Using the epoc® Point of Care Blood Analysis System Reduces Costs, Improves Operational Efficiencies, and Enhances Patient Care

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CLINICAL DILEMMA

Health care providers depend on the results of clinical laboratory testing to screen, diagnose and treat disease, and to monitor the results of treatment. Despite standard laboratory operating procedures and compliance monitoring, numerous factors can compromise the integrity of laboratory testing, resulting in errors and preventing prompt delivery of test results to providers.

An oft-cited report from the Institute of Medicine indicated that as many as 98,000 deaths and more than 1 million injuries occur each year in the United States as the result of medical errors. Included in this number are diagnostic errors, such as errors or delays in diagnosis, failure to employ indicated tests, use of outmoded tests, and failure to act on the results of monitoring or testing.1

Errors in clinical laboratory testing can occur any time during the preanalytical, analytical, or postanalytical phases and, in general, can be attributed to instrumental problems or operational processes that have gone awry.2 Preventing errors promotes patient safety, improves patient outcomes, and reduces the cost of unnecessary retesting.

THE POINT-OF-CARE SOLUTION

Point-of-care testing (POCT), first introduced in the 1990s, challenged the established paradigm of traditional laboratory testing methods that required the transportation of collected samples away from the patient to a central or near-patient laboratory while providers awaited the delivery of test results before diagnosis and treatment of the patient could occur. In contrast, POCT, which is typically performed at the patient’s bedside and may also occur in surgical suites, clinician offices, or in small decentralized laboratories, provides nearly instantaneous results. As health care providers focus increased attention on patients’ needs, POCT was perceived as one way to reduce turnaround time and improve the quality of the entire service provided. Thus, the overall effects of POCT can be assessed in terms of the benefit to the diagnostic or treatment strategy and overall health outcome of the patient.

The goal of POCT is to generate a test result quickly so that appropriate treatment can be implemented in a timely fashion.

Whereas first-generation POCT instruments offered the promise of faster turn-around time and improved provider efficiency, these benefits were often offset by higher operating costs and greater oversight requirements resulting from the need to monitor refrigerated storage and room temperature expiration dates. The increased pressure on health care providers to reduce costs, while continuing to improve patient care has led to the
development of improved POCT instruments. Today, second-generation POCT instruments are available that fulfill the initial promise of rapid test results but also do so at a lower cost and with fewer oversight requirements.

GOALS OF POCT
The objective of POCT is to generate a test result quickly so that appropriate treatment can be implemented in a timely fashion, leading to improved clinical and economic outcomes. Any test will be beneficial only if the provider takes appropriate action based on the result. Thus, the rate-limiting step in improving clinical outcomes and reducing length of hospital stay may not be rapid delivery of a test result, but acknowledgement of the result (communication, comprehension, and action).

THE PINNACLE EXPERIENCE WITH POINT-OF-CARE BLOOD GAS TESTING
Formed in 1997 through the consolidation of the Polyclinic Medical Center and Capital Health System, and a second consolidation a year later with Community General Osteopathic Hospital, Pinnacle Health is the leading hospital and health care system in Central Pennsylvania, offering services from prenatal care to geriatrics. As a nonprofit organization, the health system is dedicated to the health and wellness of the people of Central Pennsylvania, and has a long tradition of caring, dating back more than 130 years. Pinnacle Health System comprises 2 acute care hospitals, with a total of 590 beds, 41 critical care beds, 32 level III neonatal intensive care beds, and inpatient rehabilitation.

The Respiratory Care department at Pinnacle Health includes 53 staff and serves a diverse population from neonates to geriatric patients in a multitude of settings. The department provides 24-hour services to the medical/surgical intensive care units (ICUs), cardiothoracic ICU, neonatal intensive care unit (NICU), a 10-bed respiratory unit for long-term ventilator patients and patients with chronic COPD, as well as the general medical/surgical and inpatient rehabilitation units. The department staff also attends to codes and serves as a vital member of the Rapid Response Team.

Not unlike many other respiratory departments we are challenged with reducing health care-associated costs while continuing to deliver high-quality patient care. Over the past decade staffing has been reduced and the need for efficiency has grown. In the fall of 2007, the Respiratory Care department, in an effort to improve patient care and streamline the process for blood gas testing, began to investigate the opportunities for POCT in our health care system.
The epoc® Blood Analysis System (Epocal, Inc., Ottawa, ON, Canada), which had been demonstrated to department leadership while in its earliest development stages, was selected after a thorough investigation of the available POCT options. The epoc® instruments were introduced as the sole blood gas analyzing system at Pinnacle Health System in October of 2009.

**Features of the epoc® Point of Care Blood Analysis System**

The epoc® Point of Care Blood Analysis System is the only wireless bedside testing solution to use “smart card” technology. This breakthrough technology provides patient test results directly to a hand-held mobile computer while at the patient’s bedside. Fresh blood is passed across biosensors on the epoc® test card, and results are sent to the mobile computer in approximately 30 seconds. Other POCT systems often require more time between sample acquisition, sample entry, and analysis, which may result in sample degradation and possibly compromised results. Test cards can be placed at the patient bedside with the card reader, carried by the therapist, or stored in the operating suite.

The epoc® Point of Care Blood Analysis System is easy to use, requires no refrigeration of consumables, and connects and interfaces easily with the facility’s existing wireless network. A complementary system, known as the epoc® host, allows the user to enter patient information and to generate an accession number at the bedside, eliminating the need to locate an accession number and create or modify an order on a laboratory computer. The user-friendly epoc® host does not require any codes to input information, which has increased operator efficiency, decreased mistakes, and simplified and shortened the orientation process. Using this system, therapists have the ability to capture and document key respiratory parameters at the bedside while performing the testing. The epoc® Blood Analysis System also features bar code scanning for patient and operator identification, minimizing transcription errors and improving patient safety.

The epoc® data manager (EDM) provides information that enables providers to monitor both patient results and work efficiency. Therapists can access the EDM to determine whether they have entered correct information, allowing the results to be transmitted into the hospital information system (HIS) and then into the patient’s chart. The EDM also provides statistics documenting how well therapists utilize the system. We have used the information gathered from the EDM to improve staff education, analyzer allocation, and work flow.

**Correlation Results**

Our experience with the epoc® Point of Care Blood Analysis System has shown that the quality of test results from this instrument is equal to the results generated by traditional blood gas or
chemistry analyzers run in a traditional laboratory setting. We analyzed more than 50 samples in duplicate and triplicate comparing the epoc® Blood Analysis System and the standard. Hematocrit, sodium, and potassium analytes were also compared with the main laboratory standard. The method comparison, calibration verification, and results analysis were performed in accordance with the Clinical and Laboratory Standards Institute. The results demonstrated a strong correlation with the comparison methods within a 95% confidence interval.

Patient Care Benefits
We realized several patient care benefits after implementing POCT using the epoc® blood analyzers in our Respiratory Care department:

- The volume of blood necessary for analysis has been reduced from approximately 0.2 cc necessary for traditional bench blood gas analyzers to 100 µL for the epoc® Blood Analysis System, making the experience less traumatic for the patient.
- The therapist no longer has to leave the patient to transport the sample to a central location, await the results, and then return to the bedside.
- The cycle time from sample introduction to results has been reduced from approximately 3 minutes to about 30 seconds.
- The almost instantaneous delivery of blood gas and electrolyte results at the bedside enables the therapist to effect change to clinical care in a much more efficient manner.
- The immediate introduction at the bedside of a patient’s blood sample into an epoc® test card minimizes preanalytical sample degradation.
- Data entry and transcription errors have been minimized as a result of the bar code scanning process that is part of the epoc® Blood Analysis System. Additionally, the epoc® Blood Analysis System provides automated monitoring of all steps in the testing process, assuring error detection and reduction.

Operational Benefits
When the epoc® instruments were introduced in October of 2009, our 5-year projected cost reduction was $195,000. By the end of June 2010, we achieved a 48% reduction in operating costs compared with 2009, with the same utilization and sample volume. This represents an 8-month break-even return on investment.
SUMMARY

In our Respiratory Care department, implementation of POCT using the epoc® Point of Care Blood Analysis System has enabled therapists to obtain blood gas testing results in a fraction of the time it took previously using traditional bench instruments. Preanalytical sample degradation has been minimized, data entry and transcription errors have been reduced, and operating costs have decreased.

ABOUT PINNACLE HEALTH SYSTEM

Pinnacle Health System has achieved numerous awards and recognitions:

- Thomson Reuters 100 Top hospitals: Cardiovascular Benchmarks for Success winner 2008, 2009
- American Heart Association Get with the Guidelines – Heart Failure Gold Achievement Award 2010, 2011
- Society of Chest Pain Centers; Accredited Chest Pain Center 2010
- The Joint Commission, Primary Stroke Center Certification 2010
- The Joint Commission, Center of Excellence in Diabetes Care, Gold Seal Award
- Us News and World Report’s 18th Annual America’s Best Hospitals: Neurology and Orthopedics
- American Nurses Credentialing Center; Magnet recognition, redesignation 2010
- Center of Excellence, American Society of Bariatric Surgery

BIBLIOGRAPHY


Introduction

Blood gas analysis is known to be the best testing to assess the patient acid-base balance. The simultaneous and combined determination of pH, partial pressure of carbon dioxide (pCO₂), partial pressure of oxygen (pO₂), some electrolytes (Na, K, iCa), and Lactate, among others, contribute to gather very useful information to assess the clinical value of acid-base and hydro-electrolytes balances.

The Turn-Around-Time is very important in this type of analysis, since in many cases we deal with critical values. For this reason, it is now more frequent and important to use bedside systems (“point of care” systems), especially common in intensive care units, operating rooms, emergency departments and neonatology.

Objectives

Comparison of blood gas and electrolytes results, obtained with the ABL 735® (Radiometer) System vs. the results obtained with EPOC® (Alere Healthcare) Point of Care System, and evaluation of efficacy of EPOC® system.

Materials and Methods

The ABL 735® de Radiometer and the “point of care” EPOC® de Alere Healthcare are the blood gas analyzers used in this comparative study. One-hundred-fourty-eight (148) whole blood samples from pediatric patients of our center (sample volume: 100µl minimum) have been tested in parallel on both the analyzers with heparinized syringes.

Results

The Passing-Bablok comparative method shows for each analyte the following values about origin (a) and slope (b).

Coefficient of correlation (r) is also obtained (Spearman correlation):

<table>
<thead>
<tr>
<th>Analytes</th>
<th>Passing-Bablok</th>
<th>Regression</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a</td>
<td>b</td>
</tr>
<tr>
<td>pH</td>
<td>-0.4893 [-0.7322 -0.2738]*</td>
<td>1.0677 [1.0384 -1.1008]*</td>
</tr>
<tr>
<td>pCO₂ (mmHg)</td>
<td>1.798 [0.417 -3.4005]*</td>
<td>0.9673 [0.9316 -1.0022]*</td>
</tr>
<tr>
<td>pO₂ (mmHg)</td>
<td>1.3492 [-0.4402 -3.0985]*</td>
<td>1.0188 [0.9862 -1.0531]*</td>
</tr>
<tr>
<td>Na (mmol/L)</td>
<td>3 [-10,1429 -3]*</td>
<td>1 [1 -1.0952]*</td>
</tr>
<tr>
<td>K (mmol/L)</td>
<td>0.2 [0.2]*</td>
<td>1 [1]*</td>
</tr>
<tr>
<td>iCa (mmol/L)</td>
<td>-0.2626 [-0.3548 -0.1758]*</td>
<td>1.24 [1,1667 -1.3182]*</td>
</tr>
<tr>
<td>Glucose (mmol/L)</td>
<td>-1,1088 [-1,2862 -0.9129]*</td>
<td>1.0702 [1.0323 -1.1034]*</td>
</tr>
<tr>
<td>Lactate (mmol/L)</td>
<td>0.1 [0.0088 -0.1]*</td>
<td>1 [1 -1.0588]*</td>
</tr>
<tr>
<td>Hematocrit (%)</td>
<td>-2.8 [-5.3130 -0.7139]*</td>
<td>1 [0.9444 -1.0630]*</td>
</tr>
</tbody>
</table>

* confidence interval: 95%
** statistical significance: p < 0.01

Table 1. Comparative data - EPOC (Alere) “point of care” vs. ABL 735 (Radiometer) by non-parametric regression Passing-Bablok method and by a correlation analysis for each analyte.

Discussion

On the interchangeability of results, only results for pO₂ and Na prove to be interchangeable according to Passing-Bablok regression. The remaining analytes shall be referred to the reference values of each one of the techniques, since the confidence interval for the slope and the intercept did not include the values 1 and 0, respectively.

We may conclude that the EPOC® “point of care” system showed good correlation with results obtained by ABL 735® analyzer (r = 0.928- 0.979; r (Na) =0.768) and showed its efficacy at bedside when used to determine critical values, to evaluate the acid-base status and the hydro-electrolytes balance (pH, pCO₂, pO₂, Na, K, iCa), as well as the levels of glucose, lactate and hematocrit.
Evaluation of the Enterprise Point-of-Care System for Point-of-Care Blood Gas and Electrolyte Analysis

James H. Nichols, Aparna Rajadhyaksha, and Mirian Rodriguez

Objective: To evaluate the analytical performance of a new point-of-care blood gas and electrolyte analyzer, the EPOC system.

Materials and Methods: Evaluation of analytical precision and method comparison was conducted at the manufacturing facilities and at several locations including a clinical laboratory, an outpatient clinic, and an intensive care unit. A total of 143 samples were analyzed for electrolytes, hematocrit, and glucose using a handheld point-of-care blood gas analyzer. The EPOC system was comparable to the i-STAT in terms of precision and comparability of patient results to the i-STAT. The EPOC system has temperature storage of test cards and wireless connectivity that provides an operational advantage over other point-of-care blood gas analyzers on the market.

Key Words: blood gas analysis, point-of-care testing, i-Stat

Results: Within-run precision (0.07%–2.3% coefficient of variation [CV]) and total precision (0.14%–3.8% CV) were estimated by analysis of aqueous and hematocrit control materials. A total of 143 samples were analyzed, and the predicate device, the i-STAT. One sample was excluded for potential benzalkonium interference with electrolytes, and another sample was excluded because of suspected incomplete mixing. The EPOC system was comparable to the i-STAT for all analytes with correlation coefficients of 0.880 to 0.990, linear regression slopes of 0.91 to 1.07, and SE of the estimates of 1.5% to 2.5% CV for electrolytes and pH, 3.9% for hematocrit, and 4.9% to 7.3% CV for blood gases.

Conclusions: The EPOC system demonstrated excellent analytical precision and comparability of patient results to the i-STAT. The EPOC system has a temperature storage of test cards and wireless connectivity that provides an operational advantage over other point-of-care blood gas analyzers on the market.

Critical care patients have the potential for clinically significant changes in status that require prompt medical intervention. The value of point-of-care bedside blood analysis is derived from the improved medical outcomes and operational convenience of fast turnaround time of results, as compared with the much longer turnaround time of results from a central laboratory. The current point-of-care testing market is estimated at more than US $6 billion and growing at approximately 12% annually. Approximately 42% of this testing is professional hospital and physician’s office point of care, whereas the remainder of this market is patient home or self-testing, primarily for diabetes blood glucose monitoring. Critical care blood gas and electrolyte testing comprises approximately 53 million tests annually. Of this amount, 40 million tests (US $180 million) is performed by dedicated technical staff on table-top blood gas analyzers in satellite stat laboratories or on mobile carts that can be rolled to the patient’s room, and the other 13 million blood gas tests (US $91 million) are performed by clinical staff using portable devices, handheld units, and analyzer modules embedded in bedside monitoring equipment. The Enterprise Point-of-Care (EPOC) blood analysis system (Epopal Inc, Ottawa, Ontario, Canada) is a new in vitro diagnostic platform for testing whole blood samples at the point of care. This system is portable, intended for use by clinical and non-technical staff, and has a modular design that permits the same hardware to be used in multiple configurations that facilitate applications in different inpatient and outpatient settings where rapid testing is required for critical care management.

The EPOC system consists of a test card containing the sensors, a wireless card reader, and a personal data assistant (PDA) or computer running the EPOC software for data analysis. The EPOC system currently measures pH, Pco2, P02, sodium (Na), potassium (K), ionized calcium (iCa), and hematocrit (Hct) using unit-use test cards that are the size of a credit card. Each test card contains a sensor array and fluidics for delivery of calibrators and patient samples. Test cards are read by a wireless card reader that can communicate through Bluetooth wireless protocols with a portable handheld PDA or personal computer (PC). Sensor signals from the test card are transmitted by the card reader to the PDA or PC software where results are calculated and displayed and can be transmitted to a laboratory information system, hospital information system, or patient electronic medical record. Each card contains on-board calibrators and an internal quality control system to monitor the card reader, test card, operator procedure, and sample integrity with each test performed. Together, these checks provide broad monitoring against erroneous operation of the EPOC system.

This study was conducted to establish the analytical performance of the EPOC system. Enterprise Point-of-Care was tested in multiple locations including a clinical laboratory, an outpatient clinic, an intensive care unit (ICU), and a cardiac ICU (CICU). Performance by both laboratory and nursing staff was examined. Analytical precision and method correlation were evaluated based on Clinical Laboratory Standards Institute guidelines in comparison with a handheld point-of-care blood gas analyzer, the i-STAT. Data from this study will provide potential consumers in hospitals and physician’s office laboratories.
considering an EPOC purchase with an independent evaluation of device performance.

MATERIALS AND METHODS

Evaluation of the EPOC system was conducted at Baystate Health, an integrated health system located in Western Massachusetts and at Epocal manufacturing (Epocal, Ottawa, Ontario, Canada). Five locations participated in the trial; the manufacturer, Epocal, and 4 sites at Baystate including the central laboratory, a hematology/oncology outpatient clinic (the D'Amour Center for Cancer Care), an ICU, and a CICU. Aqueous controls were performed at both Epocal and Baystate locations, and patient blood testing was only performed at Baystate. Testing was performed by a technician and nursing students at Epocal and a laboratory staff at the Baystate central laboratory and satellite laboratory in the hematology/oncology clinic. Nurses conducted the testing at the patient’s beside in both the ICU and CICU. All operators were trained and allowed a period of familiarization with the operation of the EPOC system before conducting the study.

Laboratory specimens used at Baystate were collected in heparinized green-top vacuum collection tubes (Becton Dickinson, Franklin Lake, NJ), whereas specimens in the ICUs were collected from arterial indwelling lines using plain syringes. Laboratory samples were arterial, mixed venous, and venous specimens, whereas the ICUs were mostly arterial with some mixed venous specimens. The protocol was approved by expedited review through our institutional review board. Study specimens were used only after discard from clinical analysis. The intensive care specimens were analyzed immediately, within 3 minutes of collection, whereas laboratory specimens were recovered from saved samples at Baystate and may have been over 30 minutes from time of collection to analysis. Enterprise Point-of-Care analyzers and reagents were provided by Epocal, and comparative analyzers and reagents were acquired from routine clinical stock in use at Baystate Health. Epocal provided reimbursement to cover the cost of labor, reagents, and other supplies required to conduct the study.

Precision was estimated by analyzing aqueous control material (Mission Diagnostics, Holliston, Mass). Within-run precision was calculated from 10 replicates of aqueous control material performed in succession using 2 card readers. Total precision was conducted at Epocal during the pilot manufacturing stage. Two levels of aqueous controls were analyzed for each batch of test cards using up to 6 card readers. Over a 2 month period, 20 different test card lots were evaluated with 16 card readers. Hematocrit total precision was estimated using 2 levels of Hct controls (Mission Diagnostics) using 2 card readers and 6 lots of test cards at Baystate Health.

| TABLE 1. | Within-Run Precision of the EPOC System |
|---|---|---|---|---|---|---|
| | pH | P<sub>co2</sub> | P<sub>o2</sub> | Na | K | I<sub>Ca</sub> |
| Mean | 7.673 | 24.1 | 140.1 | 153.1 | 6.71 | 0.66 |
| Epocal technician | 0.007 (0.09) | 0.5 (2.1) | 2.4 (1.7) | 1.0 (0.7) | 0.06 (0.9) | 0.01 (1.5) |
| Nursing student 1 | 0.003 (0.04) | 0.5 (2.1) | 2.7 (1.9) | 0.9 (0.6) | 0.07 (1.0) | 0.01 (1.5) |
| Nursing student 2 | 0.004 (0.05) | 0.3 (1.2) | 2.3 (1.6) | 1.1 (0.7) | 0.04 (0.6) | 0.01 (1.5) |
| Nursing student 3 | 0.006 (0.08) | 0.6 (2.5) | 2.9 (2.1) | 1.1 (0.7) | 0.08 (1.2) | 0.01 (1.5) |
| Baystate operator 1 | 0.009 (0.11) | 1.0 (4.2) | 3.3 (2.4) | 1.1 (0.7) | 0.08 (1.2) | 0.01 (1.5) |
| Baystate operator 2 | 0.005 (0.07) | 0.5 (2.1) | 2.0 (1.4) | 0.8 (0.5) | 0.06 (0.9) | 0.01 (1.5) |
| Baystate operator 3 | 0.005 (0.07) | 0.4 (1.7) | 3.6 (2.6) | 1.1 (0.7) | 0.05 (0.8) | 0.01 (1.5) |
| Mean SD (% CV) | 0.006 (0.07) | 0.5 (2.3) | 2.7 (2.0) | 1.0 (0.7) | 0.06 (0.9) | 0.01 (1.5) |

Within-run precision was calculated from 10 replicates of aqueous Mission Diagnostics control material performed in succession using 2 card readers and displayed as SD (% CV). The Epocal technician and nursing students participated in the precision trials at Epocal, and both laboratorians and nursing staff were involved at Baystate.
Method comparison was first conducted at the Baystate central laboratory and was then expanded to testing in the clinical units on the ICU, CICU, and hematology/oncology clinic. The i-STAT blood gas analyzer (Abbott Laboratories, Abbott Park, Ill) was used as the comparative device. The i-STAT is in routine clinical use at Baystate in the operating rooms and critical care areas. With more than 75 i-STAT analyzers and 1500 trained staff, Baystate performs over 100,000 tests on the i-STAT annually. Two EPOC card readers and 2 i-STATs were used at each testing location during the study. A patient sample was first run on the i-STAT and that result was used for clinical treatment. Leftover sample was then used to perform a test in duplicate on the EPOC system and again on the predicate device in duplicate. Time delays between replicates were kept to a minimum, and the sequence of testing was randomized between i-STAT1, EPOC1, EPOC2, i-STAT2 and i-STAT1, EPOC1, i-STAT2, EPOC2 to minimize sample handling bias. Data analysis for each analyte followed the Clinical Laboratory Standards Institute EP9-2A guideline.\(^4\) Least squares regression was calculated using the average of the EPOC and i-STAT replicates. Precision of patient specimens was estimated from calculation of the EPOC and i-STAT methods. This sample was collected after a subclavian line change, and the elevation was suspected to be contamination with AMC Thromboshield that contains benzalkonium heparin as a coating in the triple-lumen catheter (Edwards Lifesciences, Irvine, Calif) used during the line change. Benzalkonium is a well-documented interferent containing benzalkonium heparin as a coating in the triple-lumen catheter (Edwards Lifesciences, Irvine, Calif) used during the line change. Benzalkonium is a well-documented interferent (StatSoft, Tulsa, Okla).

RESULTS

Within-run precision of aqueous control varied from 0.07% to 2.3% coefficient of variation (CV) (Table 1). Electrolytes—Na, K, and iCa—had greater precision (0.7% to 1.5% CV) than blood gases (2.0% to 2.3%). Similar precision was noted between nursing and laboratory staff at Baystate and the technician and nursing students at Epocal. Total precision of control materials on multiple lots of test cards varied from 0.14% to 3.8% CV (Table 2). Electrolytes—Na, K, and calcium—demonstrated greater precision at all levels (1.0% to 1.9% CV) than blood gases (2.0% to 3.8% CV). pH was precise at all levels (0.14% to 0.15% CV), and Hct varied from 1.8% to 2.9% CV.

A total of 143 samples were analyzed for method correlation, with 34 samples in the Baystate central laboratory performed by both Epocal and Baystate laboratory staff; 24 samples in the Baystate central laboratory analyzed only by Baystate laboratory staff, 35 samples in the hematology/oncology clinic analyzed by Baystate laboratory staff, 28 samples in the CICU performed by Baystate CICU nurses, and 22 samples in the ICU performed by Baystate ICU nurses. One sample in the CICU showed elevated results for the Na, K, pH, and oxygen electrodes by both methods. This sample was collected after a subclavian line change, and the elevation was suspected to be contamination with AMC Thromboshield that contains benzalkonium heparin as a coating in the triple-lumen catheter (Edwards Lifesciences, Irvine, Calif) used during the line change. Benzalkonium is a well-documented interferent in electrolyte measurements using membrane electrodes.\(^5\) This sample was excluded from analysis for the affected analytes. An additional sample in the central laboratory demonstrated good method agreement for all analytes except Hct, and

<table>
<thead>
<tr>
<th>pH</th>
<th>P_{O2}, mm Hg</th>
<th>P_{O2}, mm Hg</th>
<th>Na, mmol/L</th>
<th>K, mmol/L</th>
<th>iCa, mmol/L</th>
<th>Hct, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
<td>0.03 + 1.00x</td>
<td>−0.9 + 1.04x</td>
<td>−1.7 + 1.05x</td>
<td>−0.04 + 1.02x</td>
<td>8.8 + 0.94x</td>
<td>0.1 + 0.91x</td>
</tr>
<tr>
<td>i-STAT Mean</td>
<td>7.35</td>
<td>49.1</td>
<td>87.4</td>
<td>137.8</td>
<td>3.86</td>
<td>1.14</td>
</tr>
<tr>
<td>EPOC Mean</td>
<td>7.34</td>
<td>50.3</td>
<td>90.9</td>
<td>138.5</td>
<td>3.90</td>
<td>1.14</td>
</tr>
<tr>
<td>S_jx (% CV)</td>
<td>0.018 (2.5)</td>
<td>2.5 (4.9)</td>
<td>6.6 (7.3)</td>
<td>0.09 (2.4)</td>
<td>2.1 (1.5)</td>
<td>0.03 (2.5)</td>
</tr>
<tr>
<td>r</td>
<td>0.987</td>
<td>0.990</td>
<td>0.978</td>
<td>0.989</td>
<td>0.880</td>
<td>0.943</td>
</tr>
<tr>
<td>Range of results</td>
<td>6.95—7.56</td>
<td>18.5—122.3</td>
<td>22.9—232.1</td>
<td>126—147.5</td>
<td>2.5—6.6</td>
<td>0.79—1.62</td>
</tr>
<tr>
<td>n</td>
<td>142</td>
<td>143</td>
<td>142</td>
<td>142</td>
<td>142</td>
<td>143</td>
</tr>
<tr>
<td>i-STAT Precision of replicates, SD (% CV)</td>
<td>0.013 (0.17)</td>
<td>1.49 (3.0)</td>
<td>4.6 (5.3)</td>
<td>0.6 (0.4)</td>
<td>0.047 (1.22)</td>
<td>0.016 (1.4)</td>
</tr>
<tr>
<td>EPOC Precision of replicates, SD (% CV)</td>
<td>0.006 (0.08)</td>
<td>1.10 (2.2)</td>
<td>2.7 (3.0)</td>
<td>0.8 (0.6)</td>
<td>0.046 (1.18)</td>
<td>0.014 (1.2)</td>
</tr>
</tbody>
</table>

Units are noted for each analyte. Correlation equation calculated by least squares regression. N indicates number of results; r, regression coefficient; S_jx, SE of the estimate.
incomplete sample mixing was suspected. The Hct results were the following: iSTAT1 = 46%, EPOC1 = 41%, EPOC2 = 17%, and i-STAT2 = 11%. This sample was excluded for Hct.

Correlation statistics report the regression equations, mean of $x$, mean of $y$, SE of the estimate, correlation coefficient, range, and number of specimens for each method (Table 3). Replicate precision (SD and % CV) for patient specimens is also indicated with the correlation statistics for each method (Table 3). The EPOC system demonstrated comparable (Na and Hct) to better (pH, $P_{O_2}$, $P_{CO_2}$, K, and Ca) replicate precision than the i-STAT analyzer. A correlation and bias plot is shown for K as an example of the method correlation (Fig. 2). Performance of the EPOC system was comparable to the i-STAT for all analytes with correlation coefficients of 0.880 to 0.990 and SEs of the estimate of 1.5% to 2.5% CV for Na, K, Ca, and pH, 3.9% CV for Hct, and 4.9% to 7.3% CV for $P_{O_2}$ and $P_{CO_2}$. Enterprise Point-of-Care correlations were statistically different from the i-STAT with $P < 0.001$ for all analytes except iCa ($P = 0.20$) by Student $t$ test. However, the method differences were not clinically significant as judged by College of American Pathologist and Clinical Laboratory Improvement Amendments of 1988 proficiency survey total error specifications for blood gas and electrolyte analysis.

**DISCUSSION**

The need for blood gas and electrolyte analysis in the management of critical care patients is well established. Most acute care settings require rapid turnaround of test results particularly in the operating room, ICUs, and emergency department. Blood gas analysis in these settings traditionally required a bench-top analyzer and trained technologists to maintain the system. To obtain reasonable turnaround times, a satellite laboratory could be established on or near the clinical units staffed by dedicated laboratory technologists, or the specimens could be transported manually or by pneumatic tube to a stat workstation in the central laboratory.

The development of smaller portable blood analyzers, like the i-STAT, has allowed for the delivery of blood gas testing by clinical staff, at the patient’s bedside. Since its introduction more than 15 years ago, the i-STAT has demonstrated proven analytical performance compared with the standard bench-top blood gas analyzers. Clinical applications of the i-STAT have been established well beyond the critical care inpatient units and now routinely include dialysis units, exercise physiology, oncology clinics, organ donor procurement, evaluation of heat exhaustion in the wilderness, and management of patients during emergency helicopter/ambulance transfer. The i-STAT has even been used by astronauts during space travel. The i-STAT thus serves as a good comparative analyzer for this study.

The portability of a handheld blood gas analyzer, like the i-STAT, is the key feature that has allowed expansion of testing into clinical settings that were not previously available to traditional blood analyzers because of their size and maintenance requirements. The development of the EPOC system provides a new platform for test analysis that is also small, handheld, and easily portable. The i-STAT is currently the only handheld portable blood gas analyzer on the market, and the EPOC will certainly offer competition for similar clinical applications.

In this evaluation, the EPOC system demonstrated exceptional precision and was analytically comparable to the i-STAT in patient correlations. Within-run and total day-to-day precision was comparable or better than the i-STAT in the hands of a variety of clinical and laboratory staff and across different locations, including inpatient ICUs, an outpatient clinic, and a central laboratory. The EPOC system also correlated well with the i-STAT analyzer for all analytes, and no clinically significant differences were noted across the range of results in the examined patient populations. Replicate precision of patient samples during the method correlation was similar to results on aqueous and Hct controls, with the EPOC system demonstrating better precision for pH, blood gases, K, and iCa and comparable precision to the i-STAT for Na and Hct.

Participants in this study noted several operation advantages of the EPOC system. Room temperature storage is particularly useful in the point-of-care setting. Refrigeration of reagents for our current i-STAT analyzer consumes considerable labor in temperature monitoring and logging of corrective actions when the refrigerator temperatures are out of range. Because of the volume of testing performed, our institution requires multiple refrigerators to store the volume of cartridges that are consumed on a monthly basis. Conversion to room temperature storage would greatly simplify management of blood gas testing and eliminate the need for refrigeration altogether, as i-STAT reagents are the only point-of-care tests in our institution that require refrigeration.

Another advantage of the EPOC system is its wireless capabilities. With i-STAT, our health system requires
downloading on each medical unit, wired internet connections, a centralized data management computer, and additional interfaces from this data management computer to our laboratory information system and hospital information system for permanent storage of the result in the patient’s electronic medical record. This system relies on periodic docking of i-STATs to download recent patient results and to update operator lists and reagent/control lots. Unfortunately, an incorrect patient identifier can be entered before testing, and this error will not be noticed until after a download takes place. A result is thus available where clinical action has already taken place that cannot be linked to the correct patient’s medical record. Such results get stuck in our current data management computer and require the point-of-care coordinator to rectify manually with clinical staff. The availability of wireless connectivity would allow data from the test card reader to communicate with a PDA or PC on the medical unit of wireless connectivity would allow data from the test card reader to communicate with a PDA or PC on the medical unit in real time. Our ICU and CICU are already equipped with “computers on wheels” that wirelessly communicate with the hospital information system. The ability of the EPOC system to link to the existing hardware on our medical units is a great advantage that saves cost and facilitates implementation. This configuration also has the potential to use the ADT feed of patient admissions records to confirm patient identification through the unit computers on wheels before performing testing. This configuration would certainly reduce the number of results from blood gas analysis that cannot be linked with a patient’s medical record after our i-STAT downloading.

Although wireless was available, this study only focused on the analytical performance of the EPOC system and did not explore the extent of wireless features on the EPOC system. During this study, we used the test card readers connected to a PDA. No issues were found with this application. Further testing in the future will focus on the wireless capabilities of the PDA or unit computer on wheels to connect with our hospital information system and use ADT feeds in our institution.

In summary, the EPOC system is a new portable blood analyzer for conducting critical care testing at the point of care. The initial menu of blood gas and electrolytes were evaluated, and the analytical performance demonstrated excellent precision and comparability of patient results to the i-STAT. Both clinical and laboratory staff participated in the evaluation, and the EPOC system was tested in multiple locations including the manufacturer’s laboratory, a hospital central laboratory, 2 ICUs, and an outpatient clinic. Overall, the operators found the EPOC to be easy to use, with a technical performance that would meet patient needs. Room temperature storage of test cards would provide an operational advantage over current products that require refrigeration of supplies. Our staff looks forward to further evaluation of the device’s wireless features.

REFERENCES


Biologie embarquée vs biologie hospitalière : validation d’un nouveau système d’analyse délocalisé pour le dosage de différents paramètres biologiques (gaz du sang, électrolytes et lactate)

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Type de soumission: Médecin
Thème: Matériel, monitorage
Concours des résidents: Non
Type d’étude: Autre
Autre étude: Etude de reproductibilité

Introduction: La biologie embarquée est un outil diagnostique et d’aide à la décision médicale. Différents paramètres biologiques sont mesurés en médecine d’urgence pré-hospitalière lors de la réalisation d’une gazométrie artérielle (analyses de pH, gaz du sang, certains électrolytes et métabolites à partir d’échantillons de sang total artériel). Ils permettent d’avoir un reflet de l’équilibre acido-basique et hydro-électrolytique des patients. Dans une démarche qualité, il est important de réaliser une qualification technique d’un nouvel analyseur pour le confronter aux exigences cliniques actuellement admises. Le but de cette étude a été de comparer et de valider les mesures obtenues par un nouveau système d’analyse délocalisé par rapport à une méthode standard en laboratoire hospitalier.

Matériel et Méthodes: Etude de validation en laboratoire à partir de prélèvements artériels standards prescrits à des patients hospitalisés sur une durée de 3 mois (novembre 2012 à janvier 2013). Mesure simultanée et comparaison des paramètres biologiques suivants : pH, PaO₂, PaCO₂, HCO₃⁻, natrémie, kaliémie, calcémie, glycémie, hémoglobine (Hb) et lactate, soit par la technique de référence du laboratoire de biochimie, analyseur ABL837 FLEX® (Radiometer®), soit par l’appareil Epoc® (Alere®) de biologie embarquée. Pour l’Epoc®, après un étalonnage de 3 minutes les résultats sont rendus en 30 secondes une fois l’échantillon injecté. L’ordre de passage des prélèvements sanguins était aléatoire sur les 2 appareils. L’analyse statistique a fait appel au test de Bland et Altman et à la méthode de régression linéaire (test de concordance, R²). Pour chaque paramètre biologique dosé, le biais, l’écart-type, l’intervalle de confiance du biais (IC 95 %), les limites de concordance (LC) et le coefficient R² ont été calculés.

Résultats: 90 mesures ont été effectuées en temps réel et appariées. Les résultats sont résumés dans le tableau suivant:

<table>
<thead>
<tr>
<th>Paramètre</th>
<th>Biais</th>
<th>Ecart-type</th>
<th>IC Biais (95%)</th>
<th>LC (95%)</th>
<th>R²</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>- 0,004</td>
<td>0,02</td>
<td>- 0,01 ; 0,00</td>
<td>- 0,04 ; 0,03</td>
<td>0,995</td>
</tr>
<tr>
<td>PaO₂ (mmHg)</td>
<td>- 3,418</td>
<td>9,38</td>
<td>- 5,38 ; - 1,45</td>
<td>- 21,81 ; 14,98</td>
<td>0,962</td>
</tr>
<tr>
<td>PaCO₂ (mmHg)</td>
<td>1,558</td>
<td>2,98</td>
<td>0,93 ; 2,18</td>
<td>- 4,29 ; 7,41</td>
<td>0,985</td>
</tr>
<tr>
<td>HCO₃⁻ (mmol/L)</td>
<td>- 0,313</td>
<td>1,09</td>
<td>- 0,54 ; - 0,08</td>
<td>- 2,45 ; 1,82</td>
<td>0,989</td>
</tr>
<tr>
<td>Natrémie (mmol/L)</td>
<td>- 3,156</td>
<td>2,00</td>
<td>- 3,58 ; - 2,74</td>
<td>- 7,09 ; 0,77</td>
<td>0,958</td>
</tr>
<tr>
<td>kaliémie (mmol/L)</td>
<td>0,013</td>
<td>0,10</td>
<td>- 0,01 ; 0,03</td>
<td>- 0,19 ; 0,22</td>
<td>0,980</td>
</tr>
<tr>
<td>Calcémie (mmol/L)</td>
<td>- 0,026</td>
<td>0,04</td>
<td>- 0,03 ; - 0,02</td>
<td>- 0,11 ; 0,06</td>
<td>0,940</td>
</tr>
<tr>
<td>Glycémie (mmol/L)</td>
<td>0,127</td>
<td>0,25</td>
<td>0,07 ; 0,18</td>
<td>- 0,37 ; 0,62</td>
<td>0,995</td>
</tr>
<tr>
<td>Hb (g/dL)</td>
<td>0,96</td>
<td>0,80</td>
<td>0,79 ; 1,13</td>
<td>- 0,60 ; 2,52</td>
<td>0,954</td>
</tr>
<tr>
<td>Lactate (mmol/L)</td>
<td>0,603</td>
<td>0,83</td>
<td>0,43 ; 0,78</td>
<td>- 1,02 ; 2,23</td>
<td>0,973</td>
</tr>
</tbody>
</table>

IC : intervalle de confiance
LC : limites de concordance

Discussion: Ce travail valide l’utilisation de l’appareil de biologie délocalisée Epoc® pour la mesure élargie des paramètres des gaz du sang. Les résultats sont fiables (biais et limites de concordances acceptables) et corrélés avec ceux dosés en routine par le service de Biologie. Ces résultats confirment qu’en médecine d’urgence préhospitalière la biologie délocalisée représente une aide à la décision pour l’orientation diagnostique et thérapeutique des patients.