Evaluation of the Enterprise Point-of-Care (EPOC) System for Blood Gas and Electrolyte Analysis

James H. Nichols, PhD, DABCC, FACB, Aparna Rajadhyaksha, MD, and Mirian Rodriguez, MA, LA

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 in a 630-bed tertiary acute care hospital in New England, an intensive care unit, cardiac intensive care unit, an outpatient hematology/oncology clinic, and the Baystate Health system central laboratory (Springfield, Mass). The evaluation was conducted by nursing staff, medical laboratory technicians, medical technologists, and pathology residents.

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 leftover from laboratory analysis were compared with the predicate device, the i-STAT. One sample was excluded for potential benzalkonium interference with electrolytes, and another sample was excluded from the hematocrit correlation 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 room 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

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Critical care patients have the potential for clinically significant changes in status that require prompt medical intervention.[1] 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 diagnostic market is estimated at more than US $6 billion and growing at approximately 12% annually.[2,3] 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.[2,3] 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 (Epocal 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 nontechnical 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 (Fig. 1). The EPOC system currently measures pH, P_{co_2}, P_{o_2}, 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

From the Department of Pathology, Baystate Health, Springfield, MA.
Reprints: James H. Nichols, PhD, DABCC, FACB, Clinical Chemistry, Baystate Health, 759 Chestnut St, Springfield, MA 01199 (e-mail: james.nichols@bhs.org).

FIGURE 1. The EPOC system. The EPOC blood analysis system consists of individual test cards (front and back of card in lower half of figure) that can provide blood gas and electrolyte analysis in multiple configurations. This configuration uses a card reader (upper left) that detects signals from the biosensor on the test card and transmits the data wirelessly to a handheld PDA that contains the EPOC software to calculate analyte concentration from the raw card signals. Other configurations allow the card reader to wirelessly connect to PCs or other hardware running the EPOC software.

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_{CO_2}	P_{O_2}	Na	K	iCa
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.

TABLE 2. Total Precision of the EPOC System

	pH	Pco_2	Po_2	Na	K	iCa	Hct
Level 1							
Mean	6.992	86.2	74.9	113.4	2.15	2.18	23.8
SD (% CV)	0.0107 (0.15)	2.4 (2.8)	2.8 (3.8)	1.2 (1.0)	0.03 (1.5)	0.04 (1.7)	0.7 (2.9)
Level 2							
Mean	7.673	24.1	140.1	153.1	6.71	0.662	45.0
SD (% CV)	0.0108 (0.14)	0.7 (3.1)	2.8 (2.0)	1.6 (1.0)	0.07 (1.1)	0.01 (1.9)	0.8 (1.8)

Total precision was conducted at Epocal during the pilot manufacturing stage. Two levels of controls (Mission Diagnostics) 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 was performed using 2 levels of Hct control (Mission Diagnostics) at Baystate Health and was performed on 2 card readers using 6 different test card lots.

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 the pairwise replicates for each method. Student *t* test of method differences was performed using Statistica software (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 3. Correlation Statistics Between the EPOC System and i-STAT

	pH	Pco_2, mm Hg	Po_2, mm Hg	Na, mmol/L	K, mmol/L	iCa, mmol/L	Hct, %
Regression	$0.03 + 1.00x$	$-0.9 + 1.04x$	$-1.7 + 1.05x$	$-0.04 + 1.02x$	$8.8 + 0.94x$	$0.1 + 0.91x$	$-1.1 + 1.07x$
i-STAT Mean	7.35	49.1	87.4	137.8	3.86	1.14	33.7
EPOC Mean	7.34	50.3	90.9	138.5	3.90	1.14	34.8
S*y.x* (% CV)	0.018 (2.5)	2.5 (4.9)	6.6 (7.3)	0.09 (2.4)	2.1 (1.5)	0.03 (2.5)	1.4 (3.9)
r	0.987	0.990	0.978	0.989	0.880	0.943	0.987
Range of results	6.95–7.56	18.5–122.3	22.9–232.1	126–147.5	2.5–6.6	0.79–1.62	18.5–77.0
n	142	143	142	142	142	143	142
i-STAT Precision of replicates, SD (% CV)	0.013 (0.17)	1.49 (3.0)	4.6 (5.3)	0.6 (0.4)	0.047 (1.22)	0.016 (1.4)	0.58 (1.7)
EPOC Precision of replicates, SD (% CV)	0.006 (0.08)	1.10 (2.2)	2.7 (3.0)	0.8 (0.6)	0.046 (1.18)	0.014 (1.2)	0.64 (1.8)

Units are noted for each analyte. Correlation equation calculated by least squares regression. N indicates number of results; *r*, regression coefficient; S*y.x*, SE of the estimate.

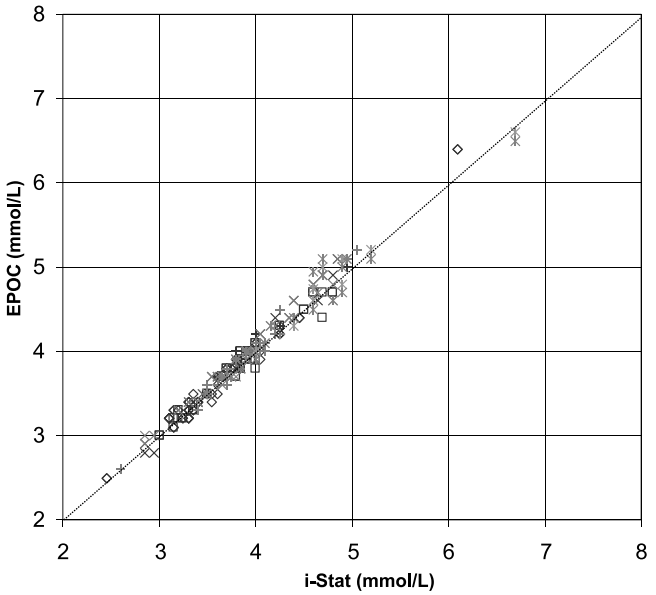

FIGURE 2. Correlation plot for K. Results from each analytical site are separated by the following data symbols:¯, Epocal laboratory; o, Baystate laboratory; +, hematology/oncology clinic; x, CICU; and *, ICU.

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_{CO_2}, P_{O_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_{CO_2} and P_{O_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.[6–12]

DISCUSSION

The need for blood gas and electrolyte analysis in the management of critical care patients is well established.[1] 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[13–15] 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,[16] exercise physiology,[17] oncology clinics,[18] organ donor procurement,[19] evaluation of heat exhaustion in the wilderness,[20] and management of patients during emergency helicopter/ambulance transfer.[21] The i-STAT has even been used by astronauts during space travel.[22] 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

downloaders 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 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 Admission, Discharge, Transfer data 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 Admission, Discharge, Transfer data 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.

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