ion torrent

Genexus™ Purification System

USER GUIDE

Catalog Number A48148

Publication Number MAN0018475

Revision A.0

For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

Manufacturer:
Life Technologies Holdings Pte Ltd |
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Marsiling Industrial Estate Road 3 |
#07-06, Singapore 739256

Products:
Genexus™ Purification System

Manufacturer:
Life Technologies Corporation |
7335 Executive Way |
Frederick, Maryland 21704 USA

Products:
Ion Torrent™ Genexus™ FFPE DNA/RNA Purification Combo Kit
Ion Torrent™ Genexus™ Multisample DNA Purification Combo Kit
Genexus™ Purification Install Kit
Genexus™ FFPE DNA and RNA Purification Kit
Genexus™ Multisample DNA Purification Kit
Genexus™ Nucleic Acid Quantitation Kit
Genexus™ Nucleic Acid Quantitation, Broad Range Kit
Genexus™ Purification Supplies 1 Kit
Genexus™ Purification Supplies 2 Kit

Manufacturer:
Life Technologies Corporation |
200 Oyster Point Blvd |
South San Francisco, California
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Products:
Genexus™ Software

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Revision history: Pub. No. MAN0018475

Revision	Date	Description
A.0	28 June 2021	New user guide for Genexus™ Purification System standalone mode.

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1 Product information

IMPORTANT! Before using this product, read and understand the information in the “Safety” appendix in this document.

Product description

The Ion Torrent™ Genexus™ Purification System automates the extraction of nucleic acids in as little as 2 hours from various sample types, including: formalin-fixed, paraffin-embedded (FFPE) lysate, plasma, whole blood, fresh or frozen tissue, peripheral blood leukocytes (PBLs) and bone marrow lysate. Consumables for the system come prefilled with reagents and support up to 12 samples per run, or 6 sampes when extracting from plasma. The system includes an onboard Qubit™ Fluorometer to automate post extraction nucleic acid quantification. The system has been validated for use with the Ion Torrent™ Genexus™ Integrated Sequencer System.

The Ion Torrent™ Genexus™ Purification System offers:

- MagMAX™ technology—providing consistent extraction results
- Prefilled consumables—reducing setup hands-on time
- Vision system—providing real time feedback on consumables during run setup to prevent setup error
- Integrated nucleic acid quantitation—reducing post run processing times

The Genexus™ Purification System automates the extraction and quantitation of nucleic acids from a variety of tissue types. With a single touch point and 5 minutes of hands-on time, the Genexus™ Purification System can extract both DNA and RNA sequentially from FFPE lysates, and DNA from whole blood, fresh or frozen tissue, PBLs and bone marrow lysates.

Prefilled Reagents—The Genexus™ Purification System consumables are prefilled with most reagents necessary to perform the extraction, so only a few pipetting steps are required per sample to setup the run. Simply remove the foil seal, add enzymes and your samples, then place the consumables onto the instrument.

Vision System—The Genexus™ Purification System uses an onboard vision system to detect and verify reagent placement catching setup errors in real time. The vision system continuously checks that the consumables are appropriate to the purification run type and prevents running expired or previously used consumables. Feedback on the consumables loaded in the system is displayed on the instrument touchscreen, alerting the user and allowing for immediate correction.

MagMAX™ Technology—MagMAX™ Technology uses magnetic beads to perform nucleic acid extraction. MagMAX™ beads offer superior binding capacity due to their large surface area, accept a greater range of samples with differing viscosities, and allow for efficient elution in small volumes.

48-Well Nucleic Acid Archive Plate—After extraction, all nucleic acids are transferred directly to the 48-well archive plate and kept cool for up to 1 hour after run completion. The 48-Well Nucleic Acid Archive Plate is barcoded to facilitate tracking sample extractions across several stored archive plates.

Automated Quantitation—The Genexus™ Purification System automates quantitation of extracted nucleic acids using an onboard Qubit™ Fluorometer. Two dyes are used to measure the concentration of DNA or RNA from each extracted sample. Automating post-run quantitation saves hands-on time and allows for for immediate use of the extracted samples in genetic analysis workflows after run completion.

Rapid Turnaround—Run times on the Genexus™ Purification System range from 2 to 5.5 hours depending on the number of samples extracted and the protocol being run. Automated quantitation significantly reduces post-run hands-on time allowing for rapid transition to subsequent genetic analysis workflows.

Post Run Clean— After each run all consumables that touch the sample are discarded by the researcher after which the Genexus™ Purification System uses a UV light to clean the deck. This automated UV cleaning prevents run to run carryover of nucleic acid which could otherwise lead to contamination of downstream sequencing.

Genexus™ Purification System

The Genexus™ Purification System includes the following components.

Components	Cat. No.
Genexus™ Purification Instrument	A47646
Genexus™ Purification Install Kit	A48549[1]

[1] Not available for separate purchase.

The Ion Torrent™ Genexus™ Purification Install Kit (Part No. A48549) is available to first-time owners of a Genexus™ Purification System and is shipped with the instrument. The kit contains the following supplies that are used during installation of the instrument.

Table 1 Genexus™ Purification Install Kit

Contents	Quantity	Storage
12-Well Tip Comb	1 each	15°C to 30°C
6-Well Tip Comb	4 each	
96 Deep-Well plate	1 plate	
Quantitation Tube	4 each	

Reagents and supplies

Genexus™ Purification System reagents and supplies can be ordered in convenient combo kits and starter packs, but most consumables can also be ordered individually as your needs require.

Note: Consumables that have catalog numbers are orderable. Components that have part numbers cannot be ordered individually.

Ion Torrent™ Genexus™ FFPE DNA/RNA Purification Combo Kit

The Ion Torrent™ Genexus™ FFPE DNA/RNA Purification Combo Kit (Cat. No. A45539) includes the following subkits sufficient for 48 sequential DNA and RNA isolations.

Component	Part No.	Storage
Genexus™ FFPE DNA and RNA Purification	A45532	15°C to 30°C
Genexus™ Nucleic Acid Quantitation	A45538	2°C to 8°C
Genexus™ Purification Supplies 2	A45574	15°C to 30°C

Genexus™ FFPE DNA and RNA Purification Kit

The Genexus™ FFPE DNA and RNA Purification Kit (Part No. A45532) includes sufficient reagents and consumables for 48 sequential DNA and RNA isolations.

Component	Quantity	Storage
FFPE DNA and RNA Purification Plate 1	4 plates	15°C to 30°C
FFPE DNA and RNA Purification Plate 2	4 plates	
12-Well Tip Comb	4 each	
DNase (yellow cap)	115 µL	
DNase Buffer (blue cap)	4 × 1.2 mL	
Proteinase K (red cap)	1.2 mL	
FFPE Protease buffer	15 mL	

Genexus™ Nucleic Acid Quantitation Kit

The Genexus™ Nucleic Acid Quantitation Kit (Part No. A45538) includes sufficient consumables for 48 DNA and 48 RNA quantitations.

Component	Quantity	Storage
Quantitation Plate[1]	4 plates	2°C to 8°C
Quantitation Tube[2]	4 each	15°C to 30°C

[1] Store the Quantitation Plate in the dark to prevent photobleaching of the preloaded reagents.
[2] Can be stored at 15°C to 30°C upon receipt.

Genexus™ Purification Supplies 2 Kit

The Genexus™ Purification Supplies 2 Kit (Part No. A45574) includes sufficient consumables for 48 isolations.

Component	Quantity	Storage
48-Well Nucleic Acid Archive Plate	4 plates	15°C to 30°C
48-Well Nucleic Acid Archive Plate Seal	4 each	
Purification Tip Cartridge	8 each	

Ion Torrent™ Genexus™ Multisample DNA Purification Combo Kit

The Ion Torrent™ Genexus™ Multisample DNA Purification Combo Kit (Cat. No. A45540) includes the following subkits sufficient for 48 DNA isolations.

Component	Part No.	Storage
Genexus™ Multisample DNA Purification	A45533	15°C to 30°C
Genexus™ Nucleic Acid Quantitation, Broad Range	A45537	2°C to 8°C
Genexus™ Purification Supplies 1	A45529	15°C to 30°C

Genexus™ Multisample DNA Purification Kit

The Genexus™ Multisample DNA Purification Kit (Part No. A45533) includes sufficient reagents and consumables for 48 DNA isolations.

Component	Quantity	Storage
Multisample DNA Purification Plate	4 plates	15°C to 30°C
12-Well Tip Comb	4 each	
Proteinase K (red cap)	2 x 1.2 mL	
DNA Enhancer (black cap)	2 x 1.2 mL	
DNA Homogenization	2 x 22 mL	

Genexus™ Nucleic Acid Quantitation, Broad Range Kit

The Genexus™ Nucleic Acid Quantitation, Broad Range Kit (Part No. A45537) includes sufficient consumables for 48 DNA and 48 RNA quantitations.

Component	Quantity	Storage
Quantitation Plate Broad Range[1]	4 plates	2°C to 8°C
Quantitation Tube[2]	4 each	15°C to 30°C

[1] Store the Quantitation Plate in the dark to prevent photobleaching of the preloaded reagents.
[2] Can be stored at 15°C to 30°C upon receipt.

Genexus™ Purification Supplies 1 Kit

The Genexus™ Purification Supplies 1 Kit (Part No. A45529) includes sufficient consumables for 48 isolations.

Component	Quantity	Storage
48-Well Nucleic Acid Archive Plate	4 plates	15°C to 30°C
48-Well Nucleic Acid Archive Plate Seal	4 each	
Purification Tip Cartridge	4 each	

Required materials not supplied

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **fisherscientific.com** or another major laboratory supplier.

Item	Source
20-, 200-, and 1,000-µL pipettes and appropriate filtered tips[1]	MLS
Microcentrifuge tubes, 1.5-mL or 1.7-mL (low retention for nucleic acids)	MLS
Vortex mixer with a rubber platform	MLS
Gloves, powder-free nitrile	MLS
Nuclease-free water, molecular biology grade	MLS
Isopropyl alcohol, 70% solution	MLS
Wipes, disposable lint-free	MLS
Uninterruptible Power Supply (UPS)[2]	MLS

[1] We recommend use of positive displacement pipettes and RNase free tips for use when isolating RNA.
[2] For laboratories that experience frequent power outages or line voltage fluctuations, we recommend that you use an uninterruptible power supply that is compatible with 2500 W output or higher.

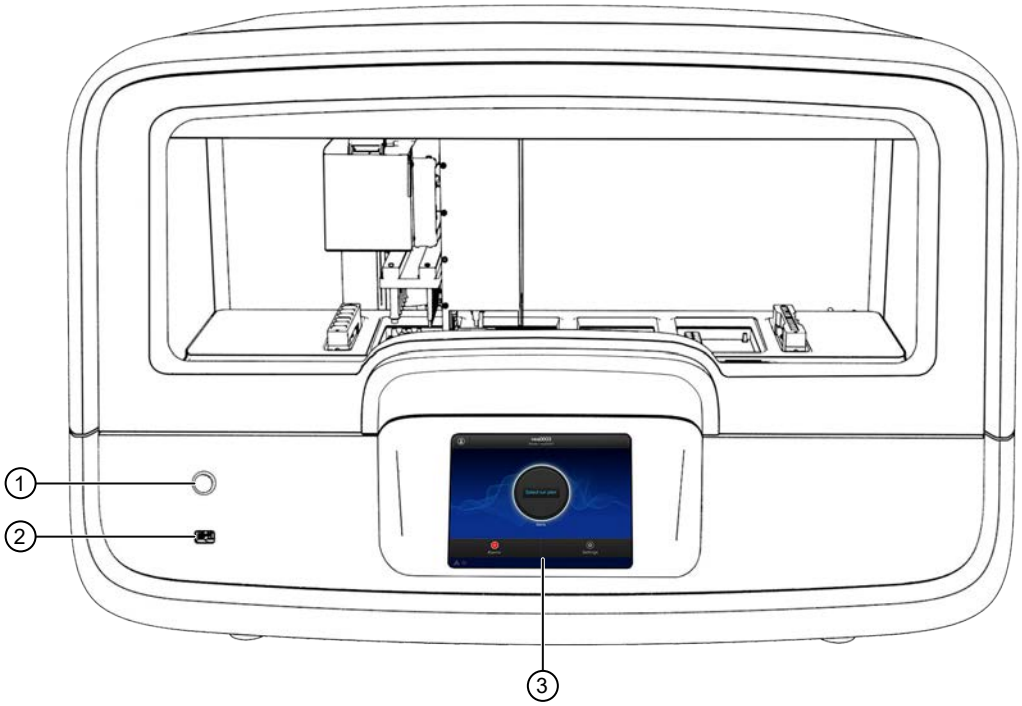
Recommended materials not supplied

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **fisherscientific.com** or another major laboratory supplier.

Item	Source
Equipment	
Bench top microcentrifuge	• Cole-Parmer EW-17414-06 • Eppendorf 022620304
Sorvall™ ST 8 Small Benchtop Centrifuge, with Thermo Scientific™ M10 Microplate Swinging Bucket Rotor, and Sealed Bucket; Capacity: 4 Standard or 2 Midi-Deepwell plates (Set of 2) (or equivalent)	75007200 75005706 75005721
Laboratory mixer (Vortex or equivalent)	**MLS**
Fisherbrand™ Bead Mill 24 Homogenizer (or equivalent)	15-340-163
Economy Lab Incubator (2, 60°C and 90°C)	S50441A **fisherscientific.com**
Heating block (2, 60°C and 90°C)	**MLS**
Equipment and consumables for AutoLys M FFPE sample extraction[1]	
AutoLys M Tubes and Caps kit.	A38738
AutoLys M Tube Rack	A37955
AutoLys M Tube Locking Lid	A37954
AutoLys M TubeLifter	A37956
AutoLys M Tube Pliers	A38261
Tubes, plates, and other consumables	
MicroAmp™ 48-Well Optical Adhesive Film	4375323
Aerosol-resistant pipette tips	**MLS**
RNase*Zap*™ RNase Decontamination Solution	AM9780
Citrisolv Clearing Agent	22-143-975
Xylene	**MLS**
Ethanol, 100%	**MLS**

[1] For use with the Genexus™ FFPE DNA and RNA Purification kit.

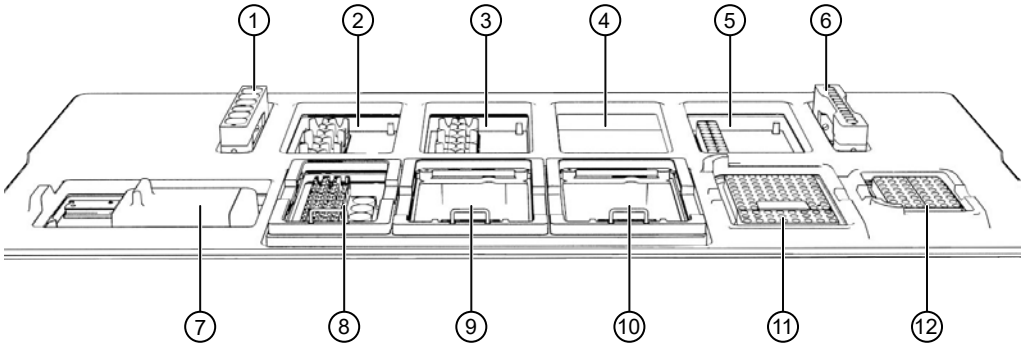
Genexus™ Purification System components



Major features and components of the exterior of the Genexus™ Purification Instrument.

① Power button
② USB port
③ Touchscreen

Genexus™ Purification Instrument deck stations

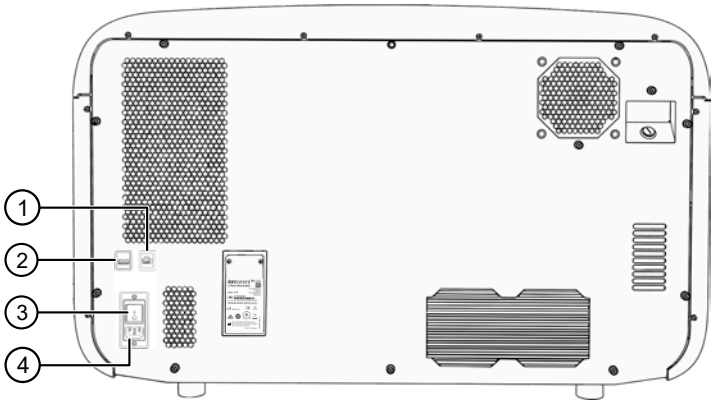


Interior Genexus™ Purification Instrument deck components and stations

1. 6 well tip comb
2. 24 Deep-well plate 1
3. 24 Deep-well plate 2
4. 96 Deep-well plate 1
5. 96 Deep-well plate 2
6. 12 well tip comb
7. Qubit Quant module
8. Quant tray
9. Tip box 1
10. Tip box 2
11. 96 well output plate
12. 48 well archive plate

Genexus™ Purification Instrument input and output connections

The connection panel, power port, and an on/off switch are located on the left side of the rear panel of the instrument.



1. Ethernet port—An RJ45 port that provides Ethernet (Gigabit) communication between the instrument and a local area network.
2. USB port—Connects a USB device to the instrument.
3. On/off switch—Power switch, where the states are on (|) or off (O).
4. Power port—100–240VAC port that provides power to the instrument.

2 Before you begin

Precautions

Avoid nucleic acid contamination

IMPORTANT! A primary source of contamination is spurious DNA fragments from previous sample processing steps. Do not introduce amplified DNA into the work area where the instrument is located.

- Use good laboratory practices to minimize cross-contamination of products and reagents.
- When designing the laboratory layout, dedicate separate areas for purification and sequencing activities. Dedicate laboratory supplies and/or equipment to the appropriate area.

Confirm consumables are installed correctly

IMPORTANT! To ensure correct and safe instrument operation, you must confirm that all consumables are installed correctly on the deck before you start a run. The instrument does not verify all aspects of the consumable setup before beginning each run.

Avoid instrument vibration

IMPORTANT! The Genexus™ Purification Instrument must be installed on a bench that is free from vibrations or in contact with equipment that can cause vibrations to the bench, such as freezers, pumps, large benchtop centrifuges, and other similar equipment. An air table is not required, nor is securing the instrument to the bench.

Avoid strong electromagnetic radiation

WARNING! Do not use the instrument in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources), as these sources can interfere with proper operation.

Protection by equipment

WARNING! The protection that is provided by the equipment can be impaired if the instrument is operated outside the environment and use specifications, the user provides inadequate maintenance, or the equipment is used in a manner that is not specified by the manufacturer (Thermo Fisher Scientific).

Power the Genexus™ Purification Instrument on or off

Note: If the Genexus™ Purification Instrument is powered on, and the touchscreen is blank, touch the screen to "wake" the touchscreen.

Power on

If the touchscreen is unresponsive, check the power switch on the back of the instrument to ensure that the switch is in the on (|) position. If the power switch is in the off (O) position, proceed with step 1. If the power switch is already in the on position, proceed to step 2.

1. Turn the power switch on the back of the instrument to the on (|) position.
2. Press the power button on the front of the instrument.
   The button illuminates.
3. In the **Sign In** screen, enter the username and password created by the field service engineer when the instrument was set up.
   When the instrument home screen appears, the instrument is ready for use.

Power off

It is not necessary to power off the instrument overnight or over the weekend. If the instrument will not be used for more than 3 days, power off the instrument as follows:

1. In the home screen, tap **Settings** ▸ **System Tools** ▸ **Shut down**.
2. Select **Shutdown** .
   A confirmation message appears. Select **Yes** to power off the instrument.

IMPORTANT! Do *not* press the power button during a run. Interrupting power to the instrument during a run can result in run failure and loss of sample.

Reboot the instrument

1. In the home screen, tap **Settings** ▸ **System Tools** ▸ **Shut down**.
2. Select **Reboot**.
   A confirmation message appears. Select **Yes** to reboot the instrument.

IMPORTANT! Do *not* press the power button during a run. Interrupting power to the instrument during a run can result in run failure and loss of sample.

3 Genexus™ FFPE DNA and RNA Purification Protocol

Standalone mode workflow for Genexus™ FFPE DNA and RNA Purification

5 min

Create a purification run plan (page 18)

System-installed purification run plans that are specifically configured for each purification kit are available in the Genexus™ Purification Instrument software. You can use the system-installed purification run plan without change. If you want to modify any settings, copy the system-installed assay that best represents your experiment, then edit the assay settings as needed.

3 hr

Prepare samples from FFPE curls (page 23)

OR

Prepare samples from FFPE slides (page 24)

Samples are deparaffinized and digested with protease in preparation for isolation of DNA and RNA.

5 min

Load the Genexus™ Purification Instrument (page 26)

The purification run plan is selected and the run initiated. The instrument performs a pre-run UV clean, then reagents and consumables are loaded on to the instrument.

2 hr

Start the run (page 35)

After the sample plate and all reagents and consumables have been loaded the instrument door is closed and the run started.

Note: Sample quantification adds ~2 hours to the run time.

5 min

Unload the purified nucleic acids (page 36)

Remove and seal the 48-Well Nucleic Acid Archive Plate or proceed immediately to sequencing of the purified sample. Used reagents and consumables are removed from the instrument and a UV clean is performed.

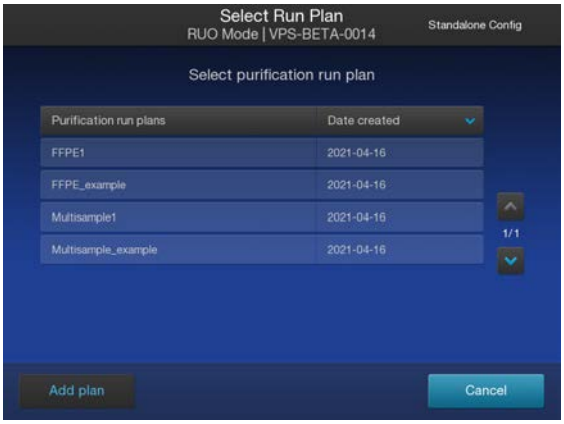
Create a purification run plan (Standalone mode)

In standalone mode users create a purification run plan through the instrument touchscreen.

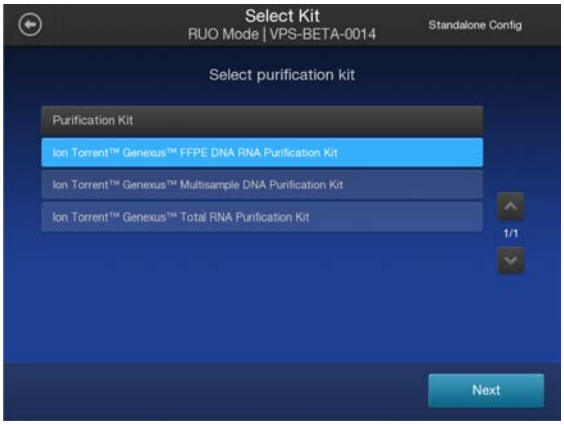
Add a purification run plan (Standalone mode)

Note: We recommend that you plan the run before preparing your samples and loading into the FFPE DNA and RNA Purification Plate 1. However, experienced users can save time by creating the purification run plan during the protease digestion step of sample preparation.

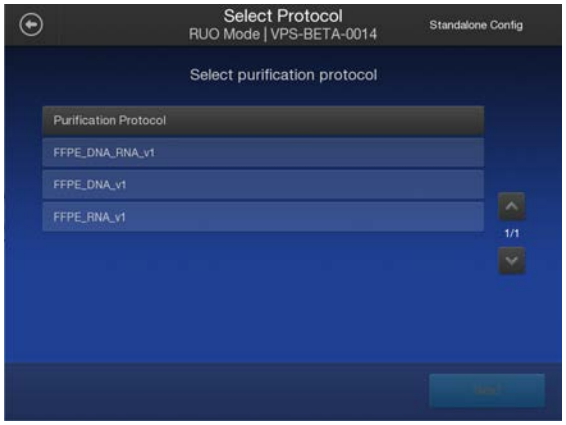
1. Tap the touchscreen to wake the instrument. If the screen remains dark, see “Power on” on page 16.
2. Enter your username and password to sign in to the instrument.
3. Tap **Run**, then tap **Add plan**.



4. Tap in the entry box, enter a unique name for the run plan, then tap **Done** ▸ **Next**.
5. Select the Ion Torrent™ Genexus™ FFPE DNA and RNA Purification Kit, then tap **Next**.



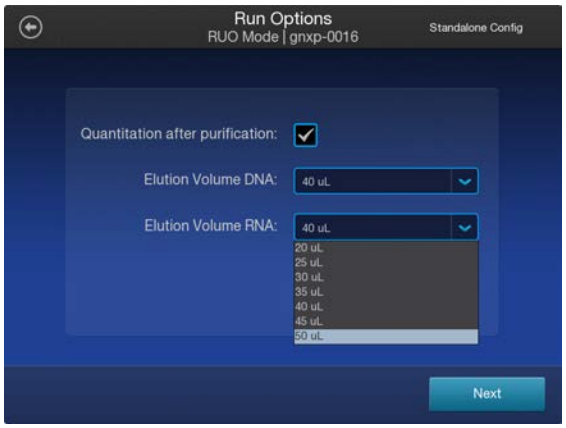
6. Select the appropriate purification protocol, then tap **Next**.
   - If sequentially purifying DNA and RNA, select **FFPE_DNA_RNA_v1**.
   - If purifying DNA only, select **FFPE_DNA_v1**.
   - If purifying RNA only, select **FFPE_RNA_v1**.



7. Enable or disable **Quantitation after Purification**.

Note:

- The Quantitation Plate is required even if **Quantitation after Purification** is disabled.
- Disabling **Quantitation after Purification** may reduce the purification run time by up to 2.5 hours.
- Quantitation requires up to 5 µL of the eluted sample. If the expected sample yield is limiting, manual sample quantitation may be preferred to preserve sample.



8. Accept the default elution volume. If needed, select the desired elution volume from the dropdown list, then tap **Next**.

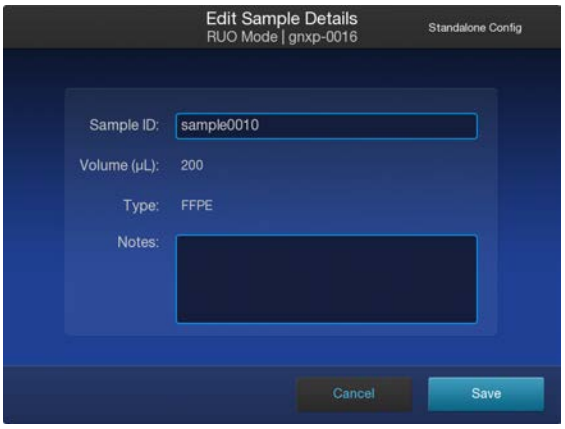
9. *(Optional)* Change the number of samples and the sample details.
   a. In the **Manage Samples** screen, deselect extra samples (for example, if you are only running ten samples, deselect samples 11 and 12).

   b. Tap on a sample ID to select the sample.

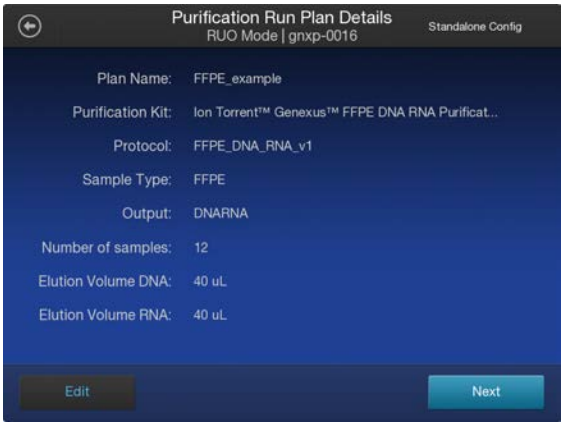
c. Tap **Edit**, enter a new **Sample ID** and any **Notes**, then tap **Save**.

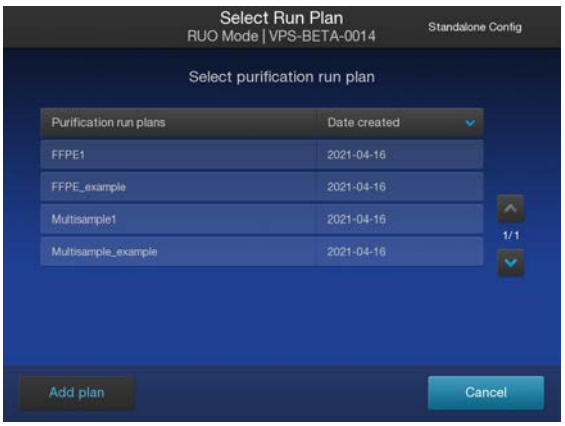
d. Repeat substep 9b and substep 9c for each additional sample.

e. Click **Next**.



10. Review the **Purification Run Plan Details**. Tap **Edit** to change any of your selections, otherwise tap **Next**.





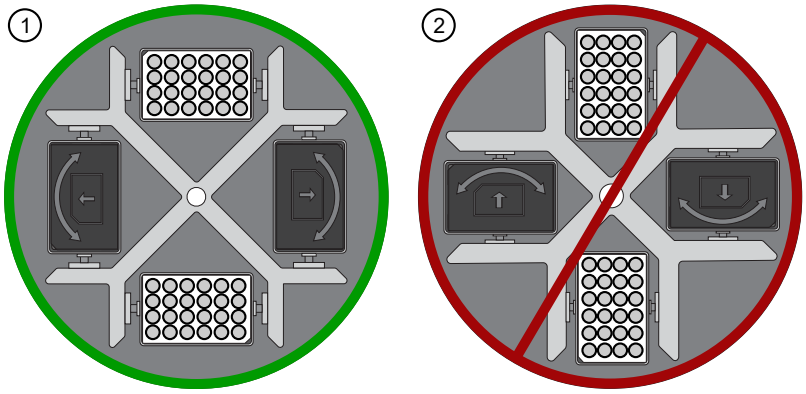
The new purification run plan will now appear in the list of available **Purification Run Plans**.

To delete an existing run plan, see “Delete a run plan” on page 66.

Prepare samples

Procedural guidelines

- Perform all steps at room temperature (20–25°C) unless otherwise noted.
- When mixing samples by pipetting up and down, avoid creating bubbles.
- Wear clean gloves and a clean lab coat.
- Change gloves whenever you suspect that they are contaminated.
- Open and close all sample tubes carefully. Avoid splashing or spraying samples.
- When working with RNA:
  - Use a positive-displacement pipettor and RNase-free pipette tips.
  - Clean lab benches and equipment periodically with an RNase decontamination solution, such as RNase*Zap*™ Solution (Cat. No. AM9780).
  - Store RNA at –80°C.
- Volumes for reagent mixes are given per sample. We recommend that you prepare master mixes for larger sample numbers. To calculate volumes for master mixes, refer to the per-well volume and add 5–10% overage.
- Incubation at 60°C can be extended 1 hour (2 hr total time) to increase DNA yields followed by the 90°C incubation for 1 hour.
- We recommend using a plate centrifuge that holds the AutoLys M Tube Rack in "landscape" orientation.



① Landscape orientation—recommended
② Portrait orientation—not recommended

- The plate chiller shuts off 60 minutes after run completion. Remove the 48-Well Nucleic Acid Archive Plate with purified nucleic acids from the instrument within 1 hour of run completion. Proceed immediately to sequencing or properly store the nucleic acids until use.
- The Quantitation Plate requires equilibration to room temperature for at least 30 minutes before use.

Before each use of the kit

- Pre-heat incubators to 60°C and 90°C.

  Note: We recommend the use of incubators when using AutoLys M Tubes.

- Prepare Protease Digestion and DNase Digestion solutions immediately before use.
- Centrifuge purification plates for 30 seconds at 1000 x *g* to collect the contents.

Materials required

Genexus™ FFPE DNA and RNA Purification (Part. No. A45532)

- FFPE DNA and RNA Purification Plate 1
- Proteinase K
- FFPE Protease Buffer

AutoLys M TubeLifter or Pliers

AutoLys M Tubes and Caps

AutoLys M Tube Rack

Plate centrifuge

Prepare 1X Protease Digestion Master Mix

Note: We recommend preparation of the protease digestion master mix immediately before use.

1. Vortex the FFPE Protease buffer and Proteinase K (red cap) supplied in the kit for ~5 seconds each, then pulse centrifuge to collect the contents.
2. In a 1.5-mL low-retention microcentrifuge tube, prepare a 1X Protease Digestion Master Mix as indicated in Table 2, where "n" is the number of tissue samples:

   Table 2

Component	Volume per reaction
FFPE Protease buffer	(n+1) × 225 µL
Proteinase K (red cap)	(n+1) × 10 µL
Total volume	**(n+1) × 235 µL**

3. Vortex for ~5 seconds to mix, then pulse centrifuge to collect.

Prepare FFPE curl samples with AutoLys M Tubes

Note: We recommend the use of AutoLys M Tubes for the preparation of FFPE samples. Alternatively, CitriSolv™ Clearing Agent, xylene or equivalent solution can be used for removal of paraffin from the FFPE samples. For more information, see Appendix B, "Supplemental Information".

Digest with Protease in AutoLys M Tubes

Note: To minimize the amount of time between protease digestion and starting the purification run on the instrument we recommend that you prepare the reagents and consumables that are required by the instrument during the 90°C incubation (step 6).

1. Label an AutoLys M tube for each FFPE tissue sample.
2. Add each FFPE section curl to a separate labeled tube.
3. Place AutoLys M tubes in an AutoLys M Tube Rack, then centrifuge at 2000 x *g* for 1 minute to collapse the curl prior to the addition of buffer.
4. Pipet 235 µL 1X Protease Digestion Master Mix into each labeled tube.

   Note: Ensure the samples are submerged in the Protease Digestion Master Mix.

5. Incubate at 60°C for ≥60 minutes in an AutoLys M Tube Rack.

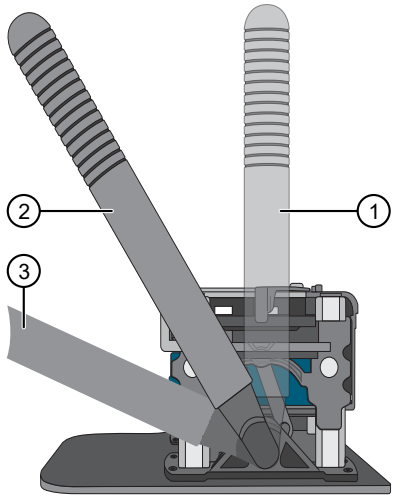
   Note: Incubation at 60°C can be extended to 2 hours to increase DNA yields.

6. Incubate at 90°C for 60 minutes.

   Note:
   - If using a single incubator, keep sample in the incubator while the temperature increases. Start timing when the temperature reaches 90°C.
   - Set up the FFPE DNA and RNA Purification Plate 1 during the incubation.
   - Prepare the reagents and consumables that are required by the instrument during the incubation. See "Prepare the consumables" on page 27.
   - Equilibrate the Quantitation Plate to room temperature during the incubation.

7. Allow samples to cool to room temperature for 3–5 minutes before proceeding to lift the tubes.

8. Lift the tubes. The following steps describe use of the AutoLys M TubeLifter to process up to 24 samples simultaneously. For more information on use of the AutoLys M TubeLifter see the *AutoLys M TubeLifter User Guide* (Pub. No. MAN0017676). Alternatively, AutoLys M Tube Pliers can be used to process tubes individually.
   a. Ensure the AutoLys M TubeLifter lever is in Position A (straight up) and the slider is in Position 1.
   b. Slide the 24-well AutoLys M Tube Rack containing the lysed samples into the AutoLys M TubeLifter.
   c. Press the lever down from Position A to Position B, then remove the rack from the lifter.



① Position A
② Position B
③ Position C

9. Slide the AutoLys M Tube Locking Lid onto the rack, then centrifuge the samples at 2000 × *g* for 10 minutes.

Note: Ensure the embossed arrow of the AutoLys M Tube Locking Lid points away from the center of rotation (landscape orientation) when placed in the centrifuge.

10. Separate filter from the outer tube.
    a. Adjust the position of the AutoLys M TubeLifter slider to position 2.
    b. Remove the AutoLys M Tube Locking Lid, then slide the rack into the AutoLys M TubeLifter.
    c. Press the lever down from Position B to Position C.

    Keep the samples on ice.

Proceed to “Add samples to FFPE DNA and RNA Purification Plate 1” on page 29.

STOPPING POINT If needed, samples can be stored over night at –20°C.

Prepare FFPE slide samples with AutoLys M Tubes

Note: We recommend the use of AutoLys M Tubes for the preparation of FFPE samples. Alternatively, CitriSolv™ Clearing Agent, xylene or equivalent solution can be used for removal of paraffin from the FFPE samples. For more information, see Appendix B, “Supplemental Information”.

Collect the tissue

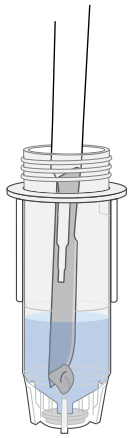
1. Label an AutoLys M tube for each FFPE tissue sample. Label each tube (cap and side) with its Sample ID using a marker that is resistant to xylene and ethanol.
2. Pipet 235 µL 1X Protease Digestion Master Mix into each labelled tube.

3. Pipet 2–4 µL of 1X Protease Digestion Master Mix from the labeled tube evenly across the fixed tissue section on the slide to pre-wet the tissue section.

   Note: Larger sections may need an additional 2–4 µL of Digestion Buffer.

4. Using a sterile disposable scalpel or clean razor blade, scrape the tissue in a single direction, then collect the tissue into a cohesive mass on the tip of the scalpel blade.

5. Carefully insert the scalpel blade with the tissue mass into the 1X Protease Digestion Buffer in the AutoLys M tube. Rinse the tissue from the blade into the buffer, then ensure that the entire mass is in solution.



6. Remove and inspect the blade to ensure that no tissue remains on it.

7. Inspect the slide to ensure that all the tissue has been removed (the slide should be translucent). Discard the scalpel in a waste container for sharp objects.

8. Gently flick the tube to mix and to immerse the tissue.

   Note: If the tissue adheres to the sides of the tube, use a pipette tip to push the tissue into the solution or centrifuge briefly to immerse the tissue in the solution.

Digest with Protease

Note: To minimize the amount of time between protease digestion and starting the purification run on the instrument, we recommend that you prepare the reagents and consumables that are required by the instrument during the 90°C incubation (step 2 on page 25).

1. Incubate at 60°C for ≥60 minutes in an AutoLys M Tube Rack.

   Note: Incubation at 60°C can be extended to 2 hours to increase DNA yields.

2. Incubate at 90°C for 60 minutes.

   Note:
   - If using a single incubator, keep sample in the incubator while the temperature increases. Start timing when the temperature reaches 90°C.
   - Set up the FFPE DNA and RNA Purification Plate 1 during the incubation.
   - Prepare the reagents and consumables that are required by the instrument during the incubation.
   - Equilibrate the Quantitation Plate to room temperature during the incubation.

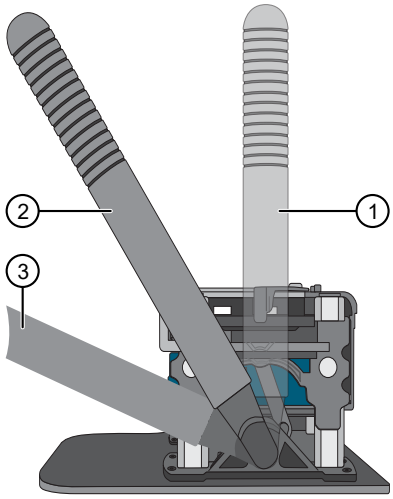
3. Allow samples to cool to room temperature for 3–5 minutes before proceeding to lift the tubes.

4. Lift the tubes. The following steps describe use of the AutoLys M TubeLifter to process up to 24 samples simultaneously. For more information on use of the AutoLys M TubeLifter see the *AutoLys M TubeLifter User Guide* (Pub. No. MAN0017676). Alternatively, AutoLys M Tube Pliers can be used to process tubes individually.

   a. Ensure the AutoLys M TubeLifter lever is in Position A (straight up) and the slider is in Position 1.

   b. Slide the 24-well AutoLys M Tube Rack containing the lysed samples into the AutoLys M TubeLifter.

   c. Press the lever down from Position A to Position B, then remove the rack from the lifter.



① Position A
② Position B
③ Position C

5. Slide the AutoLys M Tube Locking Lid onto the rack, then centrifuge the samples at 2000 × *g* for 10 minutes.

Note: Ensure the embossed arrow of the AutoLys M Tube Locking Lid points away from the center of rotation (landscape orientation) when placed in the centrifuge.

6. Separate filter from the outer tube.

   a. Adjust the position of the AutoLys M TubeLifter slider to position 2.

   b. Remove the AutoLys M Tube Locking Lid, then slide the rack into the AutoLys M TubeLifter.

   c. Press the lever down from Position B to Position C.

   Keep the samples on ice.

Proceed to "Add samples to FFPE DNA and RNA Purification Plate 1" on page 29.

STOPPING POINT If needed, samples can be stored over night at –20°C.

Load the Genexus™ Purification Instrument and start the run

This section describes how to perform the following procedures:

- Set up the Genexus™ Purification Instrument for use by loading all of the required reagents and consumables
- Start an Genexus™ Purification Instrument run

Note: Do NOT load any consumables onto the Genexus™ Purification Instrument until after the instrument has performed the pre-run UV cleaning.

Materials required

- Genexus™ FFPE DNA and RNA Purification (Part. No. A45532)
  - FFPE DNA and RNA Purification Plate 2
  - 12-Well Tip Comb
  - DNase
  - DNase Buffer
- Genexus™ Nucleic Acid Quantitation (Part. No. A45538)
  - Quantitation Plate
  - Quantitation Tube
- Genexus™ Purification Supplies 2 (Part. No. A45574)
  - 2 Purification Tip Cartridges
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- P200 pipet and filtered tips

Prepare the consumables

Note: Consumables can be prepared during the protease digestion 90°C incubation step to save time.

Remove all cartridges and consumables from their packaging, then place them on the bench at room temperature.

Prepare the following cartridges and consumables:

- Genexus™ Purification Supplies 2
  - 2 Purification Tip Cartridges
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- 12-Well Tip Comb

Equilibrate the Quantitation Plate

Note:

- The Quantitation Plate is required even if your run plan does not include sample quantitation.
- The Quantitation Plate can be equilibrated to room temperature during the protease digestion to save time.

1. Gently tap the plate on the bench to force the reagents to the bottoms of the tubes. Alternatively, briefly centrifuge the Genexus™ Nucleic Acid Quantitation at 1000 x *g* to collect the contents.
2. Replace the Quantitation Plate in the protective opaque bag, then place the plate and Quantitation Tube on the bench at room temperature.

IMPORTANT!

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- Allow at least 30 minutes for the Quantitation Plate to equilibrate to room temperature.

Add 1X DNase digestion master mix to the FFPE DNA and RNA Purification Plate 2

The FFPE DNA and RNA Purification Plate 2 contains magnetic beads in row H.

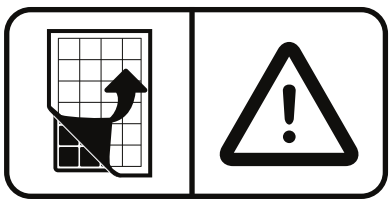
1. Vortex the DNase Buffer (blue cap) and DNase (yellow cap) supplied in the kit for ~5 seconds each, then pulse centrifuge to collect the contents.
2. In a 1.5-mL low-retention microcentrifuge tube, prepare a 1X DNase digestion master mix as indicated in Table 3, where "n" is the number of tissue samples:

Table 3

Component	Volume per reaction[1]
DNase Buffer (blue cap)	(n+1) × 99 µL
DNase (yellow cap)	(n+1) × 1.0 µL
Total volume	**(n+1) × 100 µL**

[1] Include a 5–10% overage to accommodate pipetting errors.

3. Vortex for ~5 seconds to mix, then pulse centrifuge to collect.
4. Centrifuge the FFPE DNA and RNA Purification Plate 2 at 1000 x *g* for 30 seconds to collect the contents.
5. Carefully remove the plate seal without disturbing the contents.



6. Pipet 100 µL 1X DNase digestion master mix into each well being used in Row A of the FFPE DNA and RNA Purification Plate 2.

Add samples to FFPE DNA and RNA Purification Plate 1

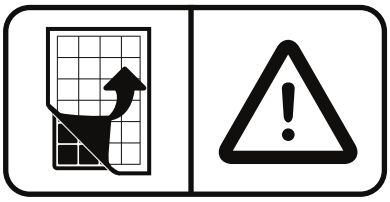
The FFPE DNA and RNA Purification Plate 1 contains magnetic beads in row B.

1. Centrifuge the plate at 1000 x *g* for 30 seconds to collect the contents.

   IMPORTANT! Do not create bubbles when preparing the plate.

2. Inspect the plate to ensure the contents of all rows are at the bottom of the wells.

3. Carefully remove the plate seal without disturbing the contents.



4. Transfer 200 µL of each sample to an individual well in row A of the prefilled FFPE DNA and RNA Purification Plate 1.

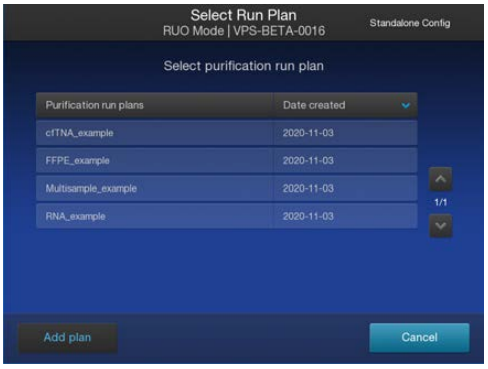
   Note:
   - Add samples to consecutive wells beginning with sample 1 in well A1, through sample 12 in well B4. Do not skip wells.
   - A precipitate may form, but this does not interfere with the DNA binding. Proceed directly to the next step.
   - Reagent consumables cannot be reused. We recommend preparing the maximum number of samples allowed.

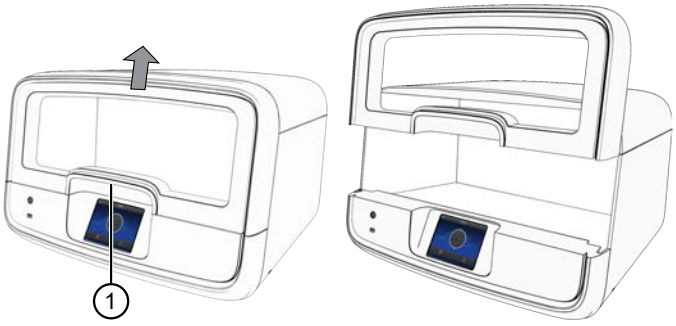
Start the purification run

1. Tap **Run**, then tap to select the run plan you created for this run.

2. Ensure that the run plan selected is correct, then tap **Next**.
   The instrument performs a 2 minute UV clean, then unlocks the door.

3. Lift the instrument door to the stop.





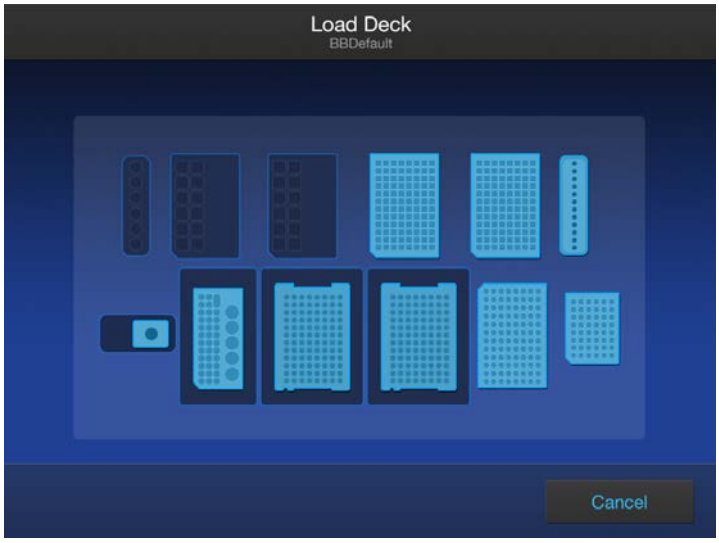
① Hold here, then lift.

Load the Genexus™ Purification Instrument

IMPORTANT!

- Ensure that all components are clean and dry before loading them onto the Genexus™ Purification Instrument.
- Ensure that the Reagent and Quantitation station compartments are free of condensate before loading components. If needed, use a lint-free wipe to dry the compartment.

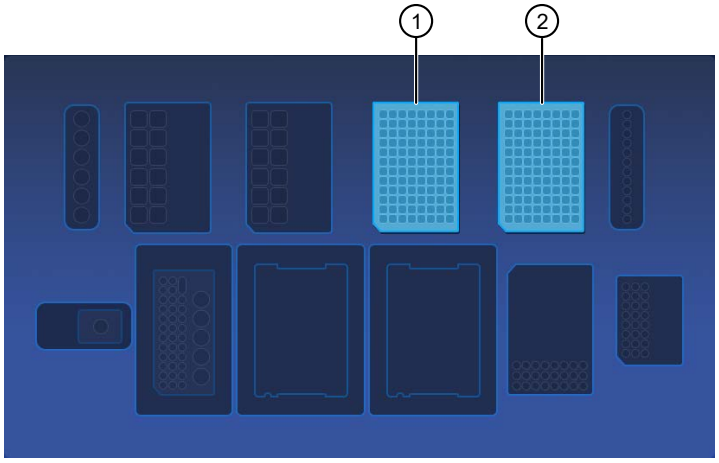
Follow the on-screen prompts to load the Genexus™ Purification Instrument.



Load FFPE DNA and RNA Purification Plate 1 & 2

1. Load the FFPE DNA and RNA Purification Plate 1 (DNA plate) prepared in step 4 of "Add samples to FFPE DNA and RNA Purification Plate 1" on page 29.

2. Load the FFPE DNA and RNA Purification Plate 2 (RNA plate) prepared in step 6 of "Add 1X DNase digestion master mix to the FFPE DNA and RNA Purification Plate 2" on page 28.

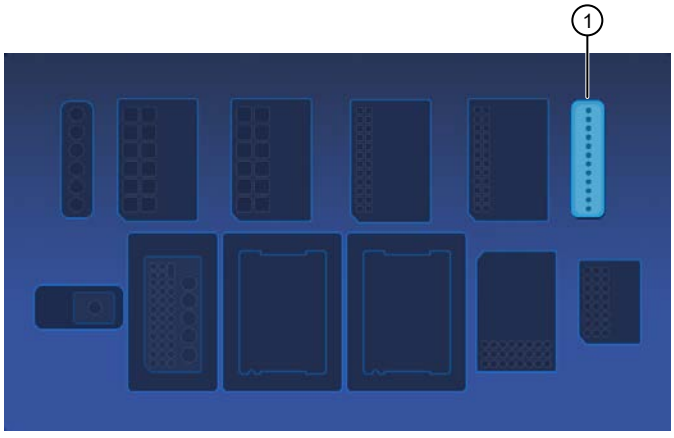


① FFPE DNA and RNA Purification Plate 1 position
② FFPE DNA and RNA Purification Plate 2 position

Load the 12-Well Tip Comb, Purification Tip Cartridges, and 48-Well Nucleic Acid Archive Plate

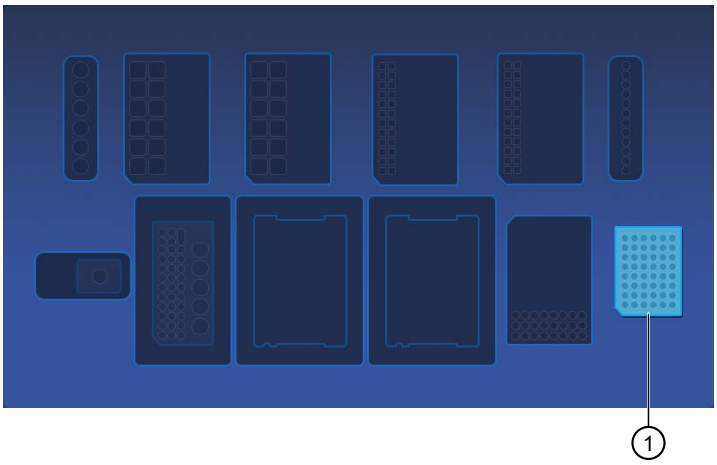
1. Unwrap, then load a new 12-Well Tip Comb.

Note: Ensure the 12-Well Tip Comb is straight and that the tabs are not bent or broken. If needed, gently bend the tip comb in the opposite direction to the curvature to straighten the tip comb before installing it.



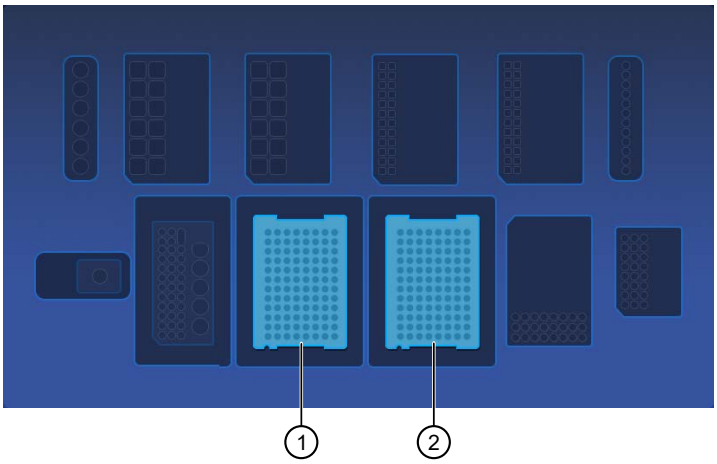
① 12-Well Tip Comb position

2. Unwrap, then load a new 48-Well Nucleic Acid Archive Plate.



① 48-Well Nucleic Acid Archive Plate position

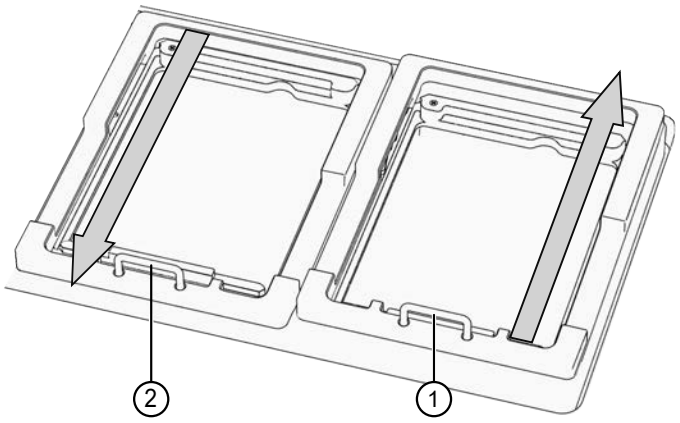
3. Unwrap two new Purification Tip Cartridges and remove the cover to expose the pipette tips, then load them in positions 1 and 2.



① Purification Tip Cartridge position 1
② Purification Tip Cartridge position 2

   a. Pull the locking mechanism handle forward (callout 2), then place the tip box in the open position.

b. Push the locking mechanism handle back (callout 1) to lock the tip box in place.



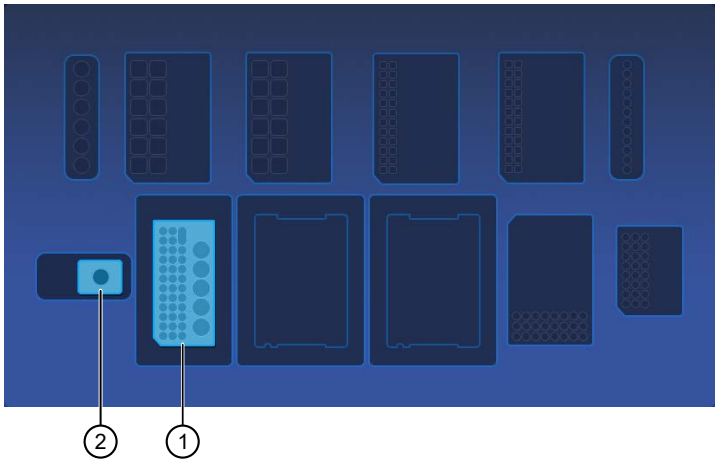
① Locked (back)
② Unlocked (forward)

Load the quantitation reagents and consumables

Note:

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- The Quantitation Plate is required even if your run plan does not include sample quantitation.
- The Quantitation Tube is not required if your run plan does not include sample quantitation.

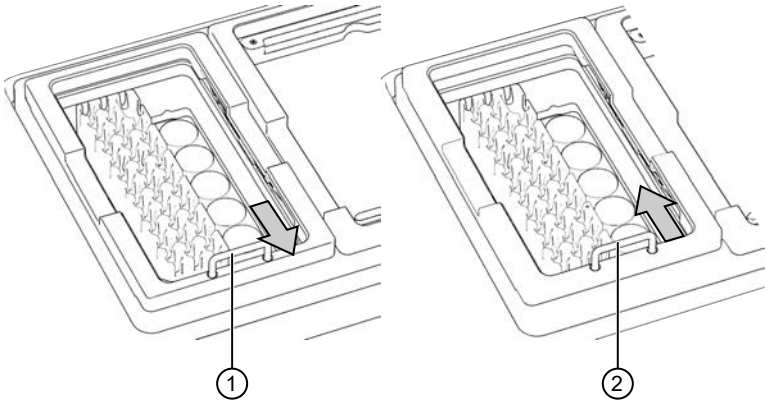
1. Gently tap the Quantitation Plate on the bench to force the reagents to the bottoms of the tubes.
2. Load the Quantitation Plate in position 1.



① Quantitation Plate position
② Quantitation Tube position

a. Pull the locking mechanism handle forward (1), then place the Quantitation Plate in the open position.

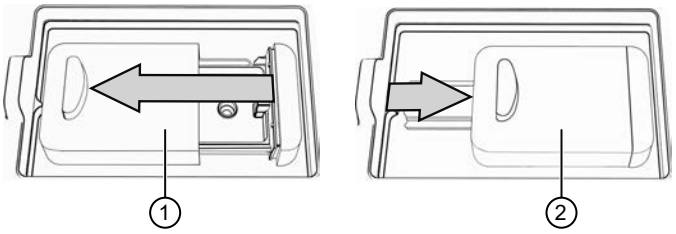
b. Push the locking mechanism handle back (2) to lock the plate in place.



① Unlocked (forward) ② Locked (back)

3. *(If needed)* Slide and hold the Qubit quantitation module cover to the left, then insert the Quantitation Tube. **Press down firmly** to properly seat the tube, then allow the module cover to close.

WARNING! Do not push the module cover closed. Forcing the module cover closed can damage the instrument.



① Open ② Closed

Confirm that all consumables are correctly installed

CAUTION! To ensure correct and safe instrument operation, you must confirm that all consumables are installed correctly on the deck before you start a run. The instrument cameras confirm that all required reagents are in place, no reagents have expired, and that foil seals have been removed. The vision system does not verify all aspects of the consumable setup before beginning each run.

1. Confirm.
   - Foil seals have been removed from the purification plate(s). Do not remove foil seal from the Quantitation Plate.
   - Each cartridge is at the correct location and in the correct orientation. Press down on all cartridges to ensure that they are firmly seated in place.
   - The 12-Well Tip Comb is in place.
   - The Quantitation Plate is in the correct location, in the correct orientation, and locked in place.
   - *(If needed)* The Quantitation Tube is firmly seated in the Qubit™ Quantitation Module.

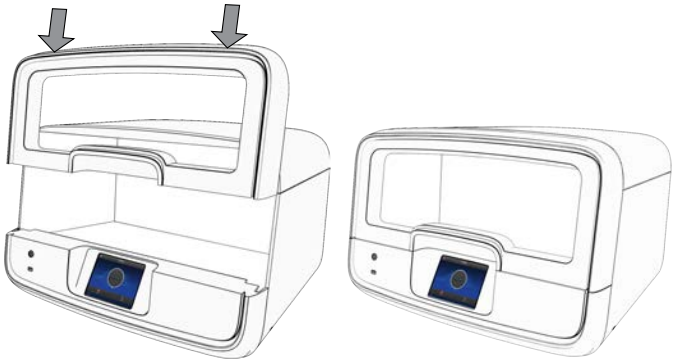
- The Purification Tip Cartridges are in the correct location, in the correct orientation, and locked in place.

If the vision system detects an error, the location indicator will not turn gray in the touchscreen.

2. If needed, tap **Help**, then accept each warning message appropriately to proceed.

Start the run

1. When you have loaded all the reagents and consumables, tap **Next**.
2. Close the instrument door by pressing down on both top corners. Ensure that the door is locked after closing it.



The onboard cameras confirm that all reagents are in place and have not expired.

3. Tap **Start**.

   The time remaining until the purification is complete is displayed and the interior lighting turns green.

Note:

- If you need to stop the run for any reason, tap **Cancel**, then tap **Yes** to confirm the cancellation.
- The interior lighting turns off during quantitation, then turns blue when the run is complete.
- If the Genexus™ Purification Instrument encounters a problem during the run, it aborts the run and displays the error on the instrument touchscreen. The interior lighting turns red.

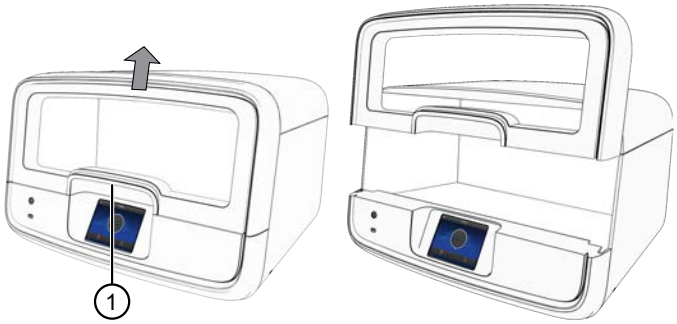
The interior light turns blue and the touchscreen displays **Run Complete** when the Genexus™ Purification System has finished the run. Quantitation results are available immediately, for more information, see “View and export quantitation results” on page 38.

Unload and UV clean the instrument

Note: Do not allow purified nucleic acids to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

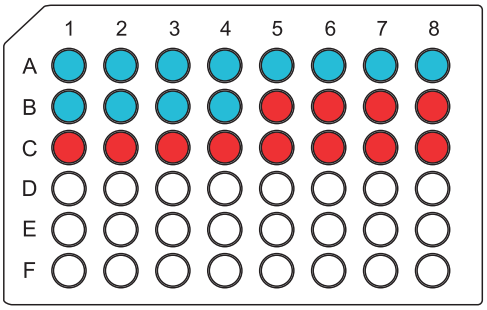
1. In the touchscreen, tap **Unload**. The door unlocks.

2. Lift the instrument door to access the instrument deck.



① Hold here, then lift.

3. Remove the 48-Well Nucleic Acid Archive Plate, containing the purified sample DNA and RNA.



- DNA is in wells A1–B4.
- RNA is in wells B5–C8.

Note: If using the purified DNA or RNA immediately, transfer the sample to a sample input plate for sequencing. To determine the sample concentrations, see "View and export quantitation results" on page 38.

4. Seal the plate with a 48-Well Nucleic Acid Archive Plate Seal.
   Store purified samples at –20°C. For long term storage, keep at –80°C.

5. Remove and discard the deep-well sample input plates.
   a. Remove the FFPE DNA and RNA Purification Plate 1 from the instrument.
   b. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

WARNING! Liquid waste contains guanidine thiocyanate, dispose of properly.

   c. Dispose of the deep-well plate in an appropriate waste container.
   d. Repeat substep 5a through substep 5c to discard the FFPE DNA and RNA Purification Plate 2.

6. Unlock, then remove and dispose of the Purification Tip Cartridges in an appropriate waste container.

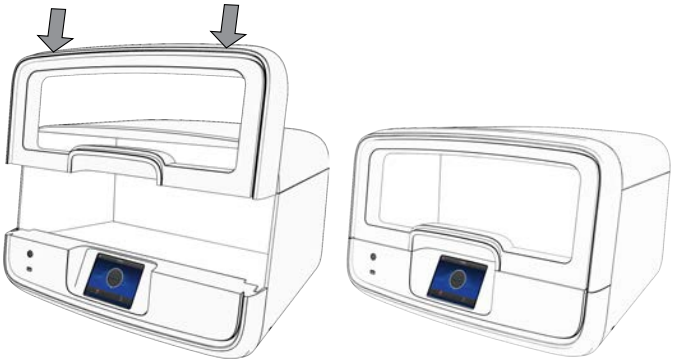
7. Unlock, then remove and dispose of the Quantitation Plate.
   a. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

WARNING! No data are currently available that address the mutagenicity or toxicity of the Qubit™ RNA BR Reagent (Component A). This reagent is known to bind nucleic acid and is provided as a solution in DMSO. Treat the Qubit™ RNA BR Reagent with the same safety precautions as all other potential mutagens and dispose of the dye in accordance with local regulations.

   b. Dispose of the deep-well plate in an appropriate waste container.

8. Open the Qubit quantition module cover, remove and discard the Quantitation Tube, then allow the module cover to close.

9. Close and lock the instrument door by pressing down on both top corners, then tap **Start UV Clean**.



The time remaining in the UV Clean is displayed. When complete, the instrument is ready to start a new purification run.

View and export quantitation results

Purification runs that include sample quantitation produce sample concentration results that can be accessed after the run is complete. Results can be accessed from the Run Complete screen or the home screen.

1. In the Run Complete screen, tap **View report**.

The **Saved Experiment Reports** screen opens. See step 5.

2. At any time after unloading and UV cleaning the instrument, sample concentration results can be accessed through the home screen. Tap ⚙ (**Settings**).

3. In the Settings screen, tap **Data Management**.

4. In the **Saved Experiment Reports** screen, tap ⌄ or ⌃ to page through the list. Locate the **Experiment Name** of interest, tap in the row to select the experiment, then tap **View Report**.

5. In the **Run Report** screen, tap **Quant Results** to view the sample concentration results.

6. Insert a USB drive into the USB port on the front of the instrument, then tap **Export Report**. Navigate to the file destination, then tap **Save**.

4 Genexus™ Multisample DNA Purification Protocol

Standalone workflow for Genexus™ Multisample DNA Purification

5 min

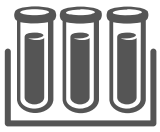
Create a purification run plan (page 42)

System-installed purification run plans that are specifically configured for each purification kit are available in the Genexus™ Purification Instrument software. You can use the system-installed purification run plan without change. If you want to modify any settings, copy the system-installed assay that best represents your experiment, then edit the settings as needed.

5–30 min

Prepare samples (page 46)

Enhancer solution, sample, and Proteinase K are added to the Multisample DNA Purification Plate, then immediately loaded on to the instrument for purification of DNA.



2 min

Load the Genexus™ Purification Instrument (page 51)

The purification run plan is selected and the run initiated. The instrument performs a pre-run UV clean, then reagents and consumables are loaded on to the instrument.

1 hr

Start the run (page 57)

After the sample plate and all reagents and consumables have been loaded the instrument door is closed and the run started.

Note: Sample quantification adds ~1 hour to the run time.

5 min

Unload the purified nucleic acids (page 58)

Remove and seal the 48-Well Nucleic Acid Archive Plate, or proceed immediately to sequencing of the purifed sample. Used reagents and consumables are removed from the instrument and a UV clean is performed.

Note: The Quantitation Plate requires equilibration to room temperature for at least 30 minutes before use. To save time experienced users can take the Quantitation Plate out of 4°C storage before creating a purification run plan and preparing samples.

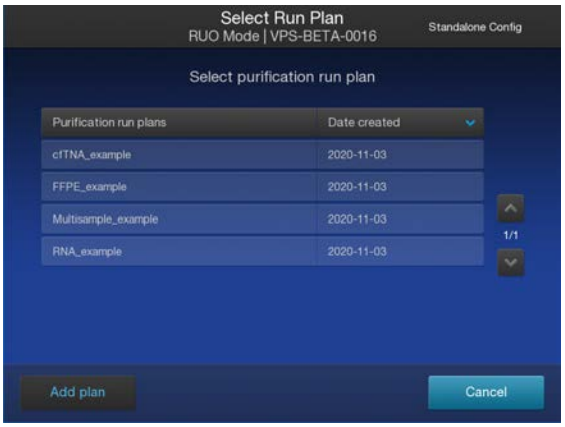
Create a purification run plan (Standalone mode)

In standalone mode users create a purification run plan through the instrument touchscreen.

Add a purification run plan (Standalone mode)

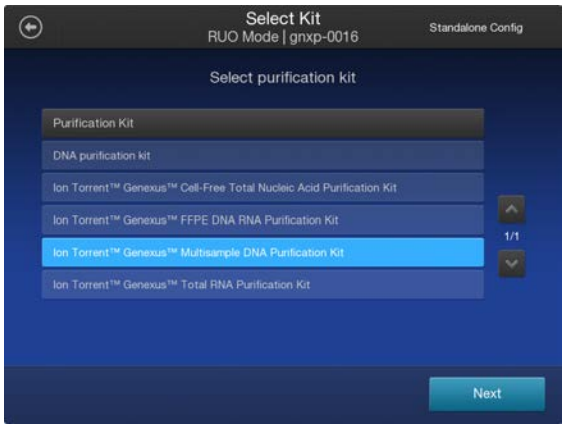
Note: We recommend that you create the run plan before preparing your samples and loading into the Multisample DNA Purification Plate.

1. Tap the touchscreen to wake the instrument. If the screen remains dark, see “Power on” on page 16.
2. Enter your username and password to sign in to the instrument.
3. Tap **Run**, then tap **Add plan**.

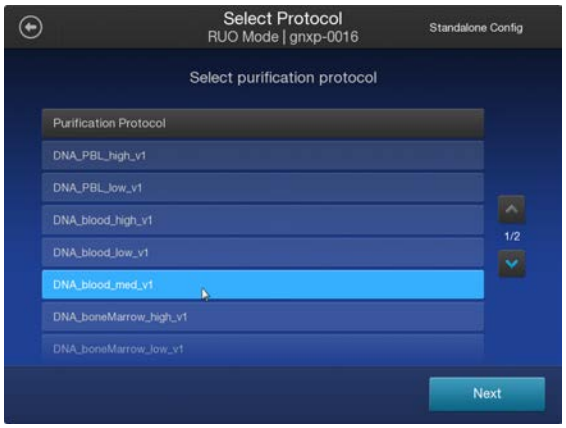


4. Tap in the entry box, enter a unique name for the run plan, then tap **Done** ▸ **Next**.

5. Select the Ion Torrent™ Genexus™ Multisample DNA Purification Kit, then tap **Next**.



6. Select the appropriate purification protocol, then tap **Next**.



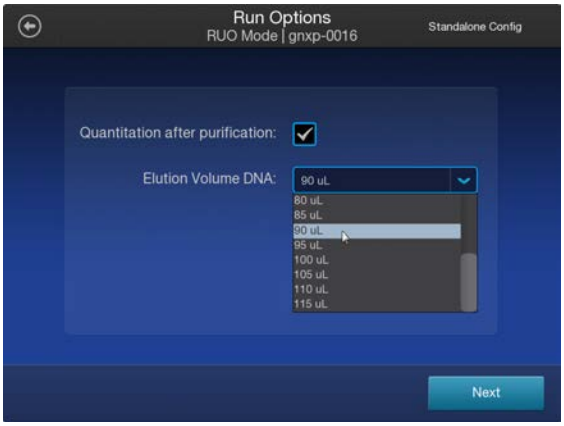
Sample type	Input volume	Select
Whole blood	50–100 µL	DNA_blood_low_v1
	100–200 µL	DNA_blood_med_v1
	200–400 µL	DNA_blood_high_v1
Peripheral blood leukocytes (PBL/buffy coat)	50–100 µL	DNA_PBL_low_v1
	100–200 µL	DNA_PBL_high_v1
Bone marrow	50–100 µL	DNA_boneMarrow_low_v1
	100–200 µL	DNA_boneMarrow_high_v1
Tissue	400 µL lysate from up to 10 mg low yield tissue	DNA_tissue_low_v1
	400 µL from up to 5 mg high yield tissue[1]	DNA_tissue_high_v1
Cell lysates[2]	400 µL	DNA_blood_high_v1

[1] For example, Spleen, Thymus, Pancreas
[2] For example, BMMC, PBMC, cell lines

7. Enable or disable **Quantitation after Purification**.

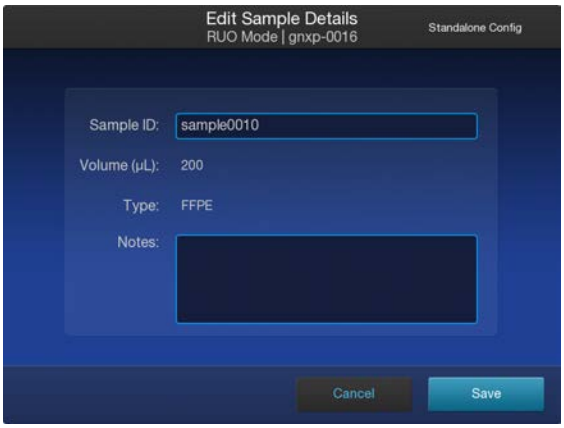
Note:

- The Quantitation Plate is required even if **Quantitation after Purification** is disabled.
- Disabling **Quantitation after Purification** may reduce the purification run time by up to 1 hour.
- Quantitation requires up to 5 µL of the eluted sample. If the expected sample yield is limiting, manual sample quantitation may be preferred to preserve sample.

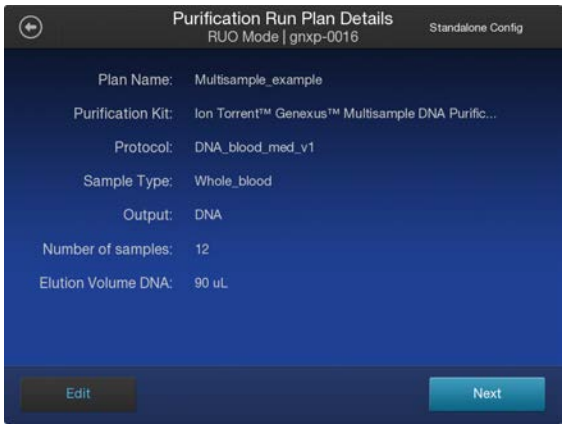


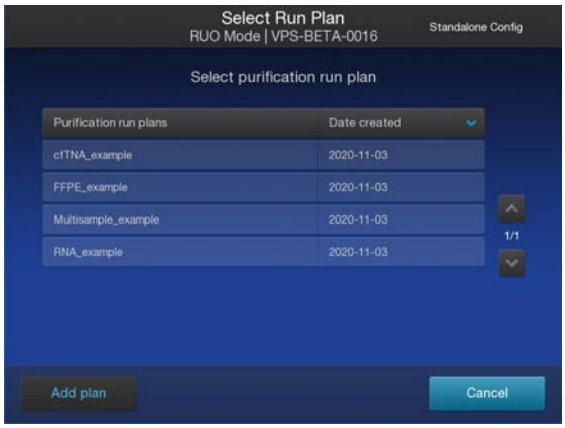
8. Accept the default elution volume. If needed, select the desired elution volume from the dropdown list, then tap **Next**.

9. *(Optional)* Change the number of samples and the sample details.
   a. In the **Sample Details** screen, deselect extra samples (for example, if you are only running 5 samples, deselect sample 6).
   b. In the **Sample Details** screen, tap on a sample ID to select the sample.
   c. Tap **Edit**, enter a new **Sample ID** and any **Notes**, then tap **Save**.
   d. Repeat substep 9b and substep 9c for each additional sample.
   e. Click **Next**.



10. Review the **Purification Run Plan Details**. Tap **Edit** to change any of your selections, otherwise tap **Next**.





The new **Run Plan** will now appear in the list of available **Purification Run Plans**.

Prepare the Quantitation Plate and consumables

Prepare the following cartridges and consumables:

- Genexus™ Multisample DNA Purification (Part. No. A45533)
  - Multisample DNA Purification Plate
  - 12-Well Tip Comb
- Genexus™ Nucleic Acid Quantitation, Broad Range (Part. No. A45537)
  - Quantitation Plate Broad Range
  - Quantitation Tube
- Genexus™ Purification Supplies 1 (Part. No. A45529)
  - Purification Tip Cartridge
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- P200 pipet and filtered tips

Equilibrate the Quantitation Plate

Note: The Quantitation Plate is required even if your run plan does not include sample quantitation.

1. Gently tap the Quantitation Plate on the bench to force the reagents to the bottoms of the wells. Alternatively, briefly centrifuge the plate at 1000 x *g* to collect the contents.

2. Replace the Quantitation Plate Plate in the protective opaque bag, then place the plate and Quantitation Tube on the bench next to the Genexus™ Purification Instrument.

   IMPORTANT!
   - Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
   - Allow at least 30 minutes for the Quantitation Plate to equilibrate to room temperature.

Prepare the consumables

Remove all cartridges and consumables from their packaging, then place them on the bench at room temperature.

Prepare the following cartridges and consumables:

- Genexus™ Purification Supplies 1
  - Purification Tip Cartridge
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- 12-Well Tip Comb

Prepare sample lysates

Procedural guidelines

- Perform all steps at room temperature (20–25°C) unless otherwise noted.
- When mixing samples by pipetting up and down, avoid creating bubbles.
- When working with whole blood:
  - Wear clean gloves and a clean lab coat.
  - Change gloves whenever you suspect that they are contaminated.
  - Open and close all sample tubes carefully. Avoid splashing or spraying samples.
  - Use a positive-displacement pipettor and RNase-free pipette tips.
  - Clean lab benches and equipment periodically with 10% bleach solution and rinse with 70% ethanol.
- Volumes for reagent mixes are given per sample. We recommend that you prepare master mixes for larger sample numbers. To calculate volumes for master mixes, refer to the per-well volume and add 5–10% overage.
- The plate chiller shuts off 60 minutes after run completion. Remove the 48-Well Nucleic Acid Archive Plate with purified nucleic acids from the instrument within 1 hour of run completion. Proceed immediately to sequencing or properly store the nucleic acids until use.

Before each use of the kit

- Thaw whole blood samples—stored at –80°C—at room temperature and store on ice until use.
- Keep fresh whole blood samples on ice until use.
- Centrifuge purification plates for 30 seconds at 1000 x *g* to collect the contents.

Materials required

Genexus™ Multisample DNA Purification (Cat. No. A45535)

- Multisample DNA Purification Plate
- Enhancer solution
- Proteinase K

Prepare bone marrow aspirate samples

Bone marrow aspirates can contain debris and a fatty layer that may interfere with isolation of nucleic acids. We recommend centrifuging the sample to isolate cells away from the debris and fatty layer.

1. Add 50–200 µL of bone marrow aspirate sample to a Eppendorf™ 1.5-mL DNA LoBind microcentrifuge tube on ice.
2. Centrifuge the sample at 0.2 x *g* for 10 minutes at 4°C.
3. Carefully remove the supernatant containing the unpelleted debris and fatty layer.

   IMPORTANT! Do not disturb the lightly pelleted cells. Leave a small amount of supernatant behind to ensure you don't disturb the cell pellet.
4. Resuspend the cell pellet in 100 µL or 200 µL of DNA homogenization buffer. Set the pipette to 50% of the total volume, then gently pipet up and down at least 10 times to resuspend the cell pellet.

Proceed to “Start the purification run”, samples are loaded in step 4 of “Add samples to Multisample DNA Purification Plate” on page 55.

Prepare tissue samples

Fresh or frozen tissue DNA yields can vary based on the tissue type. We recommend using the amounts suggested in Table 4. For more information on expected DNA yield by tissue type, see “Example tissue yields” on page 50. Adjust input amount based on your results. We recommend the use of a bead mill homogenizer for small amounts of tissue and use of a rotator-stator tissue homogenizer when processing larger amounts of tissue. Alternate methods of cell disruption can also be used. Do not exceed 5 mg of homogenized tissue for high yielding tissues or 10 mg of homogenized tissue for low yielding tissues as sample input to the Multisample DNA Purification Plate.

Table 4 Recommended input amount based on tissue type

Tissue type	Recommended tissue:buffer (mg:µL) ratio[1]	Maximum Multisample DNA Purification Plate tissue input amount[2]
Low yield tissue	1:40	10 mg
High yield tissue	1:80	5 mg

[1] Do not exceed the indicated ratio when homogenizing the sample prior to loading on the purification plate.
[2] Do not exceed the indicated amount as input into the sample purification plate.

1. Cut the sample into appropriately sized pieces. For larger samples, we recommend cutting the material into long, thin strips for faster homogenization.

2. Weigh the tissue sample, then calculate and add the recommended volume of DNA Homogenization buffer (for example, 5.0 mg high yield tissue add 400 µL DNA Homogenization buffer or for 25 mg low yield tissue add 1.0 mL DNA Homogenization buffer).

   Note: Maintain the recommended tissue to buffer ratio if using more or less tissue.

3. Homogenize the samples following the manufacturer's instructions for your homogenizer. Visually inspect the samples. If homogenization is incomplete, repeat step 3.

   Note: We recommend using a rotator-stator tissue homogenizer in 10 second pulses on ice, when homogenizing large amounts of tissue.

4. Transfer the lysate to a new tube. Ensure no beads are carried over if using a bead mill homogenizer.
   Keep homogenized samples on ice until use.

   STOPPING POINT Store homogenized samples a –80°C if not proceeding directly to sample loading.

Proceed to “Start the purification run”, samples are loaded in step 4 of “Add samples to Multisample DNA Purification Plate” on page 55.

Prepare peripheral blood leukocytes (PBL/buffy coat) samples

1. Pipet 2–5 mL fresh whole blood into 15-mL conical tubes.
2. Weigh each tube, then adjust volume if needed to properly balance tubes before centrifugation.
3. Centrifuge the samples in a swinging bucket rotor at 2,000 x *g* for 10 minutes at 4°C (Brake = 0–5). Keep samples on ice when complete.
4. Use a P1000 pipettor to transfer the plasma to a new 15-mL conical centrifuge tube.

   IMPORTANT! Leave a small amount of plasma behind. Do not disturb the buffy coat layer when transferring the plasma layer.

5. Transfer the buffycoat layer to a 1.5-mL Eppendorf LoBind™ tube on ice.

   Note: You should recover ~20% of the starting volume as buffy coat (for example, ~1 mL buffy coat from 5 mL whole blood).

6. Centrifuge at 100 x *g* for 5 minutes at 4°C, then carefully remove the remaining supernatant without disturbing the buffy coat cell layer.

Proceed to "Start the purification run", samples are loaded in step 4 of "Add samples to Multisample DNA Purification Plate".

Prepare cultured cell samples

Note: Up to 4 x 10^6 cultured cells can be processed per sample.

1. Centrifuge cells in culture media at 100 x *g* for 5 minutes at 4°C, then carefully remove the supernatant without disturbing the cell pellet.

   Note: Thaw previously frozen cell pellets on ice, then remove as much culture media as possible without disturbing the cell pellet.

2. *(Optional)* Wash the cell pellet.
   a. Resuspend the cell pellet in 1/2 volume of 1X PBS.
   b. Centrifuge cells at 100 x *g* for 5 minutes at 4°C, then carefully remove the supernatant without disturbing the cell pellet.
3. Add 400 µL of DNA Homogenization buffer to each sample cell pellet, set a P1000 pipettor to 300 µL, then slowly pipet up and down 10–15 times.

   IMPORTANT! The sample can be viscous. Pipet up and down thoroughly to ensure complete mixing.

Proceed to "Start the purification run", samples are loaded in step 4 of "Add samples to Multisample DNA Purification Plate".

Example tissue yields

Table 5 Recommended input amount based on tissue type

Tissue type	Recommended tissue:buffer (mg:µL) ratio[1]	Maximum Multisample DNA Purification Plate tissue input amount[2]	Potential yield[3]
High yielding tissues			
High yield tissue (25 mg)	1:80	5 mg	~10–30 µg
Liver (25 mg)	1:80	5 mg	10–30 µg
Brain (25 mg)	1:80	5 mg	15–30 µg
Thymus (25 mg)	1:80	5 mg	15–30 µg
Kidney (25 mg)	1:80	5 mg	15–30 µg
Spleen (25 mg)	1:80	5 mg	15–75 µg
Mouse tail (1.2 cm tip)	1:80	5 mg	10–25 µg
Low yielding tissues			
Low yield tissue (25 mg)	1:40	10 mg	~5–10 µg
Lung (25 mg)	1:40	10 mg	5–10 µg
Heart (25 mg)	1:40	10 mg	5–10 µg
Breast (25 mg)	1:40	10 mg	5–10 µg

[1] Do not exceed the indicated ratio when homogenizing the sample prior to loading on the purification plate.
[2] Do not exceed the indicated amount as input into the sample purification plate.
[3] All yields are approximate and not indicative of purification performance.

Load the Genexus™ Purification Instrument and start the run

This section describes how to perform the following procedures:

- Set up the Genexus™ Purification Instrument for use by loading all of the required reagents and consumables
- Start an Genexus™ Purification Instrument run

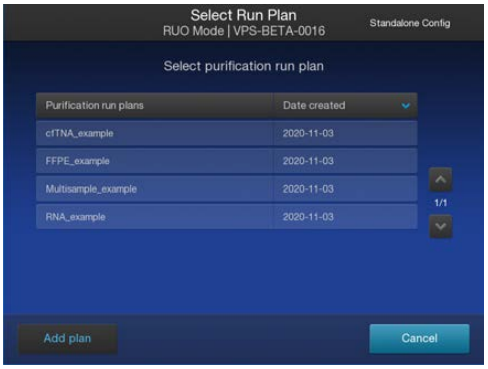
Note: Do NOT load any consumables onto the Genexus™ Purification Instrument until after the instrument has performed the pre-run UV cleaning.

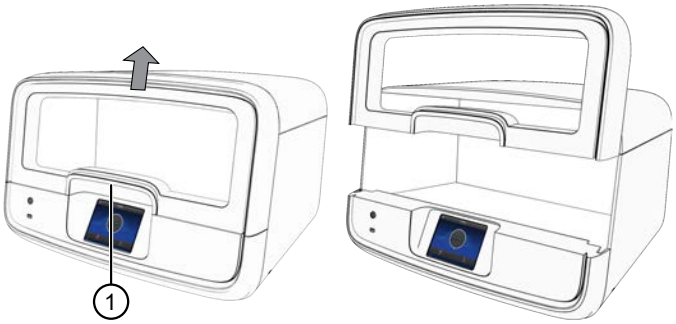
Start the purification run

1. Tap **Run**, then tap to select the run plan you created for this run.

2. Ensure that the run plan selected is correct, then tap **Next**.
   The instrument performs a 2 minute UV clean, then unlocks the door.

3. Lift the instrument door to the stop.





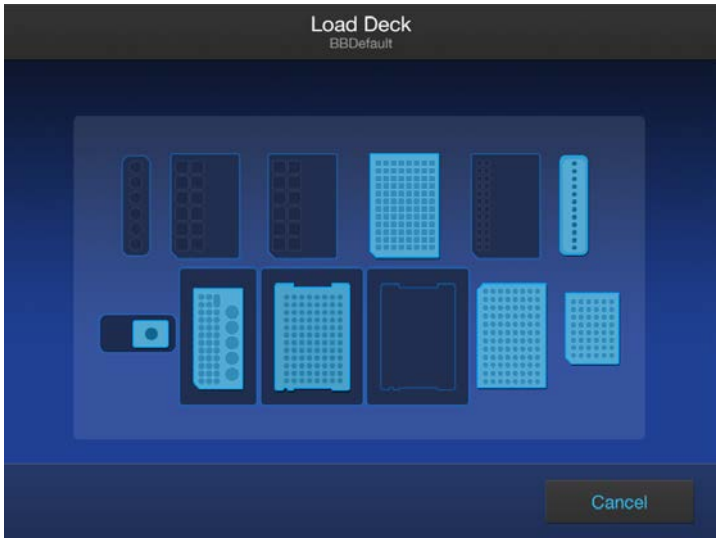
① Hold here, then lift.

Load the Genexus™ Purification Instrument

IMPORTANT!

- Do NOT load any consumables onto the Genexus™ Purification Instrument until after the instrument has performed the pre-run UV cleaning.
- Ensure that all components are clean and dry before loading them onto the Genexus™ Purification Instrument.
- Ensure that the Reagent and Quantitation station compartments are free of condensate before loading components. If needed, use a lint-free wipe to dry the compartment.

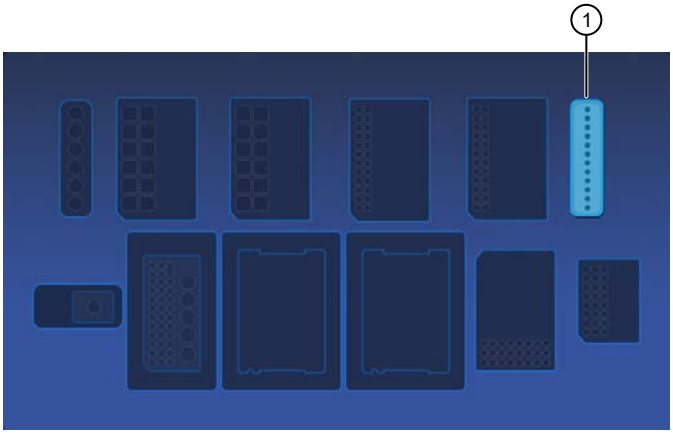
Follow the on-screen prompts to load the Genexus™ Purification Instrument.



Load the 12-Well Tip Comb, Purification Tip Cartridge, and 48-Well Nucleic Acid Archive Plate

1. Unwrap, then load a new 12-Well Tip Comb.

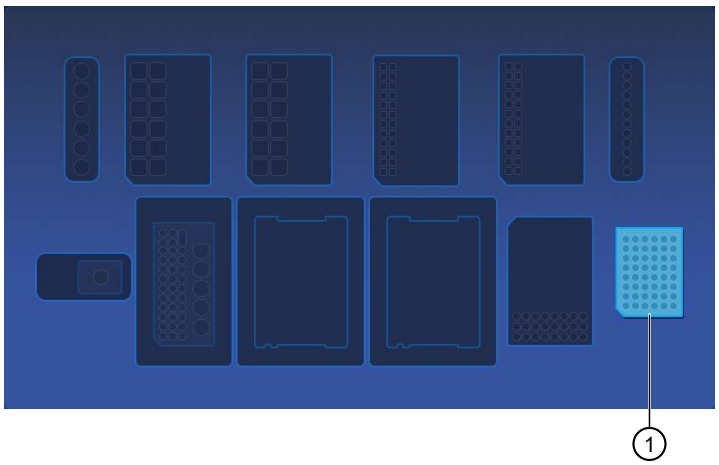
Note: Ensure the tip comb is straight and that the tabs are not bent or broken. If needed, gently bend the tip comb in the opposite direction to the curvature to straighten the tip comb before installing it.



① 12-Well Tip Comb position

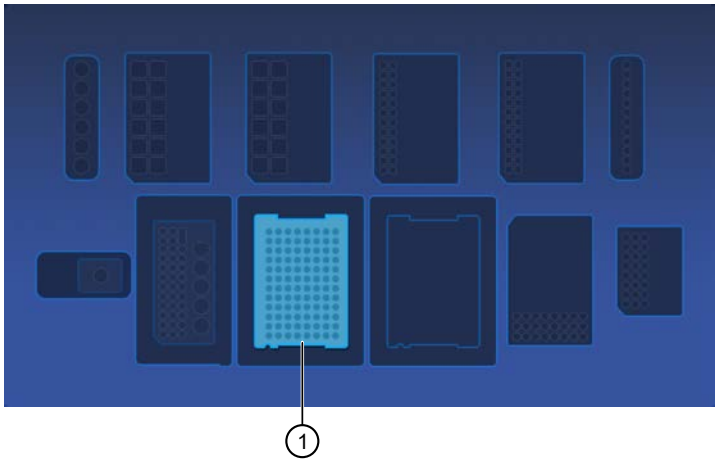
2. Unwrap, then load a new 48-Well Nucleic Acid Archive Plate.

Note: The 96-Well Nucleic Acid Output Plate is not required when performing the purification when in Standalone Only mode.



① 48-Well Nucleic Acid Archive Plate position

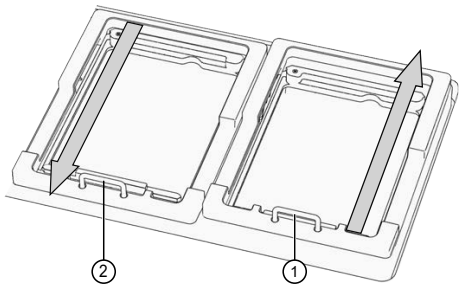
3. Unwrap a Purification Tip Cartridge and remove the cover to expose the pipette tips, then load it in position 1.



① Purification Tip Cartridge position 1

a. Pull the locking mechanism handle forward (callout 2), then place the tip box in the open position.

b. Push the locking mechanism handle back (callout 1) to lock the tip box in place.



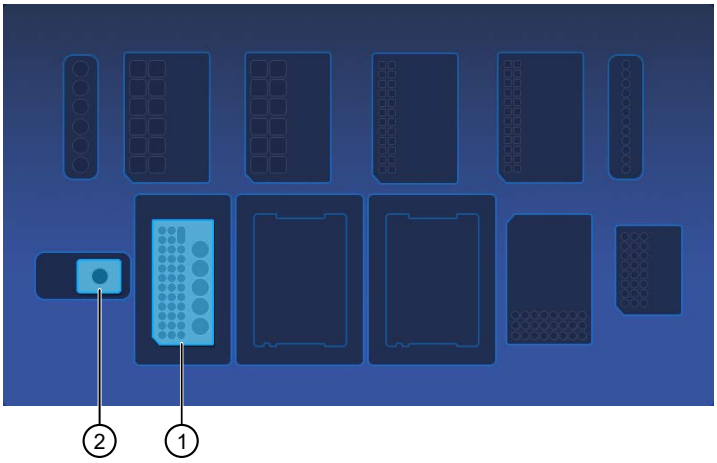
① Unlocked (forward)
② Locked (back)

Load the quantitation reagents and consumables

Note:

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- The Quantitation Plate is required even if your run plan does not include sample quantitation.
- The Quantitation Tube is not required if your run plan does not include sample quantitation.

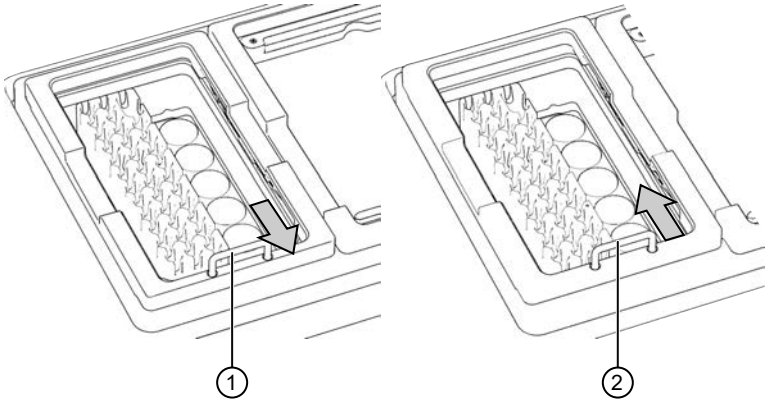
1. Gently tap the Quantitation Plate on the bench to force the reagents to the bottoms of the tubes.
2. Load the Quantitation Plate in position 1.



① Quantitation Plate position
② Quantitation Tube position

   a. Pull the locking mechanism handle forward (1), then place the Quantitation Plate in the open position.

   b. Push the locking mechanism handle back (2) to lock the plate in place.

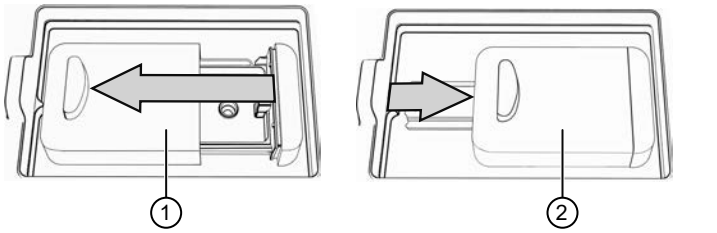


① Unlocked (forward)

② Locked (back)

3. *(If needed)* Slide and hold the Qubit quantitation module cover to the left, then insert the Quantitation Tube. **Press down firmly** to properly seat the tube, then allow the module cover to close.

WARNING! Do not push the module cover closed. Forcing the module cover closed can damage the instrument.



① Open ② Closed

Add samples to Multisample DNA Purification Plate

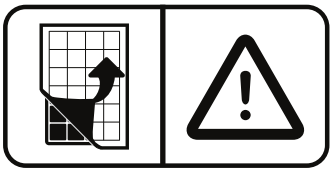
The Multisample DNA Purification Plate contains magnetic beads in row D.

1. Briefly centrifuge the sealed Multisample DNA Purification Plate at 1000 x *g* for 30 seconds to collect the contents. Alternatively, gently flick or tap the plate on the bench to force the reagents to the bottoms of the tubes.

IMPORTANT! Do not create bubbles when preparing the plate.

2. Inspect the plate to ensure the contents of all rows are at the bottom of the wells. If needed repeat step 1.

3. Carefully remove the plate seal without disturbing the contents.



4. Add the samples to the Multisample DNA Purification Plate as indicated in Table 6.

IMPORTANT!

- Do not pre-mix the DNA Enhancer solution and Proteinase K.
- Do not change the order of pipetting.
- Add samples to consecutive wells beginning with sample 1 in well A1, through sample 12 in well B4. Do not skip wells.
- Once all components are added, proceed immediately to the instrument processing. There is no need for manual mixing beforehand.

a. Add X µL DNA Enhancer solution to each well in Row A of the Multisample DNA Purification Plate.

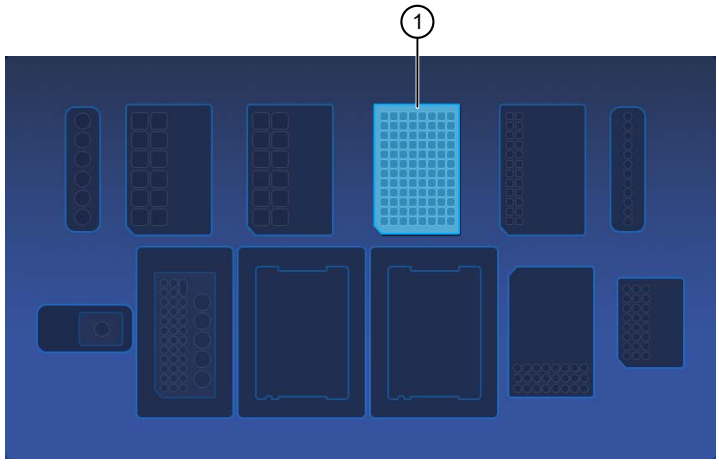
b. Add Y µL sample to each well in Row A.

c. Add Z µL Proteinase K solution to each well in Row A.

Table 6

DNA Enhancer solution (X µL)	Sample Volume (Y µL)	Proteinase K Volume (Z µL)
Sample type: whole blood		
5	50	5
10	100	10
20	200	20
30	300	30
40	400	40
Sample type: bone marrow aspirate		
10	100	10
20	200	20
Sample type: fresh frozen tissue		
—	400	—
Sample type: peripheral blood leukocytes / buffy coat		
5	50	10
10	100	20
15	150	30
20	200	40
Sample type: cell lines		
40	400	40

5. Immediately load the 96 deep-well Multisample DNA Purification Plate with the samples in position 1.



① Multisample DNA Purification Plate position

Confirm that all consumables are correctly installed

CAUTION! To ensure correct and safe instrument operation, you must confirm that all consumables are installed correctly on the deck before you start a run. The instrument cameras confirm that all required reagents are in place, no reagents have expired, and that foil seals have been removed. The vision system does not verify all aspects of the consumable setup before beginning each run.

1. Confirm.
   - Foil seals have been removed from the purification plate(s). Do not remove foil seal from the Quantitation Plate.
   - Each cartridge is at the correct location and in the correct orientation. Press down on all cartridges to ensure that they are firmly seated in place.
   - The 12-Well Tip Comb is in place.
   - The Quantitation Plate is in the correct location, in the correct orientation, and locked in place.
   - *(If needed)* The Quantitation Tube is firmly seated in the Qubit™ Quantitation Module.
   - The Purification Tip Cartridges are in the correct location, in the correct orientation, and locked in place.

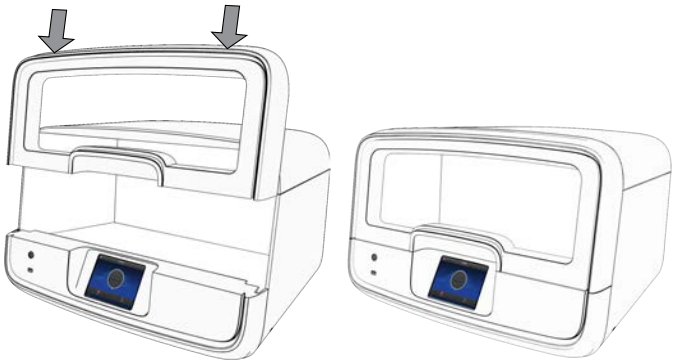
   If the vision system detects an error, the location indicator will not turn gray in the touchscreen.

2. If needed, tap **Help**, then accept each warning message appropriately to proceed.

Start the run

1. When you have loaded all the reagents and consumables, tap **Next**.

2. Close the instrument door by pressing down on both top corners. Ensure that the door is locked after closing it.



   The onboard cameras confirm that all reagents are in place and have not expired.

3. Tap **Start**.

   The time remaining until the purification is complete is displayed and the interior lighting turns green.

Note:

- If you need to stop the run for any reason, tap **Cancel**, then tap **Yes** to confirm the cancellation.
- The interior lighting turns off during quantitation, then turns blue when the run is complete.
- If the Genexus™ Purification Instrument encounters a problem during the run, it aborts the run and displays the error on the instrument touchscreen. The interior lighting turns red.

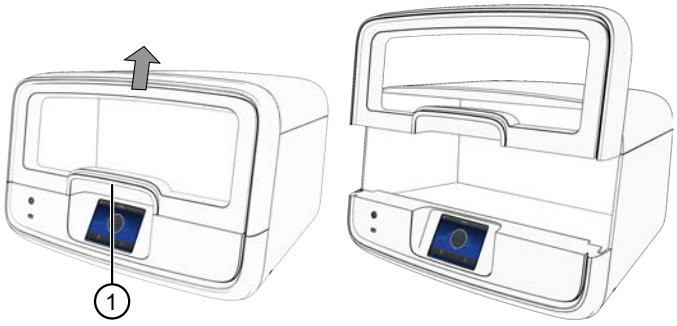
The interior light turns blue and the touchscreen displays **Run Complete** when the Genexus™ Purification System has finished the run. Quantitation results are available immediately, for more information, see "View and export quantitation results" on page 38.

Unload and UV clean the instrument

Note: Do not allow purified samples to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

1. In the touchscreen, tap **Unload**.
   The door unlocks.

2. Lift the instrument door to access the instrument deck.



① Hold here, then lift.

3. Remove the 48-Well Nucleic Acid Archive Plate, containing the purified sample DNA in rows A1–8 and B1–4.

Note: If using the purified DNA immediately, transfer the sample to a sample input plate for sequencing. To determine the sample concentrations, see "View and export quantitation results" on page 60.

4. Seal the plate with a 48-Well Nucleic Acid Archive Plate Seal.
   Store purified samples at –20°C.

5. Remove and discard the deep-well sample input plates.
   a. Remove the Multisample DNA Purification Plate from the instrument.

b. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

WARNING! Liquid waste contains guanidine thiocyanate, dispose of properly.

c. Dispose of the deep-well plate in an appropriate waste container.

6. Unlock, then remove and dispose of the Purification Tip Cartridges in an appropriate waste container.

7. Unlock, then remove and dispose of the Quantitation Plate.
   a. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

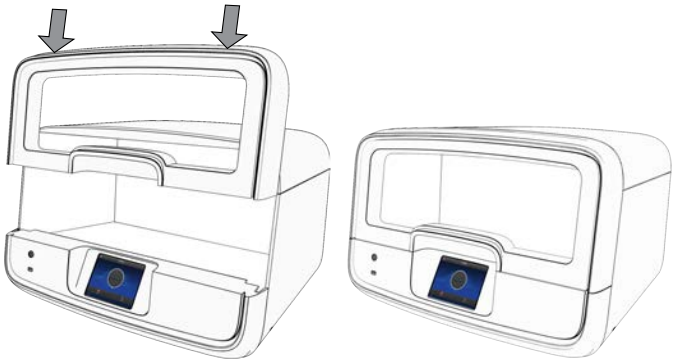
WARNING! No data are currently available that address the mutagenicity or toxicity of the Qubit™ RNA BR Reagent (Component A). This reagent is known to bind nucleic acid and is provided as a solution in DMSO. Treat the Qubit™ RNA BR Reagent with the same safety precautions as all other potential mutagens and dispose of the dye in accordance with local regulations.

   b. Dispose of the deep-well plate in an appropriate waste container.

8. Open the Qubit quantition module cover, remove and discard the Quantitation Tube, then allow the module cover to gently close.

IMPORTANT! Do not allow the module cover to spring shut.

9. Close and lock the instrument door by pressing down on both top corners, then tap **Start UV Clean**.



The time remaining in the UV Clean is displayed. When complete, the instrument is ready to start a new purification run.

View and export quantitation results

Purification runs that include sample quantitation produce sample concentration results that can be accessed after the run is complete. Results can be accessed from the Run Complete screen or the home screen.

1. In the Run Complete screen, tap **View report**.

   The **Saved Experiment Reports** screen opens. See step 5.

2. At any time after unloading and UV cleaning the instrument, sample concentration results can be accessed through the home screen. Tap ⚙ (**Settings**).

3. In the Settings screen, tap **Data Management**.

4. In the **Saved Experiment Reports** screen, tap ⌄ or ⌃ to page through the list. Locate the **Experiment Name** of interest, tap in the row to select the experiment, then tap **View Report**.

5. In the **Run Report** screen, tap **Quant Results** to view the sample concentration results.

6. Insert a USB drive into the USB port on the front of the instrument, then tap **Export Report**. Navigate to the file destination, then tap **Save**.

A

Troubleshooting

General

Observation	Possible cause	Recommended action
Run Fails	Instrument detected an error or user aborted the run.	1. Record the error message displayed on the instrument touchscreen. 2. Export the CSA file from the Run Report. 3. Remove the consumables from the deck, then clean the instrument. If possible, retain the consumables for troubleshooting. **Note:** Depending on the point during the purification run that the abort occurred, the consumables and reagents may not be suitable for reuse. 4. Restart the run beginning from "Prepare samples". If the run fails again, contact Technical Support to troubleshoot the problem.
Unexpected sample concentration	Bubble in 48-Well Nucleic Acid Archive Plate sample well.	Manually determine sample concentration.
		Check that all sample wells contain the correct volume.
Low sample volume in some 48-Well Nucleic Acid Archive Plate wells	Cause 1 for the observation specified in the title element. Insert paragraphs, notes, lists, figures, or tables as needed.	Action 1 for Cause 1. Insert paragraphs, notes, lists, figures, or tables as needed.
		Action 2 for Cause 1. This will appear in a separate row from Action 1.
Magnetic beads in 48-Well Nucleic Acid Archive Plate wells	Carry over of magnetic beads.	This can lead to lower observed quantitation value but does not affect sequencing.

Genexus™ FFPE DNA and RNA Purification

Observation	Possible cause	Recommended action
Lower than expected yield	Protease digestion incubation temperatures were below 60°C and 90°C.	Use a calibrated thermometer to verify incubation oven temperature. Reset oven temperature if needed.
		Ensure incubators have reached target temperature before starting incubation.
	Restricted airflow limits heat transfer to the sample tubes during incubation.	Incubate samples in a four way rack. Do not use a rack with a solid bottom.
	Incorrect volume of DNA Enhancer solution or Proteinase K solution added.	Ensure the correct volume of 1X DNA Digestion Master Mix (FFPE Protease buffer and Proteinase K solution) is added.
	Low lysate recovery from AutoLys M tube.	Ensure AutoLys M tube caps are securely closed before incubation.
		Allow AutoLys M tubeto cool to room temperature before centrifugation.
	Delay in starting the purification run after preparing the FFPE DNA and RNA Purification Plate 1.	Start the purification run in 5–10 minutes after addition of samples.
	Incorrect sample input amount.	Use recommended tissue input amount.
	Incorrect quantitation	Avoid prolonged exposure of the Quantitation Plate to light.
		Equilibrate the Quantitation Plate to room temperature for at least 30 minutes before starting the purification run.
		Ensure reagents properly thaw.
		Avoid introducing bubbles into samples.
Cloudy samples in some 48-Well Nucleic Acid Archive Plate wells	Incomplete deparaffinization.	Follow FFPE sample preparation with AutoLys M tube protocol closely. This does not affect sequencing.

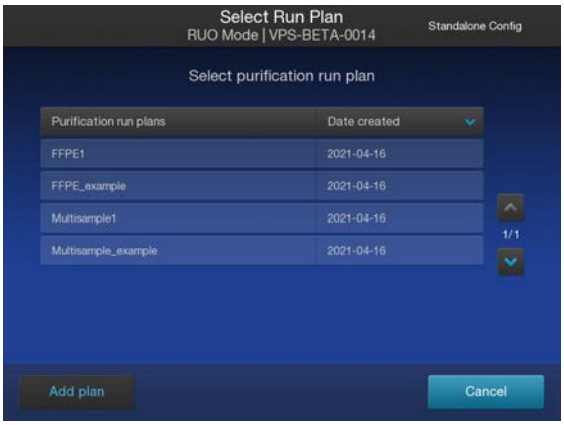
Genexus™ Multisample DNA Purification

Observation	Possible cause	Recommended action
Lower than expected DNA yield	Incorrect volume of DNA Enhancer solution or Proteinase K solution added.	Ensure correct the correct volume of DNA Enhancer solution and Proteinase K solution is added to the given volume of sample.
		Add DNA Enhancer solution and Proteinase K solution to the sample in the correct order.
	Delay in starting the purification run after preparing the Multisample DNA Purification Plate.	Start the purification run in 5–10 minutes after addition of Proteinase K solution.
	Low quality sample.	Use fresh samples if possible.
		Do not freeze samples.
	Incorrect sample processing.	Process samples at 4°C. Keep on ice. Avoid repeated freeze-thaw cycles.
		Buffy coat—Maintain correct blood to buffy coat ratio.
		Bone marrow—Centrifuge at 0.2 x *g* for 10 minutes at 4°C. Do not remove the loosely pelleted cells when removing the fatty layer and unpelleted debris.
		Bone marrow—Ensure complete removal of the fatty layer and unpelleted debris. Leave a small amount of supernatant behind to ensure you don't disturb the cell pellet.
		Tissue—Maintain correct tissue sample to DNA Homogenization bufferbuffer ratio.
	Samples left on instrument after run completion.	Unload 48-Well Nucleic Acid Archive Plate as soon as possible after the purification run is complete. The onboard plate chiller turns off after 60 minutes.
	DNase contamination	Use good laboratory technique. Wear personal protective equipment, change gloves regularly, use care when opening reagent vials and close after use. Regularly clean workspaces with 10% bleach solution or 70% isopropanol.
	Incorrect quantitation	Avoid prolonged exposure of the Quantitation Plate to light.
		Equilibrate the Quantitation Plate to room temperature for at least 30 minutes before starting the purification run.
		Ensure reagents properly thaw.
		Avoid introducing bubbles into samples.

B Supplemental Information

Delete a run plan

1. Tap **Run**, then tap the plan to be deleted.



2. In the **Purification Run Plan Details** screen, tap **Edit** , then tap **Delete**.

3. Tap **Delete** to confirm deletion of the selected purification run plan.

Note: Deletion of a purification run plan is irreversible and can not be undone.

Prepare FFPE curl samples using Citrisolv Clearing Agent

Note: We recommend the use of AutoLys M Tubes for the preparation of FFPE samples.

Before you begin

- Pre-heat heat blocks, water baths, or incubators to 50°C, 55°C and 90°C.
- Prepare Protease Digestion and DNase Digestion solutions immediately before use.

Remove paraffin from the sections

Preheat a heating block (with lid) or incubator at 50°C.

1. Label a nuclease-free 1.5-mL low-retention microcentrifuge tube for each FFPE tissue sample. Label each tube (cap and side) with its Sample ID using a marker that is resistant to xylene and ethanol.
2. Add each FFPE section curl to a separate labeled tube.
3. Add 1 mL of Citrisolv Clearing Agent, or equivalent (for example, xylene) to the section, then vortex briefly.
4. Centrifuge briefly to ensure that all the tissue is submerged in the solvent.
5. Heat the sample for 3 minutes at 50°C to melt the paraffin.
6. Centrifuge the sample at maximum speed for 2 minutes to collect the tissue at the bottom of the tube.
   - If the sample does not form a tight pellet, centrifuge again for 2 minutes.
   - If a tight pellet still does not form, proceed with caution to the next step.
7. Remove and dispose of the solvent appropriately. For more information, see “Chemical safety” on page 92.

   Note:
   - The tissue is usually clear and can be difficult to see.
   - If the pellet is loose, leave 50–100 µL of solvent in the tube to avoid removing any tissue pieces.

Wash section curls with ethanol

1. Add 1 mL of 100% ethanol to the tissue pellet and vortex.
   The tissue should turn opaque.
2. Centrifuge the sample at maximum speed for 2 minutes.
3. Remove and discard as much ethanol as possible without disturbing the pellet.

4. Repeat step 1 through step 3 to ensure complete solvent removal.

   IMPORTANT! Omit the second wash when working with small samples to avoid sample loss.

5. Dry the pellet using one of the following methods:

   - Use a centrifugal vacuum concentrator.

Temperature	Time
40–45°C (medium heat)	<20 minutes
37–40°C (low heat)	20–40 minutes

   - Air dry at room temperature for 15–45 minutes.

STOPPING POINT *(Optional)* The dried samples can be stored at room temperature up to 72 hours.

Prepare 1X Protease Digestion Master Mix

Note: We recommend preparation of the protease digestion master mix immediately before use.

1. Vortex the FFPE Protease buffer and Proteinase K (red cap) supplied in the kit for ~5 seconds each, then pulse centrifuge to collect the contents.

2. In a 1.5-mL low-retention microcentrifuge tube, prepare a 1X Protease Digestion Master Mix as indicated in Table 2, where "n" is the number of tissue samples:

   Table 7

Component	Volume per reaction
FFPE Protease buffer	(n+1) × 200 µL
Proteinase K (red cap)	(n+1) × 10 µL
Total volume	**(n+1) × 210 µL**

3. Vortex for ~5 seconds to mix, then pulse centrifuge to collect.

Digest with Protease

Note: To minimize the amount of time between protease digestion and starting the purification run on the instrument we recommend that you prepare the reagents and consumables that are required by the instrument during the 90°C incubation (step 4).

1. Pipet 210 µL 1X Protease Digestion Master Mix to each labelled tube.

2. Gently flick the tube to mix and to immerse the tissue.

   Note: If the tissue sticks to the sides of the tube, use a pipette tip to push the tissue into the solution or centrifuge briefly to immerse the tissue in the solution.

3. Incubate at 55°C for 60 minutes, then centrifuge briefly to collect any condensation droplets.

   Note:
   - If you are using an incubator, use a 4-way microtube rack to allow homogeneous incubation of the samples.
   - Incubation at 55°C can be extended overnight to increase DNA yields.

4. Incubate at 90°C for 60 minutes.

   Note:
   - Ensure that tubes are tightly capped. Tube caps can pop open during the incubation.
   - Set up the processing plates during the incubation.

5. Allow samples to cool to room temperature, then centrifuge briefly to collect any condensation droplets.

STOPPING POINT If needed, samples can be stored over night at –20°C.

Proceed to "Add samples to FFPE DNA and RNA Purification Plate 1" on page 29.

Prepare FFPE slide samples using Citrisolv Clearing Agent

Note: We recommend the use of AutoLys M Tubes for the preparation of FFPE samples.

Remove paraffin from the sections

1. Submerge the slides in Citrisolv Clearing Agent, or equivalent (for example, xylene) for 5 minutes.
2. Remove the slides, then drain the excess solvent by tilting the slide holder.
3. Submerge the slides in 100% ethanol for 5 minutes.
4. Remove the slides, then drain the excess ethanol by tilting the slide holder.
5. Air dry the slides for 15 minutes.

Prepare 1X Protease Digestion Master Mix

Note: We recommend preparation of the protease digestion master mix immediately before use.

1. Vortex the FFPE Protease buffer and Proteinase K (red cap) supplied in the kit for ~5 seconds each, then pulse centrifuge to collect the contents.
2. In a 1.5-mL low-retention microcentrifuge tube, prepare a 1X Protease Digestion Master Mix as indicated in Table 8, where "n" is the number of tissue samples:

   Table 8

Component	Volume per reaction
FFPE Protease buffer	(n+1) × 225 µL
Proteinase K (red cap)	(n+1) × 10 µL
Total volume	**(n+1) × 235 µL**

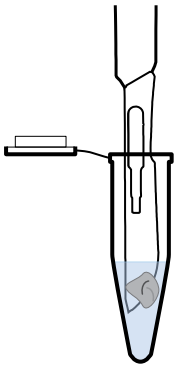
3. Vortex for ~5 seconds to mix, then pulse centrifuge to collect.

Collect the tissue

1. Label a nuclease-free 1.5-mL low-retention microcentrifuge tube for each FFPE tissue sample. Label each tube (cap and side) with its Sample ID using a marker that is resistant to xylene and ethanol.
2. Pipet 210 µL 1X Protease Digestion Master Mix to each labelled tube.
3. Pipet 2–4 µL of 1X Protease Digestion Master Mix from the labeled tube evenly across the fixed tissue section on the slide to pre-wet the tissue section.

   Note: Larger sections may need an additional 2–4 µL of Digestion Buffer.

4. Using a sterile disposable scalpel or clean razor blade, scrape the tissue in a single direction, then collect the tissue into a cohesive mass on the tip of the scalpel blade.
5. Carefully insert the scalpel blade with the tissue mass into the 1X Protease Digestion Buffer in the 1.5-mL low-retention microcentrifuge tube. Rinse the tissue from the blade into the buffer, then ensure that the entire mass is in solution.



6. Remove and inspect the blade to ensure that no tissue remains on it.
7. Inspect the slide to ensure that all the tissue has been removed (the slide should be translucent). Discard the scalpel in a waste container for sharp objects.

8. Gently flick the tube to mix and to immerse the tissue.

   Note: If the tissue sticks to the sides of the tube, use a pipette tip to push the tissue into the solution or centrifuge briefly to immerse the tissue in the solution.

Digest with Protease

Note: To minimize the amount of time between protease digestion and starting the purification run on the instrument we recommend that you prepare the reagents and consumables that are required by the instrument during the 90°C incubation (step 2).

1. Incubate at 55°C for 60 minutes, then centrifuge briefly to collect any condensation droplets.

   Note:
   - If you are using an incubator, use a 4-way microtube rack to allow homogeneous incubation of the samples.
   - Incubation at 55°C can be extended overnight to increase DNA yields.

2. Incubate at 90°C for 60 minutes.

   Note:
   - Ensure that tubes are tightly capped. Tube caps can pop open during the incubation.
   - Set up the processing plates during the incubation.

3. Allow samples to cool to room temperature, then centrifuge briefly to collect any condensation droplets.

STOPPING POINT If needed, samples can be stored over night at –20°C.

Proceed to “Add samples to FFPE DNA and RNA Purification Plate 1” on page 29.

Clean and decontaminate the Genexus™ Purification Instrument

About the decontamination protocol

The following decontamination protocol should be performed in the event of accidental spills or leaks of samples or reagents during a run.

The Genexus™ Purification System includes an automated UV cleaning function that must be performed after every run. The cleaning routine is initiated from the instrument touchscreen and is designed to minimize potential contamination. During the routine, the instrument irradiates the deck with ultraviolet light for 2 minutes after all consumables have been removed from the instrument.

IMPORTANT! Although the Genexus™ Purification Instrument cleaning routine provides some protection against contamination, it is not a substitute for good laboratory technique or precautions. When preparing samples for use or when preparing the instrument, make certain to observe sterile laboratory procedures at all times to ensure minimal contamination.

Materials required

- Lab coat
- Gloves, powder-free nitrile
- Protective safety glasses
- Bleach, 10% solution
- Isopropanol, 70% solution
- Wipes, lint-free

Decontaminate the Genexus™ Purification Instrument

WARNING! The samples can be potentially infectious. Dispose of all potentially contaminated consumables and wipes as biohazardous waste according to your local regulations.

Note: The decontamination procedure must be completed before any instrument service is performed or relocation of the instrument.

In the following scenarios begin the decontamination procedure at the indicated step.

- Sample or reagent spill occurred while loading the instrument. The instrument door is open, begin from step 1.
- Sample or reagent spill occurred while unloading the instrument. The instrument door is open, begin from substep 2a or the next consumable that needs to be removed.
- Decontamination in preparation for instrument service (no spill). Begin from step 5.

1. In the Home screen, tap **Cancel** ▸ **OK**.

2. Remove and discard reagent plates and all consumables from the instrument deck.

   a. Remove the purification plate, pour the liquid waste into an appropriate liquid biohazardous waste container by tipping the deep-well plate on one corner, then discard the empty plate in a solid biohazardous waste container.

WARNING!
- Liquid waste contains guanidine thiocyanate, dispose of properly.
- The samples can be potentially infectious. Dispose of all potentially contaminated consumables and wipes as biohazardous waste.

   b. Unlock, then remove and dispose of the Purification Tip Cartridges in an appropriate biohazardous waste container.

   c. Unlock, remove and empty the Quantitation Plate by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container, then discard the empty plate in a solid biohazardous waste container.

WARNING! No data are currently available that address the mutagenicity or toxicity of the Qubit™ RNA BR Reagent (Component A). This reagent is known to bind nucleic acid and is provided as a solution in DMSO. Treat the Qubit™ RNA BR Reagent with the same safety precautions as all other potential mutagens and dispose of the dye in accordance with local regulations.

   d. Open the Qubit quantition module cover, remove and discard the Quantitation Tube, then allow the module cover to gently close.

   e. Remove, then dispose of the combs, output and archive plates into an appropriate solid biohazardous waste container.

3. Using lint-free wipes soak up as much liquid as possible, then dispose of all liquid and solid waste in the appropriate biohazardous waste containers.

4. Spray the affected area with 10% bleach solution, allow to stand for 5 minutes, then wipe surfaces with a clean wipe to soak up residual bleach solution.

5. Spray the affected surfaces with 70% isopropanol, wipe surfaces with a clean wipe, then allow to air-dry.

6. Close the instrument door.

   - If the run was not cancelled the instrument will automatically perform a UV Clean.
   - If the run was cancelled the instrument will automatically perform a UV Clean when the next run is started.
   - To perform a UV Clean in preparation for instrument service. Start a new run, then cancel the run after the pre-run UV Clean has been performed.

   The instrument is now ready to perform a new purification run.

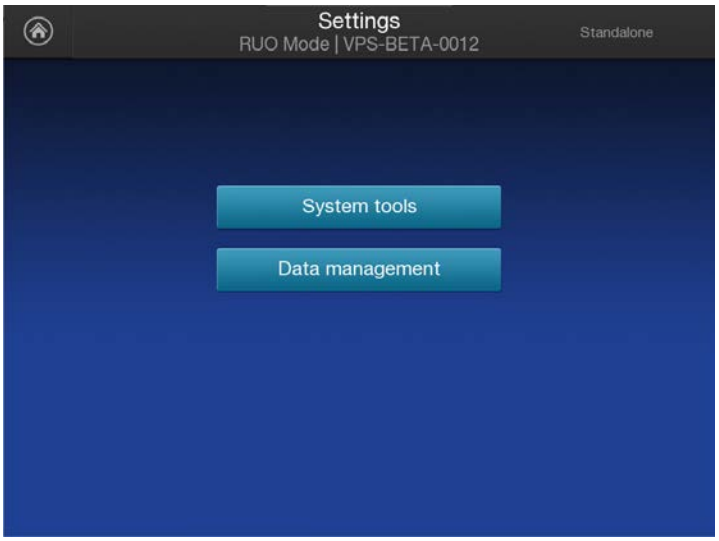
C Touchscreen reference

Touchscreen icons

Number	Icon	Description
1		User profile
2		USB – available
		USB – not available
3		Network connectivity – connected
		Network connectivity – not connected

Settings

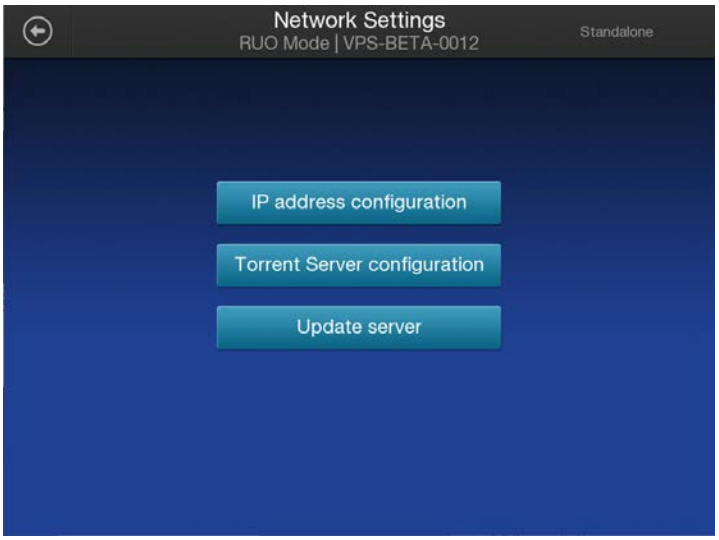
In the **Settings** menu, users can view and/or change instrument settings, and manage data.,

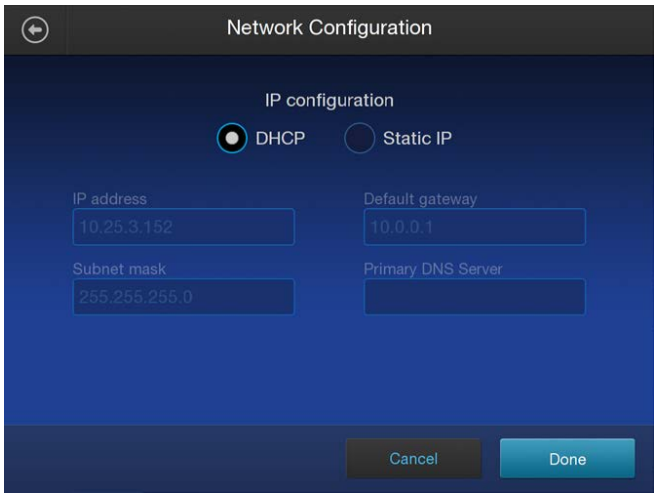
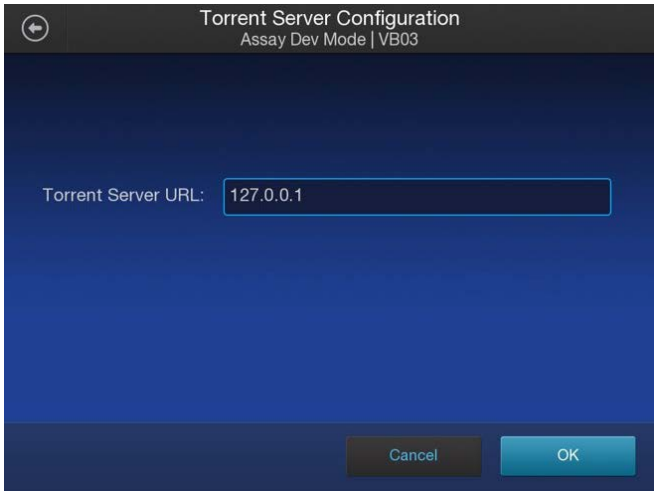


Note: The **System tools** option is for use by trained service personnel only.

Network Settings

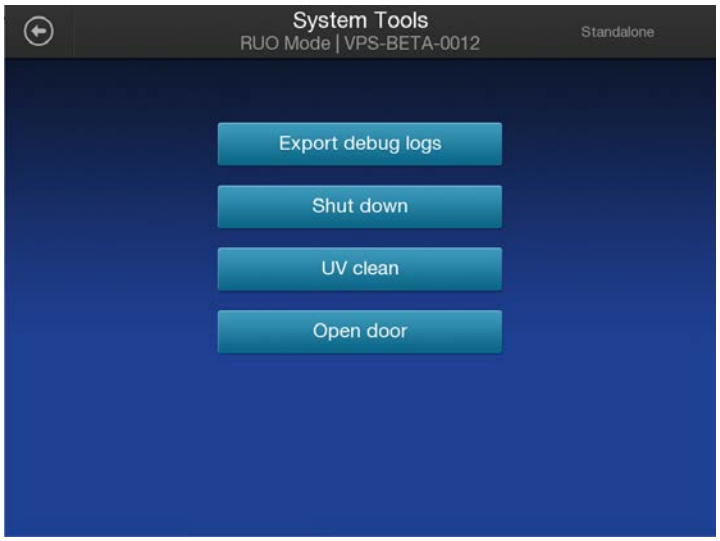
The **Network Settings** menu allows you to update the server and configure IP address, and Ion Torrent™ Server.

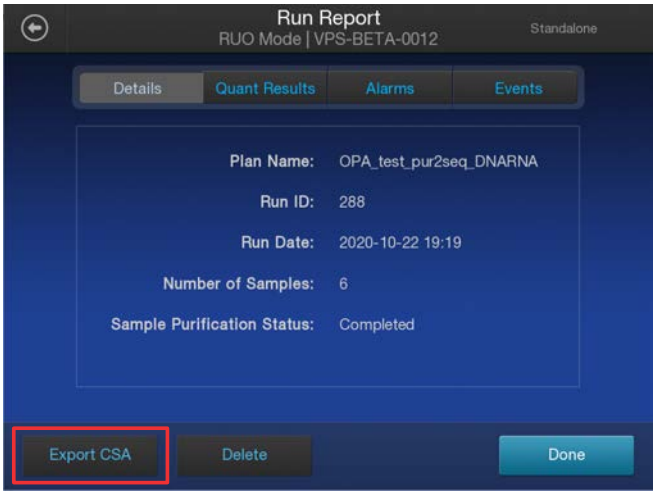


Item	Description	When/How to use
IP Address Configuration	Allows users to set or change the IP configuration (DHCP or Static IP). 	1. Select either the **DHCP** or **Static IP** radio button. 2. Touch the screen in the field you want to edit to activate the field. A virtual keyboard appears. 3. Enter the new information, then press **Done**.
Ion Torrent™ Server Configuration	Allows users to change the Ion Torrent™ Server IP address and user information.  Enter the following IP address in the **Torrent Server URL** field for your instrument: 127.0.0.1	When a change to the Ion Torrent™ Server IP address or user information is required. **Note:** Do not change address unless directed to do so by a Thermo Fisher Scientific field service engineer.

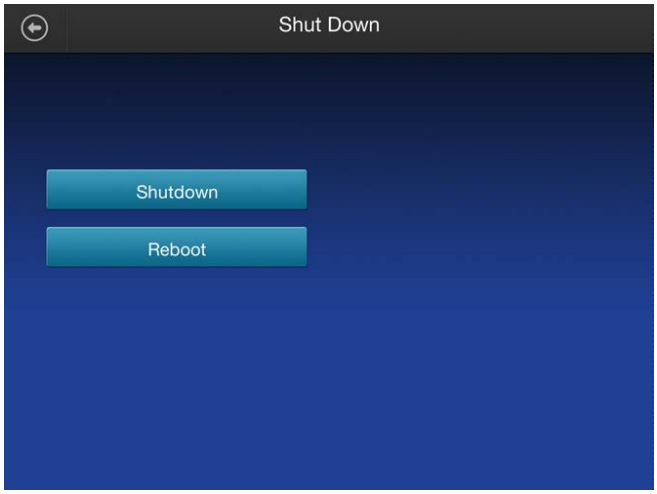
System Tools

The **System Tools** menu enables you to upload instrument diagnostics, manage data, and shut down or reboot the instrument.



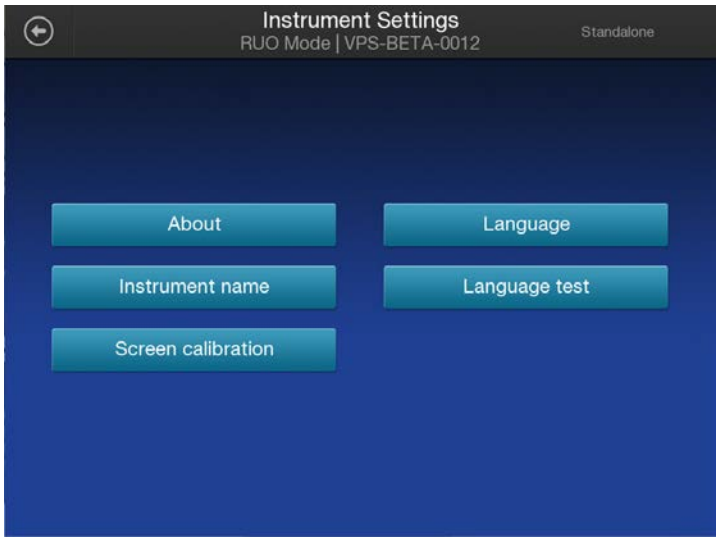
Item	Description	When/How to use
Export debug logs	Provides instrument error mode information. 	For troubleshooting if directed to do so by Technical Support. 1. Tap ⚙ **(Settings)** ▸ **Data management**, then tap in the row of the **Experiment Name** of interest. 2. In the **Run Report** screen, tap **Details** ▸ **Export CSA**. 3. Insert a USB drive into the USB port on the front of the instrument. Navigate to the file destination, then tap **Save**.

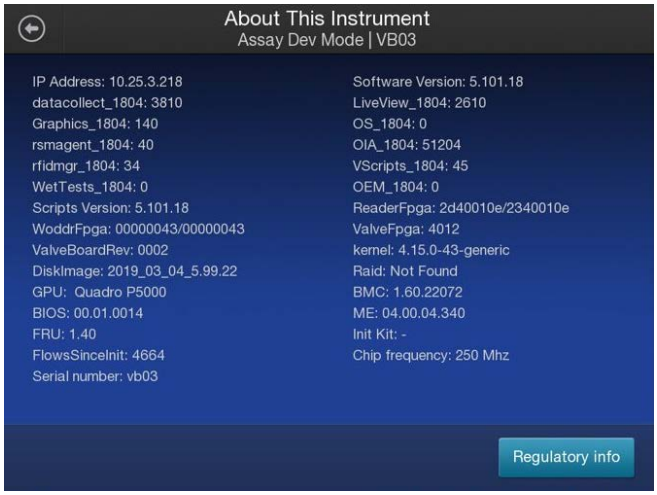
(continued)

Item	Description	When/How to use
Shut down	Access to "Shut Down" and "Reboot" commands. 	If directed to do so by Technical Support as part of a troubleshooting procedure, or if the instrument will not be used for more than three days. **Note:** It is not necessary/recommended to shut down the instrument overnight or over the weekend. To power on the instrument after a shut down, see “Power the Genexus™ Purification Instrument on or off” on page 16.
UV clean	Performs a UV Clean of the instrument deck.	In the event of a reagent or sample spill on the instrument deck. For more information, see “Clean and decontaminate the Genexus™ Purification Instrument” on page 72.
Open door	Unlocks and opens the instrument door.	In the event of an aborted run allows the user to open the instrument door to remove consumables in preparation for a subsequent run.

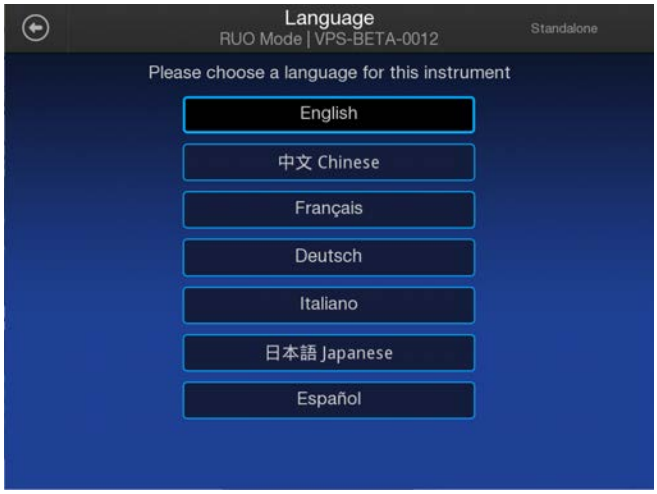
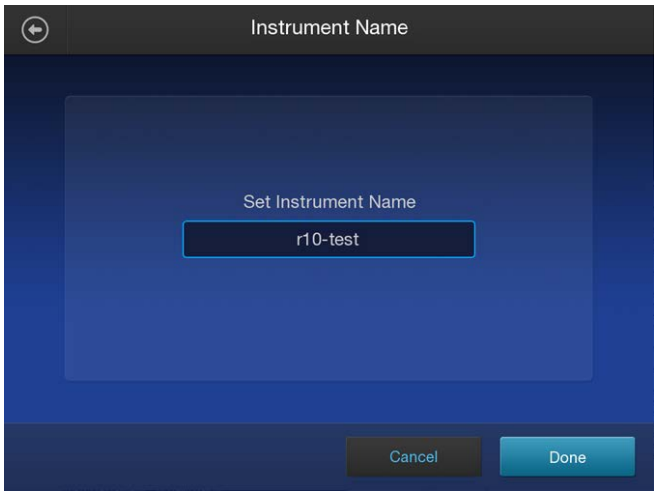
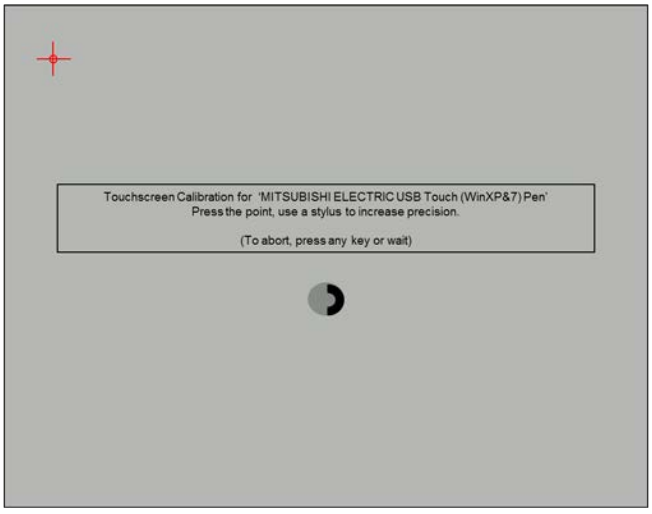
Instrument settings

The **Instrument Settings** menu provides information about the instrument and allows you to set the instrument name and calibrate the touchscreen.



Item	Description	When/How to use
About	Provides instrument details. 	To view instrument reference information or access regulatory information. Click **Regulatory info** to view the following screen.

(continued)

Item	Description	When/How to use
Language	Lists available user interface languages. 	Tap to select a language, then tap ⊖ (Back) to return to the **Instrument Settings** screen.
Instrument Name		To change the instrument name.
Screen Calibration		For troubleshooting if directed to do so by Technical Support. Touch the red cross with your finger or a stylus each time it appears. In total, you touch the screen 4 times, one time in each corner.

D

Safety

WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, see the "Documentation and Support" section in this document.

Symbols on this instrument

Symbols may be found on the instrument to warn against potential hazards or convey important safety information. In this document, the hazard symbol is used along with one of the following user attention words.

- **CAUTION!**—Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.
- **WARNING!**—Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
- **DANGER!**—Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.

Standard safety symbols

Symbol and description
CAUTION! Risk of danger. Consult the manual for further safety information.
CAUTION! Risk of electrical shock.
CAUTION! Hot surface.
CAUTION! Potential biohazard.
CAUTION! Ultraviolet light.

Symbole et description
MISE EN GARDE ! Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité.
MISE EN GARDE ! Risque de choc électrique.
MISE EN GARDE ! Surface chaude.
MISE EN GARDE ! Danger biologique potentiel.

(suite)

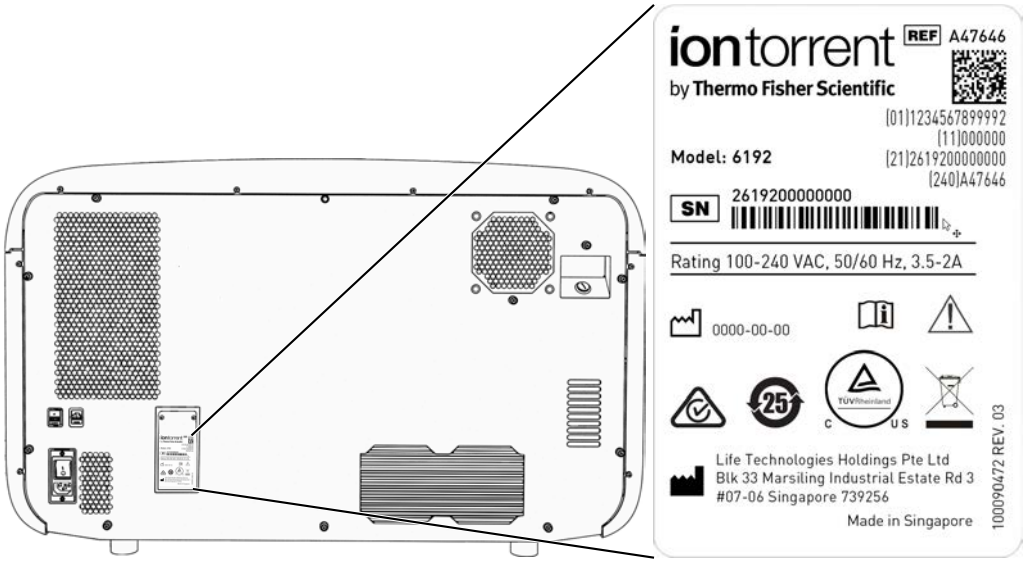
Symbole et description
MISE EN GARDE ! Rayonnement ultraviolet.

Additional safety symbols

Symbol and description
CAUTION! Moving parts.
CAUTION! Piercing hazard.

Symbole et description
MISE EN GARDE ! Parties mobiles.
MISE EN GARDE ! Danger de perforation.

Location of safety labels

Label and location
 Rear panel

Control and connection symbols

Symbols and descriptions	
	On (Power)
	Off (Power)
	Protective conductor terminal (main ground)
	Alternating current

Conformity symbols

Conformity mark	Description
	Indicates conformity with safety requirements for Canada and U.S.A.
	Indicates conformity with China RoHS requirements.
	Indicates conformity with Australian standards for electromagnetic compatibility.
	Indicates conformity with the WEEE Directive 2012/19/EU. **CAUTION!** To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

Instrument safety

General

CAUTION! Do not remove instrument protective covers. If you remove the protective instrument panels or disable interlock devices, you may be exposed to serious hazards including, but not limited to, severe electrical shock, laser exposure, crushing, or chemical exposure.

Physical injury

CAUTION! Moving and Lifting Injury. The instrument is to be moved and positioned only by the personnel or vendor specified in the applicable site preparation guide. Improper lifting can cause painful and permanent back injury.

Things to consider before lifting or moving the instrument or accessories:

- Depending on the weight, moving or lifting may require two or more persons.
- If you decide to lift or move the instrument after it has been installed, do not attempt to do so without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques.
- Make sure that the path from where the object is to where it is being moved is clear of obstructions.
- Participants should coordinate lift and move intentions with each other before lifting and carrying.

CAUTION! Moving Parts. Moving parts can crush, pinch and cut. Keep hands clear of moving parts while operating the instrument. Disconnect power before servicing.

Electrical safety

WARNING! Ensure appropriate electrical supply. For safe operation of the instrument:

- Plug the system into a properly grounded receptacle with adequate current capacity.
- Ensure the electrical supply is of suitable voltage.
- Never operate the instrument with the ground disconnected. Grounding continuity is required for safe operation of the instrument.

AVERTISSEMENT ! Veiller à utiliser une alimentation électrique appropriée. Pour garantir le fonctionnement de l'instrument en toute sécurité :

- Brancher le système sur une prise électrique correctement mise à la terre et de puissance adéquate.
- S'assurer que la tension électrique est convenable.
- Ne jamais utiliser l'instrument alors que le dispositif de mise à la terre est déconnecté. La continuité de la mise à la terre est impérative pour le fonctionnement de l'instrument en toute sécurité.

WARNING! Power Supply Line Cords. Use properly configured and approved line cords for the power supply in your facility.

AVERTISSEMENT ! Cordons d'alimentation électrique. Utiliser des cordons d'alimentation adaptés et approuvés pour raccorder l'instrument au circuit électrique du site.

WARNING! Disconnecting Power. To fully disconnect power either detach or unplug the power cord, positioning the instrument such that the power cord is accessible.

AVERTISSEMENT ! Déconnecter l'alimentation. Pour déconnecter entièrement l'alimentation, détacher ou débrancher le cordon d'alimentation. Placer l'instrument de manière à ce que le cordon d'alimentation soit accessible.

Cleaning and decontamination

CAUTION! Cleaning and Decontamination. Use only the cleaning and decontamination methods that are specified in the manufacturer user documentation. It is the responsibility of the operator (or other responsible person) to ensure that the following requirements are met:

- No decontamination or cleaning agents are used that can react with parts of the equipment or with material that is contained in the equipment. Use of such agents could cause a HAZARD condition.
- The instrument is properly decontaminated a) if hazardous material is spilled onto or into the equipment, and/or b) before the instrument is serviced at your facility or is sent for repair, maintenance, trade-in, disposal, or termination of a loan. Request decontamination forms from customer service.
- Before using any cleaning or decontamination methods (except methods that are recommended by the manufacturer), confirm with the manufacturer that the proposed method will not damage the equipment.

MISE EN GARDE ! Nettoyage et décontamination. Utiliser uniquement les méthodes de nettoyage et de décontamination indiquées dans la documentation du fabricant destinée aux utilisateurs. L'opérateur (ou toute autre personne responsable) est tenu d'assurer le respect des exigences suivantes:

- Ne pas utiliser d'agents de nettoyage ou de décontamination susceptibles de réagir avec certaines parties de l'appareil ou avec les matières qu'il contient et de constituer, de ce fait, un DANGER.
- L'instrument doit être correctement décontaminé a) si des substances dangereuses sont renversées sur ou à l'intérieur de l'équipement, et/ou b) avant de le faire réviser sur site ou de l'envoyer à des fins de réparation, de maintenance, de revente, d'élimination ou à l'expiration d'une période de prêt (des informations sur les formes de décontamination peuvent être demandées auprès du Service clientèle).
- Avant d'utiliser une méthode de nettoyage ou de décontamination (autre que celles recommandées par le fabricant), les utilisateurs doivent vérifier auprès de celui-ci qu'elle ne risque pas d'endommager l'appareil.

Instrument component and accessory disposal

To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

Safety and electromagnetic compatibility (EMC) standards

The instrument design and manufacture complies with the following standards and requirements for safety and electromagnetic compatibility.

Safety standards

Reference	Description
EU Directive 2014/35/EU	European Union “Low Voltage Directive”
IEC 61010-1 EN 61010-1 UL 61010-1 CAN/CSA C22.2 No. 61010-1	*Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*
IEC 61010-2-010 EN 61010-2-010	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*
IEC 61010-2-081 EN 61010-2-081	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*
IEC 61010-2-101 EN 61010-2-101	*Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*

EMC standards

Reference	Description
EU Directive 2014/30/EU	European Union “EMC Directive”
EN 61326-1 IEC 61326-1	*Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements*
EN 61326-2-6 IEC 61326-2-6	*Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment*
FCC Part 18 (47 CFR)	U.S. Standard “Industrial, Scientific, and Medical Equipment”
AS/NZS CISPR 11	*Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment*
ICES-001, Issue 4	*Industrial, Scientific and Medical (ISM) Radio Frequency Generators*

(continued)

Reference	Description
FCC Part 15 Subpart B (47 CFR)	*U.S. Standard Radio Frequency Devices* This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. The Genexus™ Purification System has no user serviceable parts. Contact your Thermo Fisher Scientific field service engineer for instrument service or repair with approved parts.
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Table 9 IEC 60601-1-2 immunity tests

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/-8 kV contact +/-15 kV air	Use flooring made of wood, concrete or ceramic tile. If floors are covered with synthetic material, maintain the relative humidity at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV 100 Hz repetition frequency	+/- 2 kV 100 Hz repetition frequency	Use mains power quality of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line to line	+/- 1 kV line to line	Use mains power quality of a typical commercial or hospital environment.
	+/- 2 kV line to earth	+/- 2 kV line to earth	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Maintain power frequency magnetic fields at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 9 IEC 60601-1-2 immunity tests *(continued)*

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz 80 MHz - 2.7 GHz 80% AM at 1 kHz	3V/m 80 MHz to 2.5 GHz 80 MHz - 2.7 GHz 80% AM at 1 kHz	
Note: • UT is the AC mains voltage prior to application of the test level. • At 80 MHz and 800 MHz, the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. Over the frequency range of 150 kHz to 80 MHz, maintain field strengths less than 3 V/m.			

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1 Class A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Environmental design standards

Reference	Description
Directive 2012/19/EU	European Union “WEEE Directive”—Waste electrical and electronic equipment
Directive 2011/65/EU	European Union “RoHS Directive”—Restriction of hazardous substances in electrical and electronic equipment
SJ/T 11364-2014	“China RoHS” Standard—Marking for the Restricted Use of Hazardous Substances in Electronic and Electrical Products For instrument specific certificates, visit our customer resource page at **www.thermofisher.com/us/en/home/technical-resources/rohs-certificates.html**.

Chemical safety

WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with sufficient ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer cleanup procedures as recommended in the SDS.
- Handle chemical wastes in a fume hood.
- Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
- After emptying a waste container, seal it with the cap provided.
- Characterize (by analysis if needed) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
- **IMPORTANT!** Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.

AVERTISSEMENT ! **PRÉCAUTIONS GÉNÉRALES EN CAS DE MANIPULATION DE PRODUITS CHIMIQUES.** Pour minimiser les risques, veiller à ce que le personnel du laboratoire lise attentivement et mette en œuvre les consignes de sécurité générales relatives à l'utilisation et au stockage des produits chimiques et à la gestion des déchets qui en découlent, décrites ci-dessous. Consulter également la FDS appropriée pour connaître les précautions et instructions particulières à respecter :

- Lire et comprendre les fiches de données de sécurité (FDS) fournies par le fabricant avant de stocker, de manipuler ou d'utiliser les matériaux dangereux ou les produits chimiques. Pour obtenir les FDS, se reporter à la section « Documentation et support » du présent document.
- Limiter les contacts avec les produits chimiques. Porter des équipements de protection appropriés lors de la manipulation des produits chimiques (par exemple : lunettes de sûreté, gants ou vêtements de protection).
- Limiter l'inhalation des produits chimiques. Ne pas laisser les récipients de produits chimiques ouverts. Ils ne doivent être utilisés qu'avec une ventilation adéquate (par exemple, sorbonne).
- Vérifier régulièrement l'absence de fuite ou d'écoulement des produits chimiques. En cas de fuite ou d'écoulement d'un produit, respecter les directives de nettoyage du fabricant recommandées dans la FDS.
- Manipuler les déchets chimiques dans une sorbonne.

- Veiller à utiliser des récipients à déchets primaire et secondaire. (Le récipient primaire contient les déchets immédiats, le récipient secondaire contient les fuites et les écoulements du récipient primaire. Les deux récipients doivent être compatibles avec les matériaux mis au rebut et conformes aux exigences locales, nationales et communautaires en matière de confinement des récipients.)
- Une fois le récipient à déchets vidé, il doit être refermé hermétiquement avec le couvercle fourni.
- Caractériser (par une analyse si nécessaire) les déchets générés par les applications, les réactifs et les substrats particuliers utilisés dans le laboratoire.
- Vérifier que les déchets sont convenablement stockés, transférés, transportés et éliminés en respectant toutes les réglementations locales, nationales et/ou communautaires en vigueur.
- **IMPORTANT !** Les matériaux représentant un danger biologique ou radioactif exigent parfois une manipulation spéciale, et des limitations peuvent s'appliquer à leur élimination.

WARNING! **HAZARDOUS WASTE (from instruments).** Waste produced by the instrument is potentially hazardous. Follow the guidelines noted in the preceding General Chemical Handling warning.

Biological hazard safety

WARNING! **Potential Biohazard.** Depending on the samples used on this instrument, the surface may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.

WARNING! **BIOHAZARD.** Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020
  https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2020-P.pdf
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs)
  www.who.int/publications/i/item/9789240011311

Documentation and support

Related documentation

Document	Publication number
Genexus™ Purification System Site Preparation Guide	MAN0018477
Genexus™ Integrated Sequencer User Guide	MAN0017910
Genexus™ Integrated Sequencer Quick Reference	MAN0017912
Genexus™ Software 6.2 User Guide	MAN0018955
Oncomine™ Precision Assay GX User Guide	MAN0018508
Oncomine™ Comprehensive Assay v3 GX User Guide	MAN0018512
Oncomine™ TCR Beta-LR Assay GX User Guide	MAN0018513

Customer and technical support

Visit **thermofisher.com/support** for the latest service and support information.

- Worldwide contact telephone numbers
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  - Product FAQs
  - Software, patches, and updates
  - Training for many applications and instruments
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- Product documentation
  - User guides, manuals, and protocols
  - Certificates of Analysis
  - Safety Data Sheets (SDSs; also known as MSDSs)

  Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have any questions, please contact Life Technologies at **www.thermofisher.com/support**.