µL Range

Parameter	Linear	Quadratic	Cubic
Intercept	-6.72	7.94	0.417
Intercept Significance	0.708	0.669	0.923
Slope	235.34	206.02	259.92
Slope Significance	0.000	0.008	0.022
Quadratic		7.32	-30.271
Quadratic Significance		0.248	0.116
Cubic			6.26
Cubic Significance			0.093

Table 15.6, Linearity Analysis for Blood Dilutions in the 0 to 1,000/µL Range demonstrates that the only parameter significant in the linear, quadratic, and cubic regressions is the **slope** parameter whose significance is always well below 0.05, indicating that the iQ Body Fluids Module estimates particulate concentrations linearly in the 0 to 1000/µL.

Concentration Agreement and Sample-to-Sample Precision (Except Synovial Fluids)

The performance summary below reports the combined findings of studies conducted at two outside institutions. A total of 308 body fluid specimens were processed (151 cerebrospinal fluid specimens – CSF and 157 serous fluid specimens). When possible, specimens are run in duplicate (2 samples) to allow for precision study. Of the 151 CSF specimens, 107 had sufficient volume to be run in duplicate, while 150 of the 157 serous fluid were run in duplicate.

Each sample is processed by the iQ Body Fluids Module and a report of the RBC and Nucleated cell counts is obtained after operator editing. In parallel, a manual count of the RBC and Nucleated cells is performed of each sample using the standard hemacytometer chamber counting method.

Summary of linear regression comparisons of all specimens iQ Body Fluids Module and manual counts concentration results showing very high R^2 values, slopes close to 1 and non-zero intercept values that are not statistically significant.

Table 15.7 Linear Regression Comparisons of All Specimens - iQ and Manual Counts

Cell	Number of Samples	R^2	Regr. Sig.	Slope	Slope 95% Confidence Interval	Intercept	Intercept Significance
RBC	304[2]	0.992	0.000	0.906	0.896 to 0.915	671.90	0.110
Nucleated Cells	299[3]	0.967	0.000	1.015	0.993 to 1.037	18.06	0.163

[2] 4 outliers have been removed increasing R^2 from 0.973 to 0.992

[3] 9 outliers have been removed increasing R^2 from 0.940 to 0.967

Summary of linear regression comparisons of CSF iQ Body Fluids Module and manual counts concentration results showing very high R^2 values, slopes close to 1 and non-zero intercept values that are not statistically significant.

Table 15.8 Linear Regression Comparisons of CSF - iQ and Manual Counts

Cell	Number of Samples	R^2	Regr. Sig.	Slope	Slope 95% Confidence Interval	Intercept	Intercept Significance
RBC	151	0.992	0.000	0.895	0.882 to 0.908	1217.91	0.091
Nucleated Cells	149[4]	0.990	0.0000	1.016	1.000 to 1.033	9.21	0.046

Summary of linear regression comparisons of Serous iQ Body Fluids Module and manual counts concentration results showing very high R^2 values, slopes close to 1 and non-zero intercept values that are not statistically significant.

Table 15.9 Linear Regression Comparisons of Serous - iQ and Manual Counts

Cell	Number of Samples	R^2	Regr. Sig.	Slope	Slope 95% Confidence Interval	Intercept	Intercept Significance
RBC	154[5]	0.985	0.000	0.875	0.858 to 0.8/92	876.10	0.194
Nucleated Cells	149[6]	0.960	0.000	1.014	0.980 to 1.048	33.15	0.220

The regression correlation coefficient (R^2) indicated above in bold are all above 0.967 indicating that the concentration reported by the iQ Body Fluids Module for CSF and Serous fluids RBC and Nucleated cells agree very well with the manual estimation using the standard hemacytometer chamber count.

The slope of the linear regression between the iQ Body Fluids Module and the manual estimation for RBC and Nucleated cells are all close to the ideal value of 1. The linear regression Intercept values are not statistically significant except for the CSF Nucleated cells.

Thus, in general, concentrations reported by the iQ Body Fluids Module based on expert identification of particulate images for both CSF and Serous fluids agree very well with those determined by the counting chamber reference method. Accuracy of the DxU Microscopy Series Body Fluids Module is therefore substantially equivalent to the counting chamber method.

[4] 2 outliers have been removed increasing R^2 from 0.948 to 0.990

[5] 3 outliers have been removed increasing R^2 from 0.965 to 0.985

[6] 8 outliers have been removed increasing R^2 from 0.935 to 0.960

Summary of paired t-test comparisons of all specimens iQ Body Fluids Module and manual counts concentration results showing that there is no statistical difference between results obtained from each of the two replicates.

Table 15.10 t-test Comparisons of All Specimens - iQ and Manual Counts

Cell	Number of Samples	t-value	Significance	pmean
RBC	257	0.890	0.374	791.75
Nucleated Cells	257	1.321	0.188	29.24

Summary of paired t-test comparisons of CSF iQ Body Fluids Module and manual counts concentration results showing that there is no statistical difference between results obtained from each of the two replicates.

Table 15.11 t-test Comparisons of CSF - iQ and Manual Counts

Cell	Number of Samples	t-value	Significance	pmean
RBC	107	1.358	0.177	1503.27
Nucleated Cells	107	0.289	0.773	6.03

Summary of paired t-test comparisons of Serous iQ Body Fluids Module and manual counts concentration results showing that there is no statistical difference between results obtained from each of the two replicates.

Table 15.12 t-test Comparisons of Serous - iQ and Manual Counts

Cell	Number of Samples	t-value	Significance	pmean
RBC	150	0.218	0.828	284.2
Nucleated Cells	150	1.313	0.191	45.80

The sample-to-sample repeatability analysis above shows no statistically significant difference between RBC and nucleated cells concentrations determined by the iQ Body Fluids Module from

each of the replicates. All significance results are above the usual minimum significance levels of 0.05, 0.025 and 0.01.

The iQ Body Fluids Module demonstrates a very good analytical sample-to-sample repeatability for reporting RBC and nucleated cells in both CSF and serous fluids.

Linearity Range for Synovial Fluids

To demonstrate that iQ BF Module for Synovial Fluids reports linear counts estimates of specimens, a study was conducted following the CLSI EP6A protocol.

Freshly drawn blood is diluted with synovial fluid to create an evenly distributed sequence of seven (7) pool dilutions ranging from 0/µL to 83,500/µL for RBC to 61,125/µL for Nucleated Cells. Two (2) replicates for each pool dilutions are processed independently.

Summary of the NCCLS EP6A linearity analysis for blood dilutions in synovial fluid in the range of 0 to 83,500/µL for RBC showing that the higher order coefficients of the quadratic and cubic fit are not statistically significant.

Table 15.13 Linearity Analysis for Blood Dilutions in Synovial Fluid in the 0 to 83,500/µL Range

Parameters	Linear	Quadratic	Cubic
Intercept	1115.21	67	-607.2
Intercept Significance	0.41835	0.9679	0.7337
Slope	1.0123	1.096	1.2804
Slope Significance	<0.0001	<0.0001	<0.0003
Quadratic		-1.023 E^{-06}	-7.04 E^{-06}
Quadratic Significance		0.3320	0.2742
Cubic			4.82 E^{-11}
Cubic Significance			0.3370

Summary of the NCCLS EP6A linearity analysis for blood dilutions in synovial fluid in the range of 0 to 61,125/µL for Nucleated Cells showing that the higher order coefficients of the quadratic and cubic fit are not statistically significant.

Table 15.14 Linearity Analysis for Blood Dilutions in Synovial Fluid in the 0 to 61,125/µL Range

Parameters	Linear	Quadratic	Cubic
Intercept	305.14	-314.39	-326.25
Intercept Significance	0.7064	0.7574	0.8506
Slope	1.0302	1.0977	1.0685
Slope Significance	<0.0001	<0.0001	<0.0008
Quadratic		-1.115 E^{-06}	2.016 E^{-07}
Quadratic Significance		0.3448	0.9801

Table 15.14 Linearity Analysis for Blood Dilutions in Synovial Fluid in the 0 to 61,125/µL Range *(Continued)*

Parameters	Linear	Quadratic	Cubic
Cubic			-1.425 E $^{-11}$
Cubic Significance			0.8703

Table 15.13, Linearity Analysis for Blood Dilutions in Synovial Fluid in the 0 to 83,500/µL Range and Table 15.14, Linearity Analysis for Blood Dilutions in Synovial Fluid in the 0 to 61,125/µL Range demonstrate that the only parameter significant in the linear, quadratic, and cubic regressions is the slope parameter whose significance is always well below 0.05, indicating that the iQ BF Synovial Fluids Module estimates particulate concentrations linearly in the 0 to 83,500/µL for RBC and 0 to 61,125/µL for Nucleated Cells.

Concentration Agreement for Synovial Fluids

Sample-to-Sample results of red blood cell (RBC) and nucleated cell counts determined from expert identification of analyte images obtained from the DxU Microscopy Series were compared with those from hemacytometer (counting chamber) analysis, the predicate method. The comparison demonstrated equivalent analytical performance of the DxU Microscopy Series Body Fluids Module Synovial Fluid with the hemacytometer predicate method.

Individual analyte concentration, based on the hemacytometer method was determined. This determination was initially based on the average concentrations for two (2) aliquots from each specimen. In this way, the iQ Body Fluids Module with Synovial Fluid human edit method is compared to the predicate method. The duplicate analyses, described as Run #1 and Run #2, were compared to each other to first determine the reproducibility of the proposed device and the reference method.

The objective of the iQ Body Fluids Module with Synovial Fluid correlation study is to demonstrate that the RBC, and the combined WBC and other nucleated cell concentrations determined by the iQ Body Fluids Module with Synovial Fluid method are equivalent to those determined from the hemacytometer manual method. Equivalence is defined as statistically equivalent or better accuracy and precision. Two (2) aliquots from each specimen were analyzed by each method – provided there was sufficient specimen volume.

Summary of the Deming regression comparison between iQ Synovial Fluids Module (Run #1) and the average of the two manual counts concentration results showing **high R^2 values, slopes close to 1 and non-zero intercept values that are not statistically significant.**

Table 15.15 Summary of the Deming Regression Comparison Between iQ and Manual Counts Average

Cell	Number of Samples	R^2	Intercept	P-Value	Slope	P-Value
RBC	55	0.9909	9.15	0.9916	0.9972	< 0.0001
NUCL	55	0.9794	-79.08	0.8299	0.9435	< 0.0001

The regression correlation coefficient R^2 are all above 0.97 indicating that the concentration reported by the iQ BF Synovial Fluids Module and the standard hemacytometer chamber count for

RBC and Nucleated Cells (NUCL) are close to the ideal value of 1. The linear regression intercept values are not statistically significant.

Thus, concentration reported by the iQ BF Synovial Fluids Module based on expert identification of particulate images for Synovial Fluids agree very well with those determined by the counting chamber reference method. Accuracy of the iQ BF Synovial Fluids Module is therefore substantially equivalent to the counting chamber method.

CHAPTER 16

Auto-Release (Edit-Free Release)

Auto-Release (Edit-Free Release Settings)

NOTE Only a manager can enter or modify the user-defined settings. Any operator can view the settings.

The Auto-Release screen allows the operator to automatically release results obtained by the software and the APR without human intervention according to user-defined parameters. Results are released according to the destination setup. See Release Settings in CHAPTER 9, Setup.

User-defined criteria for specific demographic locations and age ranges can be entered according to the laboratory specific parameters.

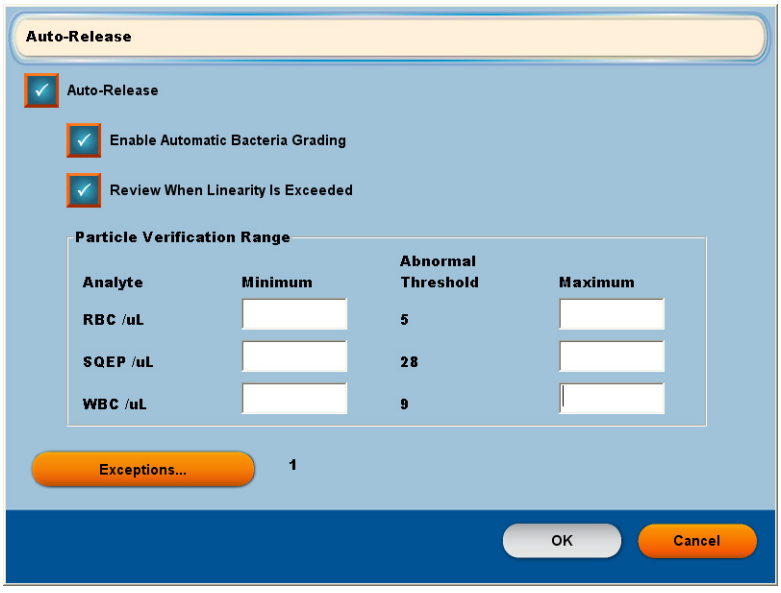
If a specimen results matches **any** criteria from the Auto-Release or any Exception screen, that specimen will be displayed on the Work List for review.

NOTE Auto-Release is an integral part of the Edit-Free Release.

Access/Enable Auto-Release Screen

1 To access the Auto-Release screen, see Accessing a Setup Screen in CHAPTER 9, Setup.

2 To enable the Auto-Release of results, select the **Auto-Release** checkbox.



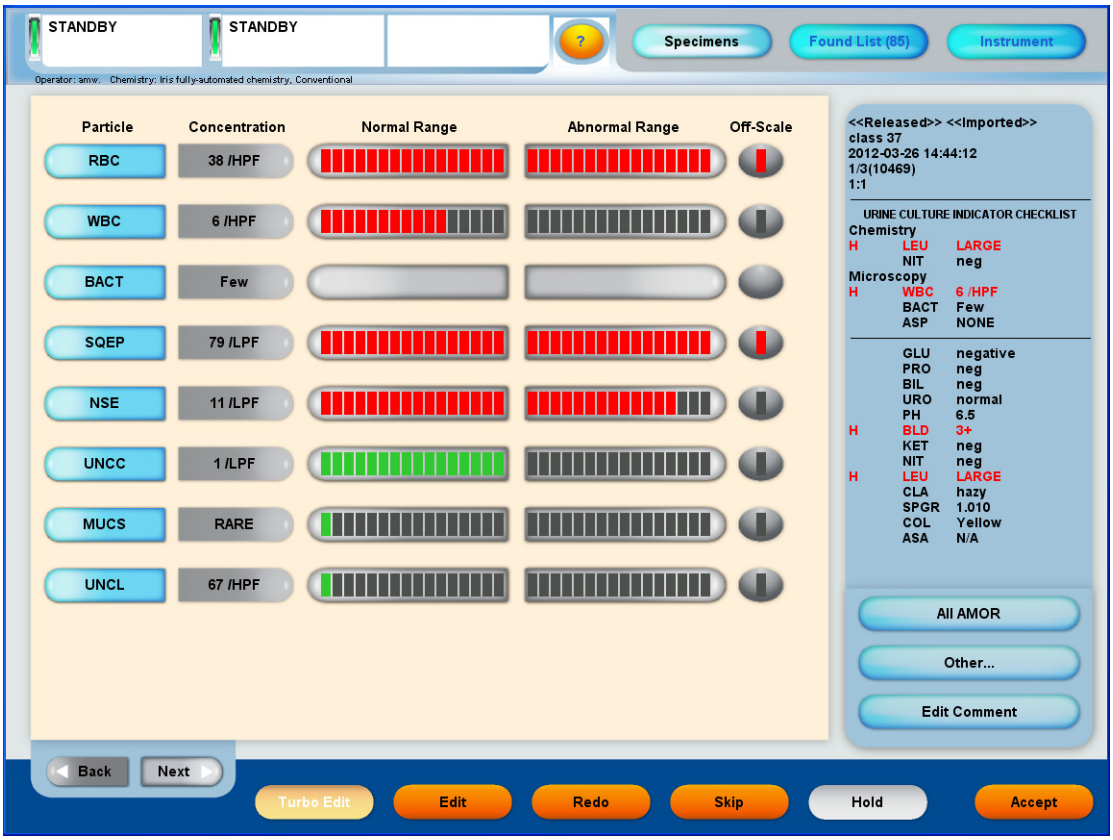
Enable Automatic Bacteria Grading

With the Enable Automatic Bacteria Grading option, you do not have to hold results for on-screen verification based on the bacteria concentration.

1 Enable the **Autorelease** checkbox, and enter the minimum and maximum values for the particle verification ranges for RBCs, SQEPs, and WBCs.

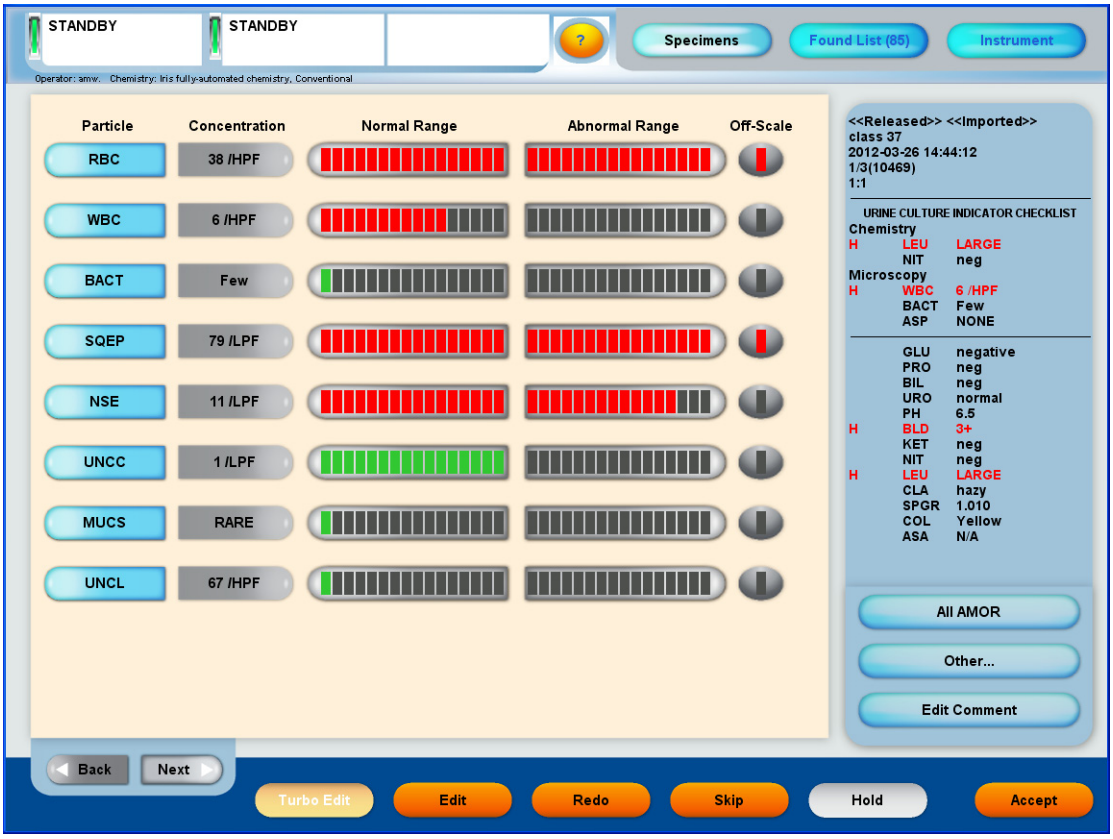
2 Check the **Enable Automatic Bacteria Grading** checkbox to enable this function; the default setup is enabled. When **Enable Automatic Bacteria Grading** is enabled, *Urine Culture Recommended* appears on the Result screen if any urine culture candidate indicator is abnormal.

When this box is checked, the range indicators are displayed as gray as shown in the following screen.



3 Deselect the **Enable Automatic Bacteria Grading** checkbox to disable this function.

When this box is not selected, the particle's name button for Bacteria is displayed in blue, the range indicators are displayed in green or red depending on the user-defined settings as shown in the screen below.



Review When Linearity is Exceeded

The DxU Microscopy Series linearity ranges for the Formed Particles are the following:

- 0-182/HPF (high power field)
- 0-2900/LPF (low power field)
- 0-1000/µL (microliter)

If this box is checked, the range indicator for the particle is displayed in yellow, indicating that the operator needs to review the results. An exception to this is UNCL.

Particle Verification Range

The Particle Verification Range defines the range of values that cannot be auto-released and must be verified by the operator. The range extends above and below the clinically decision point. The minimum and maximum values on either side of the abnormal threshold represent a confidence

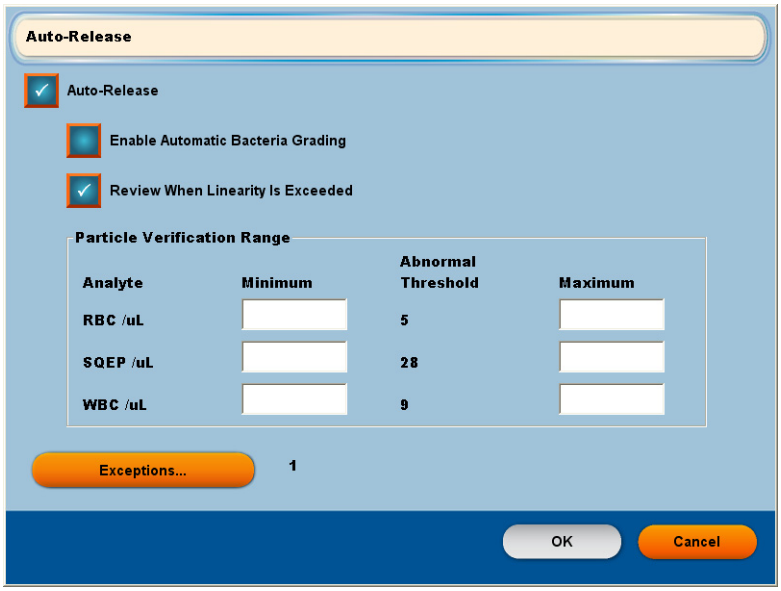
interval based on statistical analysis of study data. This function minimizes the on-screen verification using an intuitive method for verification of particle classification.

NOTE A study must be performed by the laboratory to define their specific minimum and maximum values for the particle verification range.

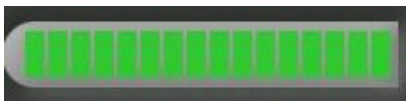
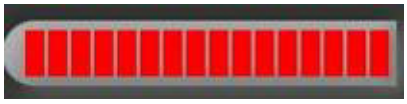
If results are expresses as a range (example: 6-10/HPF), enter a minimum value for the particle verification range that is one range lower than the range required.

Only a manager can enter a user-defined range for the specified particles. The range is based on the abnormal threshold for the particles (RBC, SQEP, and WBC). The Abnormal Threshold is auto-populated from the particle specific settings. See Formed Particles Settings in CHAPTER 9, Setup.

Figure 16.1 Auto-Release Screen - Range for Specified Particles

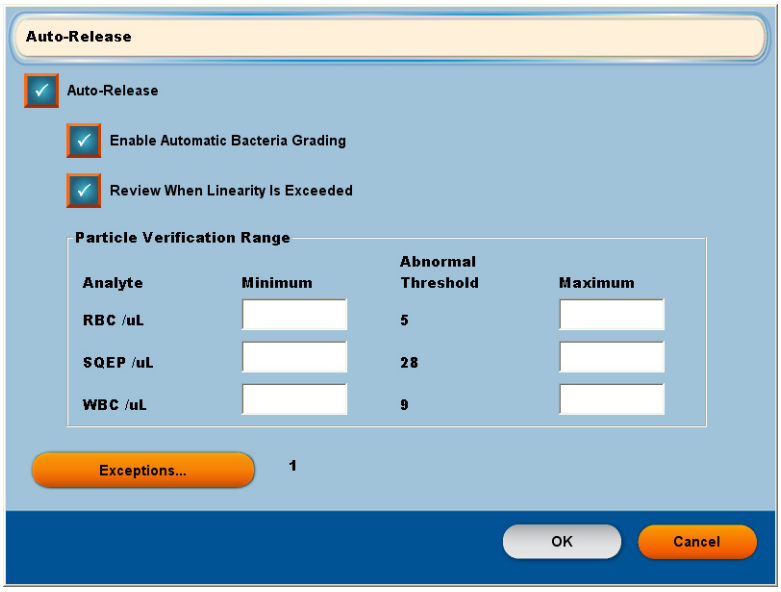


Results will be displayed as follows in the range indicator(s):

Color indicator	Meaning
	Results are below the minimum verification value, and are accepted as normal.
	Results are within the particle verification range, and need to be reviewed by the operator.
	Results are above the maximum verification value, and are accepted as abnormal.

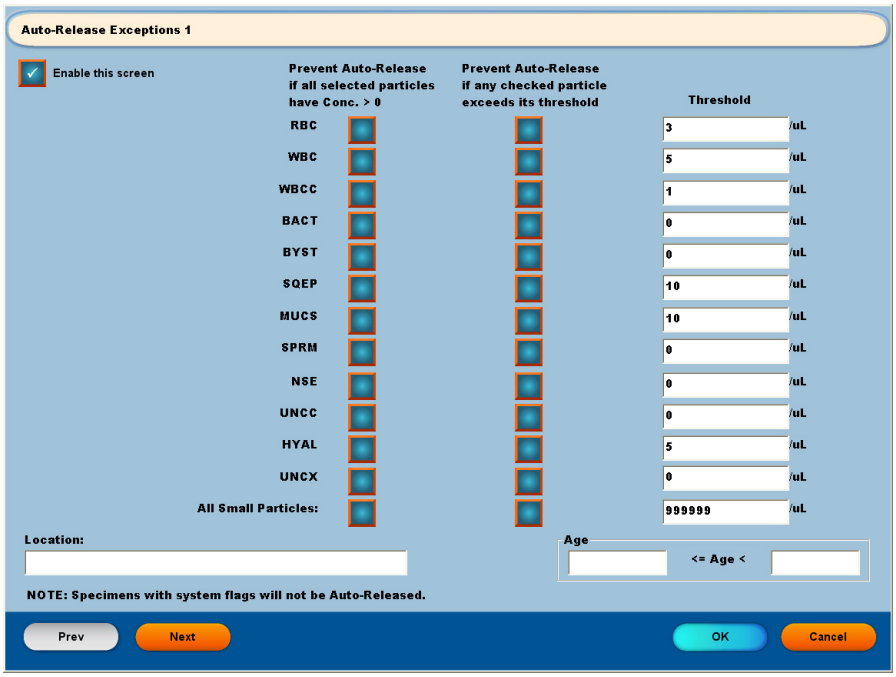
Exceptions

Figure 16.2 Auto-Release Screen - Exceptions



Selecting **Exceptions** can access up to ten (10) Auto-Release. Exceptions are user-defined screens according to a specific location and age range. Each screen is numbered from 1 to 10, and the number located next to **Exceptions** on the Auto-Release screen indicates the number of Auto-Release Exceptions screens enabled.

Figure 16.3 Auto-Release Screen Exceptions: 1



NOTE When entering the specific location, make sure to use the same terminology and spelling as used by the LIS. Location and age fields are optional.

1 Select the **Enable this screen** checkbox. The auto-release criteria for each particle category will be displayed.

2 Enter the specific location in the *Location* field.

3 Enter the Age range for the specific location in the <= (less than or equal to) and < (less than) fields. The age should be entered in decimal units; for example 2 years and 3 months, should be 2.25; 2 years and 6 months should be 2.50.

4 Select the **Prevent Auto-Release** criteria for the specific location and age range:

- First column: select the checkboxes that will disable auto-release if the concentration result is above 0 for ALL the specific categories checked.
- Second column: select the checkboxes that will disable auto-release if the result is above the threshold (entered in column 3) for one or more of the categories checked.
- Third column: available when the particle box is checked in the second column. To change the threshold, select the box to highlight the value and enter the specific threshold desired for the particle. The fields in the third column can be edited and saved even if the second column is unchecked.

5 To enter another Auto-Release Criteria, select **Next**. Repeat steps 2 to 4.

6 To review the previous Auto-Release Criteria, select **Prev**.

7 When all Auto-Release Exception Criteria have been entered, select **OK**.

If a specimen presents multiple auto-release criteria and **any** of the enabled screens' criteria would keep the specimen from being released, the results for this specimen will not be auto-released.

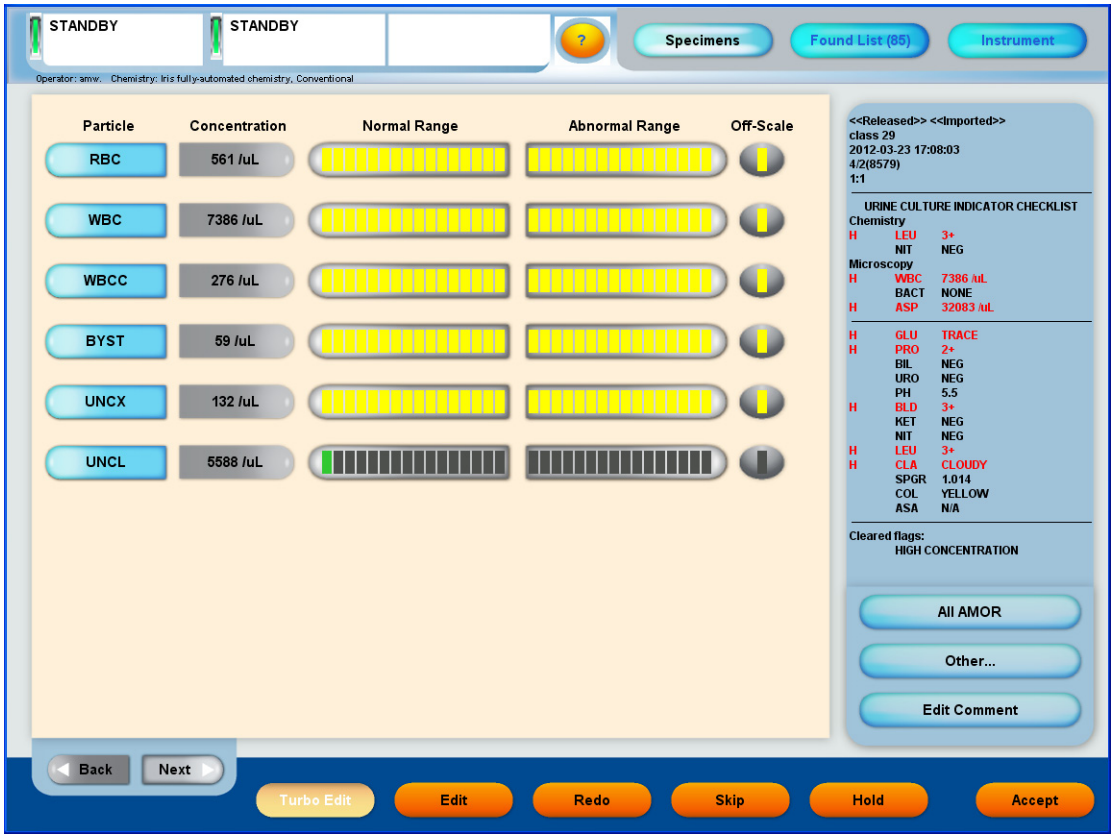
NOTE Specimens with system flags will not be Auto-Released. If specimen results for All Small Particles are above the specified threshold, the ASP count will be displayed in red on the Specimen screen. Any particle not checked will not be considered in the auto release of the specimen.

Auto-Released Results

Yellow range indicators apply only if the Auto-Release feature is enabled. See Access/Enable Auto-Release Screen.

On the Results screen, particles to review are indicated by their indicator range(s) displayed in yellow.

Figure 16.4 Auto-Released Results - Particles to Review



Single-Class Abnormal Range

Particles subject to the single-class abnormal range criteria are:

- HYAL
- BYST
- SPRM
- MUCS
- UNCX

The abnormal range auto-release criteria checks for a particle at or above its abnormal range. Results at or above the abnormal range are displayed in yellow.

Two-Class Abnormal Range

Particles subject to the two-class abnormal range criteria are (primary/secondary classes).

NSE/UNCL - UNCC/UNCL

The abnormal range auto-release criteria checks for a particle at or above its abnormal range. Results at or above abnormal for the primary class are displayed in yellow. If results are available for the secondary class, they are also displayed in yellow.

WBC/WBCC

If WBCC results are at or above abnormal threshold and WBC results are zero, none or no results, WBCC are displayed in yellow.

Amorphous Flag

This function is performed automatically. The amorphous flag criteria checks if the sample results have the Possible Amorphous flag. If the Possible Amorphous flag is present, all auto-classified particles with abnormal levels are displayed in yellow. The option *Automatically Clear "Possible Amorphous" Flag* must not be selected. See Specimen Settings in CHAPTER 9, Setup.

Linearity Exceeded

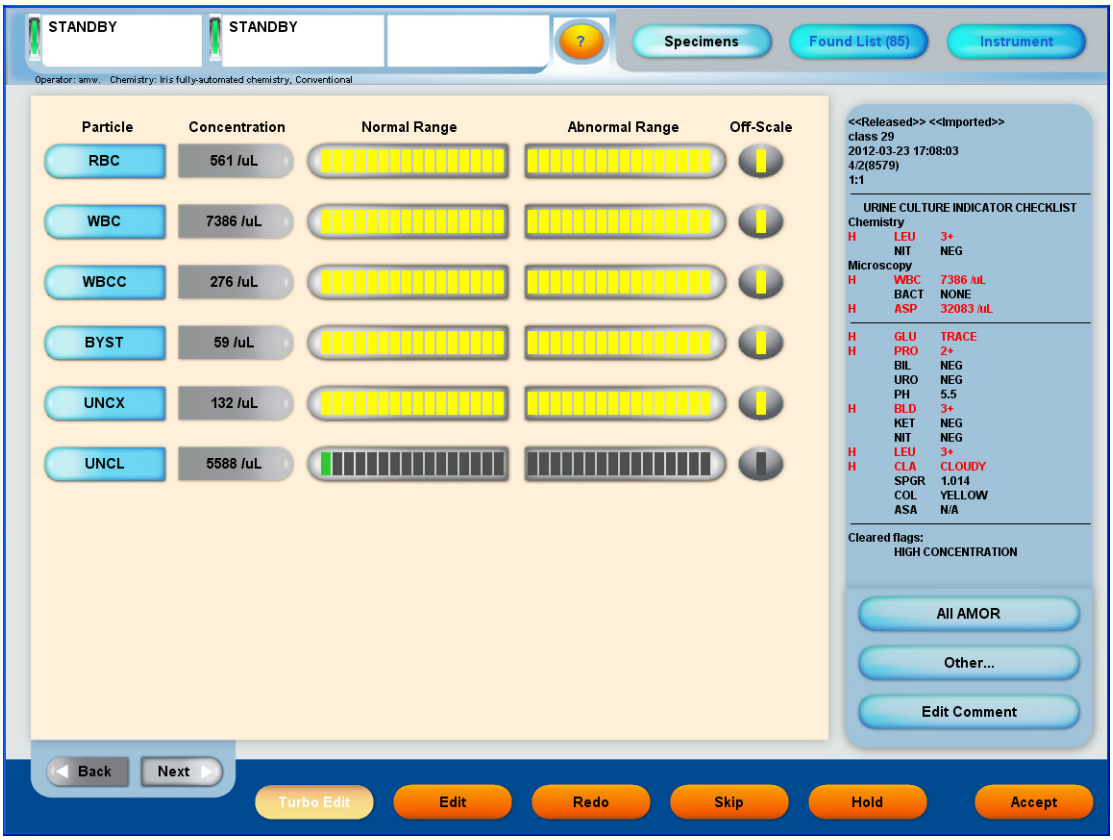
If the **Review When Linearity is Exceeded** checkbox is selected, any auto-classified particle exceeding 1000/µL, 182/HPF, or 2900/LPF is displayed in yellow.

The linearity check compares the RBC and WBC results to the linearity. If the RBC result is greater than the linearity and the WBC result is not, the WBC range indicator is displayed in yellow. If the WBC result is greater than the linearity and the RBC result is not, the RBC range indicator is displayed in yellow.

Editing a Specimen with Yellow Range Indicator

1 To display the Work List, select **Work List** located on the top right part of the screen. The Work List screen is displayed.

2 To review a specimen, double-click the specimen row on the Work List, or select the row and select **Specimens.** The Specimens screen is displayed.



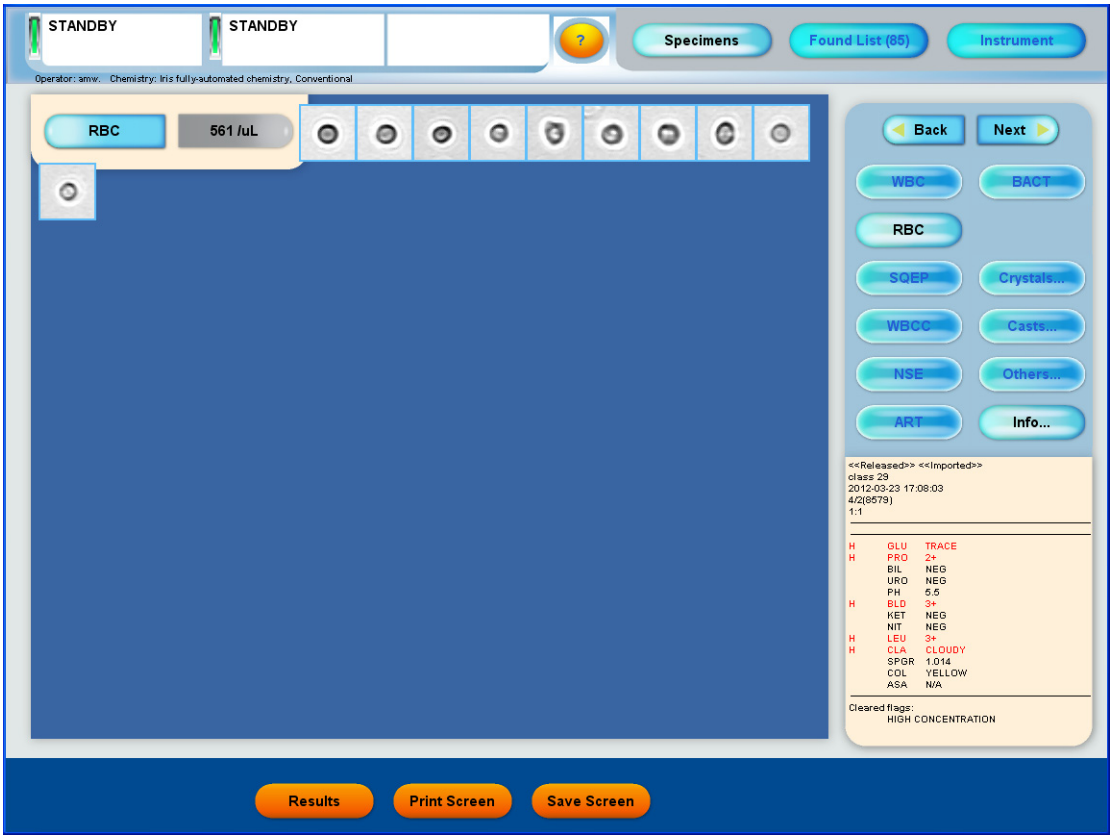
Full Edit Button

When the Auto-Release function is enabled, Beckman Coulter recommends reviewing the results using the *Full Edit* mode.

Changing the Edit mode (Turbo to Full) recalculates the application of Yellow.

Edit Button

1 Select **Edit** to review images for the first yellow particle category displayed in the Results screen.



2 To display the previous or next yellow particle, select ◄**Back** or **Next** ►. If there is no previous or next yellow particle, the Results screen is displayed.

NOTE When images for a yellow range have been accessed, the particle range indicator is no longer yellow.

3 To access a non-yellow particle category, from the Results screen, select the particle's name button.

Redo Button

Select **Redo** to restore the particle classifications to the instrument classifications, including yellow range indicator.

Skip Button

Select **Skip** to display the next specimen on the Work List/Found List.

Hold Button

The **Hold** button is enabled when an edit has been made by the operator. Select **Hold** to save all edits made to this specimen. The operator can then exit the specimen screen without losing their edits or accepting the results.

Before leaving the Specimen screen, select **Hold**.

Accept Button

Table 16.1 Specimen - Accept

If...	Select Accept to...
The specimen was flagged and the **Review Flag Specimen** button was used	Assign the new identifier to the specimen if it had the ID flag Clear the specimen's flags and display the next specimen on the Work List
The specimen was flagged and the **Delete Flagged Specimen** button was used	Delete the specimen and display the next specimen on the Work List
The specimen was not flagged	Release the specimen results with any changes made and display the next specimen on the Work List
The specimen was selected for separation of chemistry and microscopy results	Separate the specimen results Release the chemistry results to the printer and the LIS Display the released chemistry result on the Work List Place the microscopy results on the Work List pending review

When a specimen has been accepted, the yellow particle range indicators no longer apply.

Edit-Free Release Optimization

Edit-Free Release involved optimizing settings for the following screens:

- Specimen
- Abnormal Thresholds
- Auto-Release
- Urine Auto-Classify

CHAPTER 17

Consumables Traceability

Consumables Information

This feature allows you to keep track of the system consumables and to verify when a specific lot was in use by the system. This function provides usage tracking for the following consumables:

Table 17.1 Consumables Information

Instrument	Material	Data Entry
DxU Microscopy Series		
REF Calibration	iQ Calibrator	Barcode label
Urine Microscopy Controls	Auto-Focus	Barcode label
	Primary Positive	Barcode label
	Primary Negative	Barcode label
	Secondary Positive	Barcode label
	Secondary Negative	Barcode label
Diluent	Iris Diluent	Manual
Cleanser	Iris System Cleanser	Manual
Lamina	Lamina	Manual
Body Fluid Background Check	Iris Diluent	Manual
	Lysing Reagent	Manual
Body Fluids Controls	Background Control	Barcode label
Samples	Iris Diluent	Manual
	Lysing Reagent	Manual
Chemistry		
DxU 810c Iris		
Calibration	CalChek Strips	Barcode label
	CalChek Liquid Reagents	
Urine Chemistry Controls	IRISpec CA	Manual
	IRISpec CB	Manual
	IRISpec CC	Manual
iChem Wash Solution	Wash Solution	Manual
DxU 810c Iris Urine Chemistry Strips	Chemistry Test Strips	Manual

Consumables tracking data are stored in the system for patient specimens currently stored or up to 18 months, whichever is greater. In order for the system to purge consumables tracking data, the

related patient data must be purged from the database. The system maintains 10,000 patient results in the database.

Entering Consumables Data

There are two ways for the consumables data to be entered in the system: automatically using barcode labels or manual entry. See Consumables Information.

In many cases, the consumables are run in barcoded tubes on special racks. Via the barcode reader, the information contained in the barcode label is transmitted to the system and entered automatically in the Consumables Traceability function.

When barcode labels are not available for the consumable, the information needs to be manually entered the system. Data for chemistry test strips and quality control material are entered using the Chemistry QC option. All the other consumables data are entered using the Traceability option.

1 To access the Consumables menu, select **Instrument** on the top right side of the main screen.

2 Select **Go Off line**. A Confirm window pops up (with warnings).

3 Select **Yes**.

4 Select **Consumables** located at the bottom of the Instrument screen. The Consumables window is displayed.

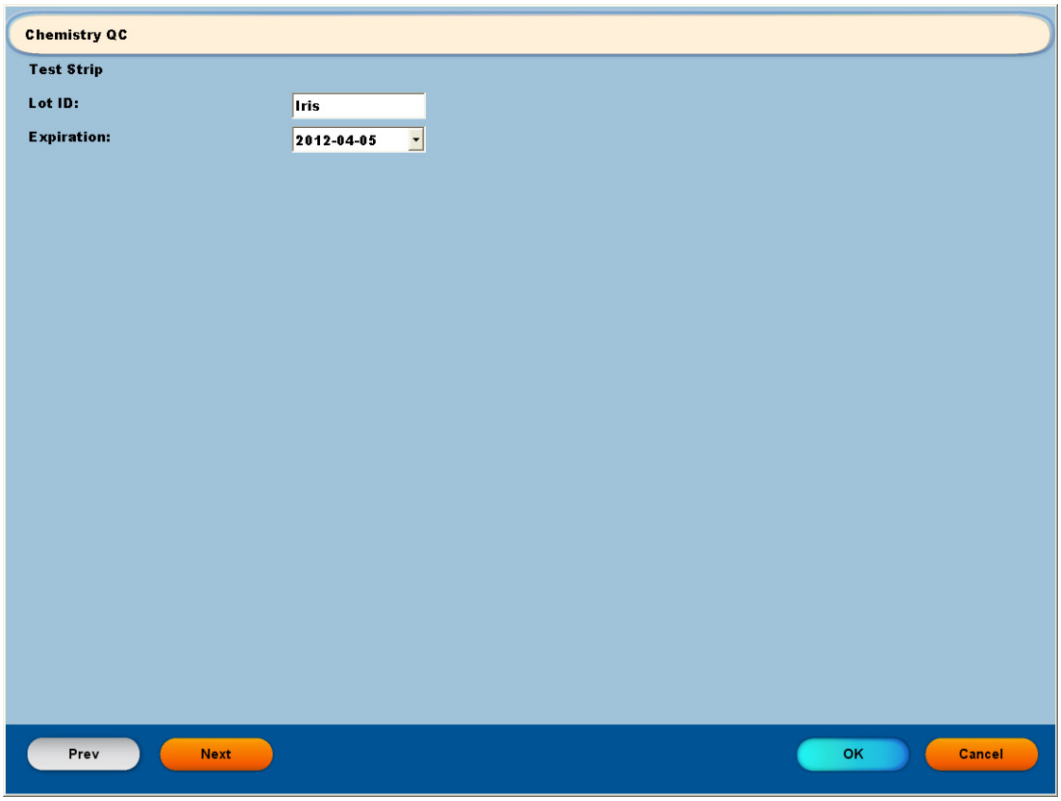
Chemistry QC Consumables

NOTE Whenever a change is made to the lot ID/expiration date for the chemistry strips, the Primary or Backup settings should be saved again in order to be up to date when switching the Chemistry Instrument. See Enter Primary Chemistry Settings in CHAPTER 9, Setup.

The Chemistry QC screens allow any operator to enter strip lot information and chemistry QC such as name, lot ID, Expiration date, and lower and upper limit for each analyte.

1 From the Consumables windows, select **Chemistry QC**.

2 On the first Chemistry QC screen, enter the lot ID and expiration date for the chemistry test strips.



3 To access the first chemistry control level, select **Next**.

4 Enter the name of the control material, lot ID, and expiration date. Select the lower and upper limits for each analyte listed.

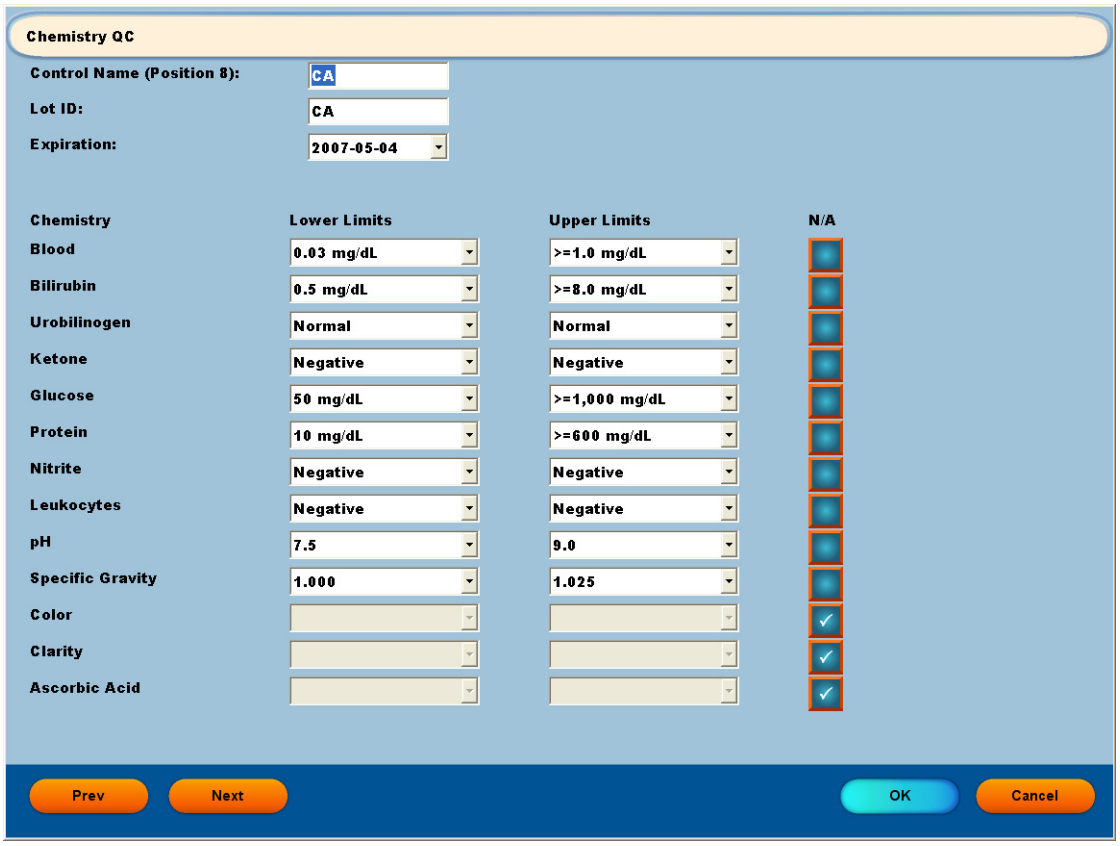
NOTE The lower and upper limits can be selected by using the drop-down options only.

Color, Clarity, and Ascorbic Acid are not applicable for CA and CB. Ascorbic Acid is applicable for CC.

5 To access the next control level, select **Next**.

6 Repeat the process for the second control, using **Next**.

7 Enter the acceptable range for each analyte for that control.



8 To access the next control level, select **Next**.

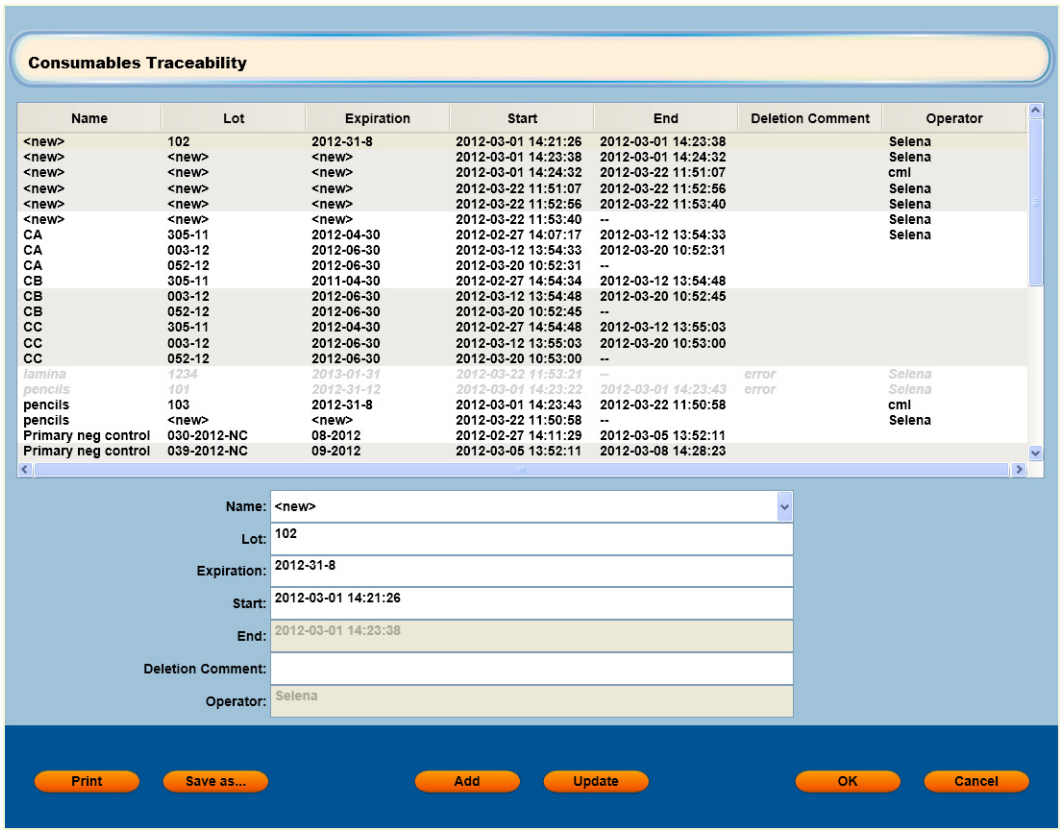
9 After setting up all the control levels, select **OK** to return to the Consumables window.

Consumables Traceability Screen

From the Consumables windows, select **Traceability**. The Consumables Traceability screen is displayed.

The Consumables Traceability screen can also be accessed using the Search screen. See Consumables Search.

Figure 17.1 Consumables Traceability Screen



Print Button

Select this button to print the consumables list. See Consumables Report.

Save As Button

Select this button to display a Save As window. By default the destination is Reports, and the file name is Consumables Traceability current date/time.

Another destination and file name can be selected. The file is saved in htm format.

Add Button

Select this button to add a new consumable. See Adding a New Consumable for more information.

Update Button

Select this button to edit a consumable. See Editing a Consumable for more information. In case of additions or deletions, the end dates are automatically recalculated.

OK Button

Select this button to validate any entry or change from the list and return to the Consumables window.

Cancel Button

Select this button to cancel any entry or change from the list and return to the Consumables window.

Adding a New Consumable

1 From the Consumables Traceability window, select **Add**.

2 Complete the following fields:

- Name
- Lot: Lot number
- Expiration: See Consumables Information
- Start: Filled automatically with the current date/time

3 Select **OK** to return to the Consumables window.

Editing a Consumable

1 From the Consumables Traceability window, select the consumable to edit.

2 Edit the fields, as needed.

3 Select **Update**.

4 Select **OK** to return to the Consumables window.

Deleting a Consumable

1 From the Consumables Traceability window, select the consumable to delete.

2 Enter a comment in the *Deletion Comment* field.

The consumable is not removed from the list, but it will no longer be part of the date/time sequence.

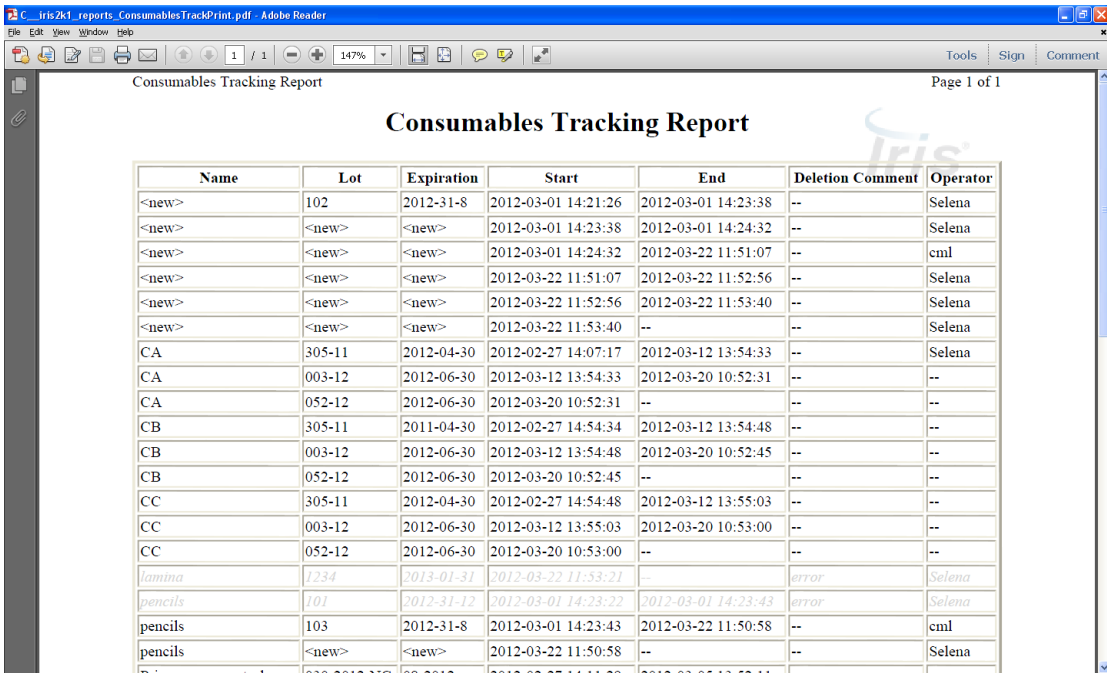
3 Select **OK** to return to the Consumables window.

Consumables Report

1 From the Consumables Traceability window, select **Print**. The Consumables Traceability report will be printed.

2 Select **OK** to return to the Consumables window.

Below is an example of a Consumables Traceability report.



Consumables Tracking Report

Name	Lot	Expiration	Start	End	Deletion Comment	Operator
<new>	102	2012-31-8	2012-03-01 14:21:26	2012-03-01 14:23:38	--	Selena
<new>	<new>	<new>	2012-03-01 14:23:38	2012-03-01 14:24:32	--	Selena
<new>	<new>	<new>	2012-03-01 14:24:32	2012-03-22 11:51:07	--	cml
<new>	<new>	<new>	2012-03-22 11:51:07	2012-03-22 11:52:56	--	Selena
<new>	<new>	<new>	2012-03-22 11:52:56	2012-03-22 11:53:40	--	Selena
<new>	<new>	<new>	2012-03-22 11:53:40	--	--	Selena
CA	305-11	2012-04-30	2012-02-27 14:07:17	2012-03-12 13:54:33	--	Selena
CA	003-12	2012-06-30	2012-03-12 13:54:33	2012-03-20 10:52:31	--	--
CA	052-12	2012-06-30	2012-03-20 10:52:31	--	--	--
CB	305-11	2011-04-30	2012-02-27 14:54:34	2012-03-12 13:54:48	--	--
CB	003-12	2012-06-30	2012-03-12 13:54:48	2012-03-20 10:52:45	--	--
CB	052-12	2012-06-30	2012-03-20 10:52:45	--	--	--
CC	305-11	2012-04-30	2012-02-27 14:54:48	2012-03-12 13:55:03	--	--
CC	003-12	2012-06-30	2012-03-12 13:55:03	2012-03-20 10:53:00	--	--
CC	052-12	2012-06-30	2012-03-20 10:53:00	--	--	--
lamina	*1234*	*2013-01-31*	*2012-03-22 11:53:21*	--	*error*	*Selena*
pencils	*101*	*2012-31-12*	*2012-03-01 14:23:22*	*2012-03-01 14:23:43*	*error*	*Selena*
pencils	103	2012-31-8	2012-03-01 14:23:43	2012-03-22 11:50:58	--	cml
pencils	<new>	<new>	2012-03-22 11:50:58	--	--	Selena

Alarms

Alarm #46

CAUSES	REMEDIES
This alarm was triggered because the primary positive control material is expired.	This condition should be remedied by running a control rack with a new primary positive control material.

Alarm #47

CAUSES	REMEDIES
This alarm was triggered because the primary negative control material is expired.	This condition should be remedied by running a control rack with a new primary negative control material.

Alarm #48

CAUSES	REMEDIES
This alarm was triggered because body fluid level I control material is expired.	This condition should be remedied by running a control rack with a new body fluid level I control material.

Alarm #49

CAUSES	REMEDIES
This alarm was triggered because body fluid level II control material is expired.	This condition should be remedied by running a control rack with a new body fluid level II control material.

Alarm #53

CAUSES	REMEDIES
This alarm was triggered because Calibrator material is expired.	This condition should be remedied by running a control rack with a new Calibrator material.

Alarm #55

CAUSES	REMEDIES
This alarm was triggered because the primary positive control material is expired.	This condition must be remedied for the instrument to run more specimens. Run a control rack with a new positive control material or Check the **Expired Consumable Lockout Override** checkbox in the QC setting window.

Alarm #56

CAUSES	REMEDIES
This alarm was triggered because the primary negative control material is expired.	This condition must be remedied for the instrument to run more specimens. Run a control rack with a new negative control material or Check the **Expired Consumable Lockout Override** checkbox in the QC setting window.

Alarm #57

CAUSES	REMEDIES
This alarm was triggered because the body fluid level I control material is expired.	This condition must be remedied for the instrument to run more specimens. Run a control rack with a new body fluid level I control material or Check the **Expired Consumable Lockout Override** checkbox in the QC setting window.

Alarm #58

CAUSES	REMEDIES
This alarm was triggered because body fluid level II control material is expired.	This condition must be remedied for the instrument to run more specimens. Run a control rack with a new body fluid level II control material or Check the **Expired Consumable Lockout Override** checkbox in the QC setting window.

Alarm #62

CAUSES	REMEDIES
This alarm was triggered because the Calibrator material is expired.	This condition must be remedied for the instrument to run more specimens. Run a control rack with a new Calibrator material or Check the **Expired Consumable Lockout Override** checkbox in the QC setting window.

Alarm #64

CAUSES	REMEDIES
This alarm was triggered because the auto focus material is expired.	This condition must be remedied for the instrument to run more specimens. Run a control rack with a new auto focus material.

Alarm #65

CAUSES	REMEDIES
This alarm was triggered because the auto focus material is expired.	This condition must be remedied for the instrument to run more specimens. Run a control rack with a new auto focus material or Check the **Expired Consumable Lockout Override** checkbox in the QC setting window.

Use of Expired Material

The software compares the expiration date of Quality Control/Calibration material and chemistry strip against current instrument date/time, to verify that the material or chemistry strips are not expired.

Below is an example of a red alarm for use of expired quality control material

Figure 17.2 Red Alarm for Use of Expired Quality Control Material - Example

Quality Control/Calibration Material

If expired QC or calibration material was used, a comment is added next to the run results status in the Quality Review screen and the affected Quality Control or Calibration reports indicating that expired Quality Control/Calibration material was used.

A red alarm is raised to prevent running a sample being on the instrument until a manager overrides the lockout.

Figure 17.3 Quality Review Screen

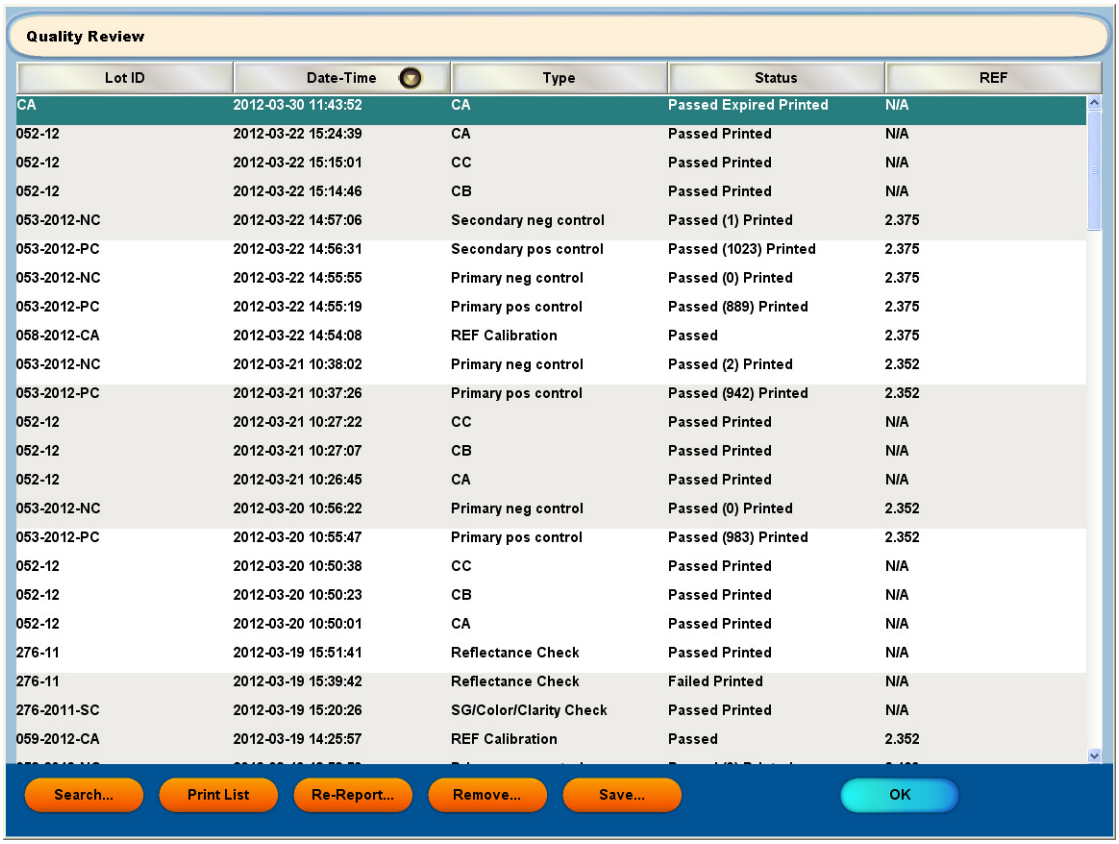
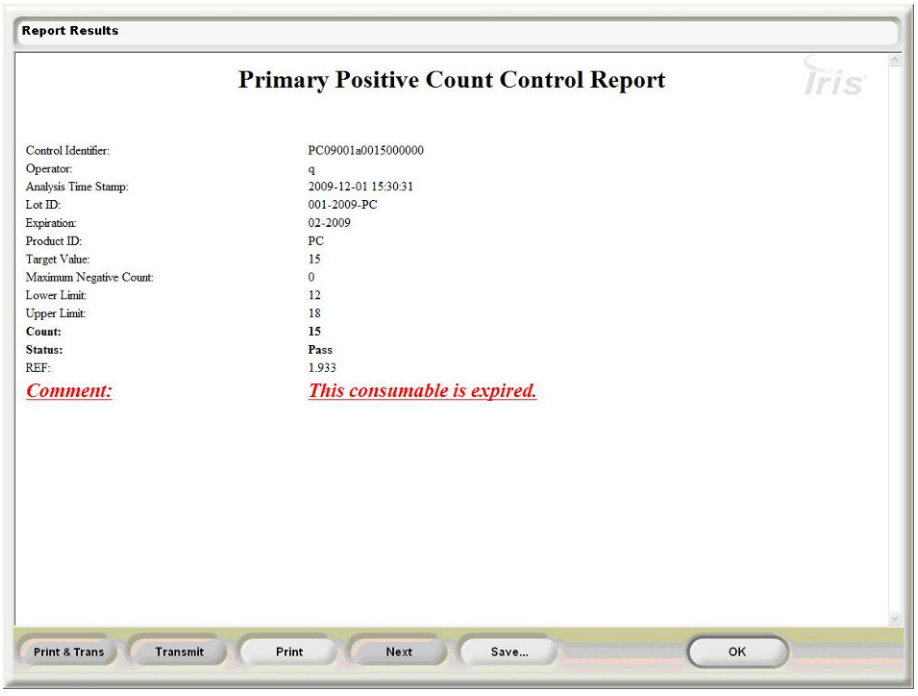
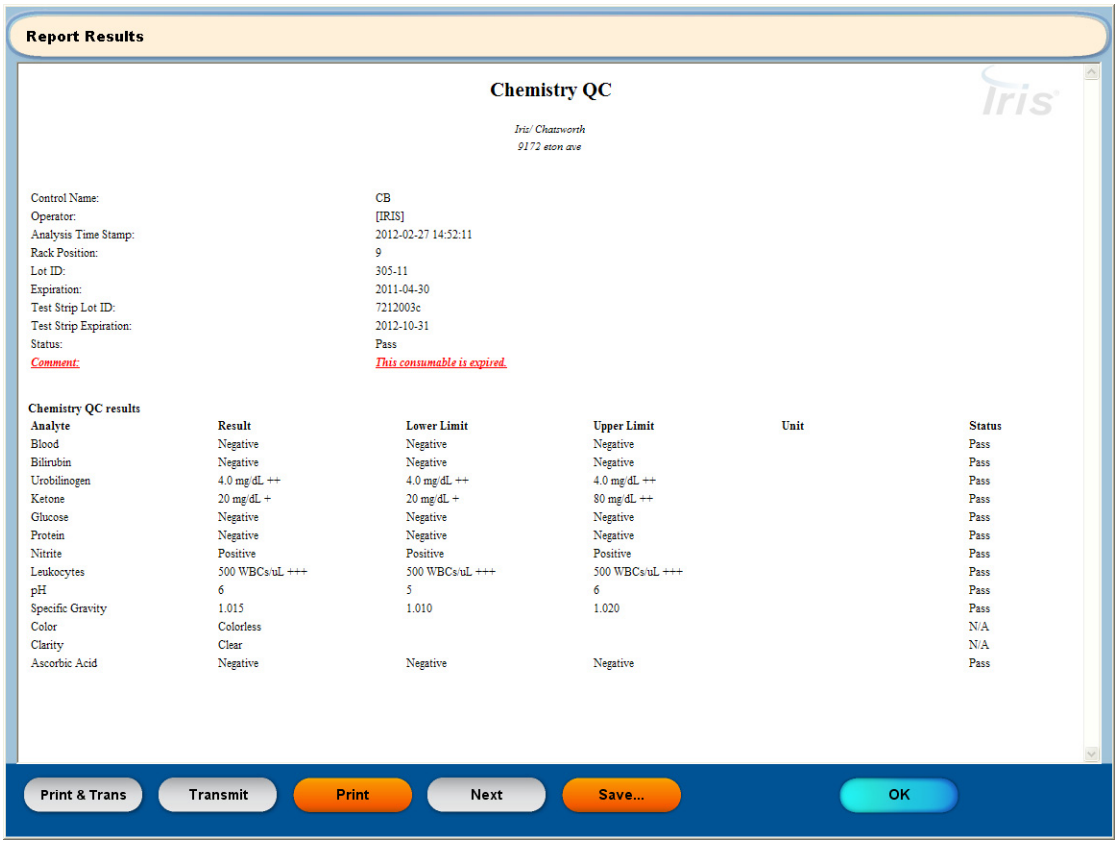


Figure 17.4 Primary Positive Count Control Report



Chemistry Test Strips

Figure 17.5 Chemistry QC Report



Expired Consumable Lockout Override

Only a manager can enable the Expired Consumable Lockout Override function for a sample to be run on the instrument. This checkbox is enabled only if an expired consumable material is used.

⚠ WARNING

This feature is only there for training purposes. It is not to be used when reporting diagnostic results. Do not use for diagnostic purposes.

When a manager overrides the lockout, the Expired Consumable red alarm becomes a yellow alarm and the **Expired Consumable Lockout Override** checkbox is disabled again until another expired consumable material is used.

Accessing the Expired Consumable Lockout Override Option

1 Select **Instrument** located on the top right side of the main screen.

2 Select **Go Off line**. A confirm window pops up (with warnings). Select **Yes**.

3 Select **Settings** located at the bottom of the Instrument screen. The Settings screen is displayed.

4 Select **QC**. The QC screen is displayed.

5 Select the checkbox for **Expired Consumable Override**, and then select **OK**.

Consumables Search

The Search screen allows you to display information concerning results obtained with a specific lot of consumables.

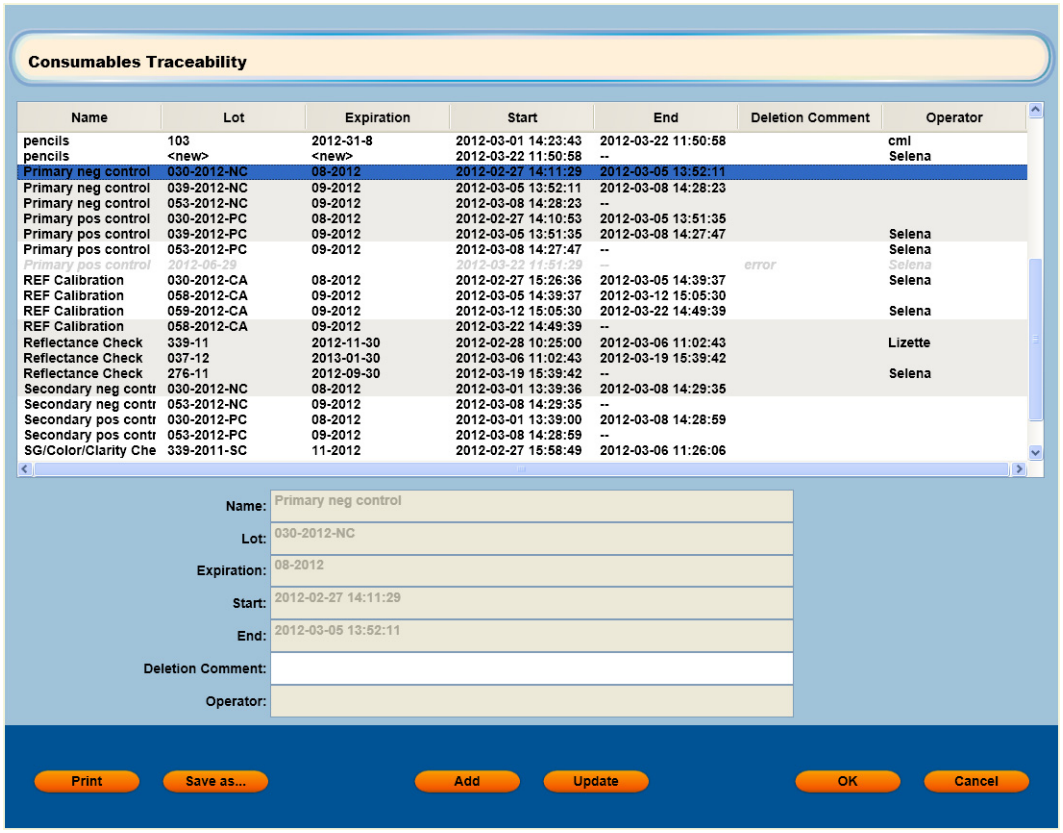
1 From the main screen, select **Work List**. The Work List screen is displayed.

2 From the Work List screen, select **Search**. The Search screen is displayed.

3 From the Search screen, select **Lot**, and then select **OK**. The Consumables Traceability screen is displayed.

4 Select the consumable lot to be searched. It is highlighted in blue. Select **OK**.

The Search screen is displayed and the *Date/Time* fields during which the consumable was used are updated.



5 Select **OK**. Results matching the search criteria are displayed in the Found List screen.

Abbreviations

µL — microliter

LIS — Laboratory Information System

SG — specific gravity

Glossary

clarity — see turbidity.

coefficient of variation — The normalized standard deviation; i.e., the standard deviation expressed as a percentage of the mean.

CV = (SD / mean) * 100 (%)

color — specific reportable color of the sample as measured by the instrument. It may also be *colorless* to indicate no detectable color.

Levey-Jennings graph — A commonly used control chart in which individual control measurements are plotted directly on a control chart with limit lines drawn either as mean ± 2SD or mean ± 3SD. Time is displayed on the x-axis usually in terms of days or runs.

LIS — A computer system used by some laboratories to collect and store clinical test results gathered from various instruments.

mean — The arithmetic average of a set of values. A measure of central tendency of the distribution of a set of replicate results. Often abbreviated by an x with a bar over it: x. In this usage, x is the running mean of the points on the graph.

$$\text{mean} = \frac{\sum x_i}{n} = \bar{x}$$

standard deviation — A statistic that describes the dispersion or spread of a set of measurements. Calculated from the equation:

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{(n - 1)}}$$

where n is the number of measurements, and x_i is an individual measurement.

target value — The bottle value of the specific lot.

turbidity — A measure of the opacity of the specimen being examined.

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