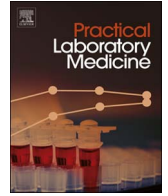


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# Practical Laboratory Medicine

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## Validation of capillary blood analysis and capillary testing mode on the epoc Point of Care system



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### ABSTRACT

**Background:** Laboratory test in transport is a critical component of patient care, and capillary blood is a preferred sample type particularly in children. This study evaluated the performance of capillary blood testing on the epoc Point of Care Blood Analysis System (Alere Inc).

**Methods:** Ten fresh venous blood samples was tested on the epoc system under the capillary mode. Correlation with GEM 4000 (Instrumentation Laboratory) was examined for Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>2+</sup>, glucose, lactate, hematocrit, hemoglobin, pO<sub>2</sub>, pCO<sub>2</sub>, and pH, and correlation with serum tested on Vitros 5600 (Ortho Clinical Diagnostics) was examined for creatinine. Eight paired capillary and venous blood was tested on epoc and ABL800 (Radiometer) for the correlation of Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>2+</sup>, glucose, lactate, hematocrit, hemoglobin, pCO<sub>2</sub>, and pH. Capillary blood from 23 apparently healthy volunteers was tested on the epoc system to assess the concordance to reference ranges used locally.

**Results:** Deming regression correlation coefficients for all the comparisons were above 0.65 except for ionized Ca<sup>2+</sup>. Accordance of greater than 85% to the local reference ranges were found in all assays with the exception of pO<sub>2</sub> and Cl<sup>-</sup>.

**Conclusion:** Data from this study indicates that capillary blood tests on the epoc system provide comparable results to reference method for these assays, Na<sup>+</sup>, K<sup>+</sup>, glucose, lactate, hematocrit, hemoglobin, pCO<sub>2</sub>, and pH. Further validation in critically ill patients is needed to implement the epoc system in patient transport.

**Impact of the study:** This study demonstrated that capillary blood tests on the epoc Point of Care Blood Analysis System give comparable results to other chemistry analyzers for major blood gas and critical tests. The results are informative to institutions where pre-hospital and inter-hospital laboratory testing on capillary blood is a critical component of patient point of care testing.

### 1. Introduction

Air and ground transport are increasingly used in pre-hospital or inter-hospital transfer of patients in life-threatening situations. Blood gas analysis and other critical tests performed during patient transport are substantial to patient care.

The epoc Point of Care Blood Analysis System has gained popularity as the point-of-care-testing (POCT) device used in transport due to several advantages, including ease of use, small sample volume, requiring no refrigeration of consumable reagents, and real-time data communication via wi-fi network. The system performs a broad menu of tests including Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>2+</sup>, glucose, creatinine, lactate, hematocrit, hemoglobin, partial pressures of oxygen (pO<sub>2</sub>) and carbon dioxide (pCO<sub>2</sub>), and pH on arterial, venous

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and capillary blood.

Although the gold standard samples for blood gas analysis are arterial blood collected from arterial catheter or by arterial puncture, the proper sampling of arterial blood is difficult, painful, and sometimes risky to obtain in patient transport. Venous blood sampling, on the other hand, is less painful and risky, but does not manifest the accurate blood oxygen supply status [1,2]. Capillary blood samples have become an alternative to arterial blood for blood gas and other critical tests especially in patient transport, because they are least painful and easiest to obtain, from various sites such as fingertip, heel or earlobe [3,4].

Limited data are available on the performance of epoc system on capillary blood for patients in transport. There have been studies comparing the epoc system to another model of POCT device (iSTAT) or Radiometer ABL835 on arterial and venous samples [5,6], however, no report on the validation of epoc testing using capillary blood is available, despite that type of blood samples are important pre-analytical factors that can affect blood gas and other critical testing [3]. Our institution, Texas Children's Hospital (TCH), was among the first large academic medical centers to implement the epoc system in patient transport, which has benefited our large pediatric patient population. In a period of eight months, 48% of the epoc testing was carried out in patient transport. However, due to the difficulties to sometimes procure enough arterial or venous sample, we examined the possibility of using capillary blood for blood gas and other critical tests. Thus, the objective of this study was to evaluate capillary blood analysis on the epoc system.

## 2. Methods

### 2.1. Study participants and samples

Institutional Research Board waiver was obtained prior to study initiation at TCH General Laboratory. Ten venous blood samples were used to assess the correlation between reference methods and the capillary mode testing on epoc, which refers to collecting sample with the capillary tube provided followed by selecting “capillary” as the sample type on epoc for testing. For method comparison of Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>2+</sup>, glucose, lactate, hematocrit, hemoglobin, pO<sub>2</sub>, pCO<sub>2</sub>, and pH, fresh venous blood samples were collected in heparinized vacutainer tubes, and were tested on the predicate analyzer GEM Premier 4000 (Instrumentation Laboratory, Bedford, MA) with a minimum volume of 150 µl and on epoc Point of Care Blood Analysis System (Alere Inc, Waltham, MA) under the capillary mode according to manufacturer's instructions (minimum volume of 90 µl). For method comparison of creatinine, fresh venous blood samples were collected and centrifuged within an hour from collection, and were tested on the predicate analyzer Vitros 5600 Integrated System (Ortho Clinical Diagnostics, Raritan, NJ) with a minimum volume of 41 µl and the epoc system under the capillary mode. Eight paired capillary and venous blood was tested on epoc and ABL800 (Radiometer, Brea, CA) respectively for the correlation of Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>2+</sup>, glucose, lactate, hematocrit, hemoglobin, pCO<sub>2</sub>, and pH. Twenty three study participants (17 female, 6 male) were recruited to donate capillary blood for the reference range concordance study. Health screening questionnaires were answered prior to participation in the study. Fresh capillary blood from fingertip was collected in a heparinized capillary glass tube (epoc Care Fill capillary tube) and was analyzed immediately on the epoc system.

### 2.2. Laboratory tests

Creatinine was tested on Vitros 5600 with an enzymatic assay. Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>2+</sup>, glucose, lactate, hematocrit, hemoglobin, pO<sub>2</sub>, pCO<sub>2</sub>, and pH were tested on GEM 4000 using amperometry, potentiometry, conductivity, or spectrophotometry method. All the tests were also performed on the epoc System.

The US Food and Drug Administration approved the epoc blood gas and electrolyte analysis system in 2006 for testing of the analytes evaluated in this study as described previously [6,7]. The single-use, self-calibrated epoc BGEM Test Card contains a full menu of 12 analytes that requires 90 µl of sample volume. Fresh blood is passed through channels to biosensors, and results are available in approximately 30 s.

### 2.3. Data analyses

The complementary epoc Host system generates an accession number at the testing and allows the entering of patient information. Test results were uploaded via Wi-Fi to the epoc Middleware Data Manager after each test and later were downloaded for analysis. Correlation with Vitros 5600, GEM 4000 and ABL800 was assessed with Deming Regression. Distribution of results from healthy individuals was examined for reference rang concordance. EP Evaluator (Data Innovation, Burlington, VT) was used for data analyses.

## 3. Results

### 3.1. Method correlation

The method correlation study was performed using fresh venous blood. Correlation between tests on the epoc system under the capillary mode and GEM 4000 (n = 10) was examined for Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>2+</sup>, glucose, lactate, hematocrit, hemoglobin, pO<sub>2</sub>, pCO<sub>2</sub>, and pH. Correlation between tests on the epoc system under the capillary mode and serum tested on Vitros 5600 (n = 10) was examined for creatinine. The assay analytical measurement range (AMR), sample result range, mean, standard deviation (SD),

**Table 1**

Correlation of epoc capillary tests with GEM 4000 or Vitros 5600 tests (n = 10). Reference method is venous whole blood testing on GEM 4000 except for creatinine which is venous plasma tested on Vitros 5600. Comparison method is venous whole blood tested on capillary mode of epoc. AMR: Analytical Measurement Range. SD: Standard Deviation. R: Correlation coefficient of Deming regression.

Analyte	Reference method		Comparison method		R	Mean bias (% Bias)	SD differences
	AMR (Result range)	Result mean (SD)	AMR (Result range)	Result mean (SD)			
pH	7.01–7.70 (7.33–7.43)	7.365 (0.034)	6.5–8.0 (7.34–7.42)	7.379 (0.025)	0.8184	0.014 (0.190)	0.02
pCO <sub>2</sub> (mmHg)	10.5–124.9 (34.0–58.0)	49.10 (7.08)	5–250 (35.4–54.3)	46.39 (5.73)	0.7178	–2.71 (–5.68)	4.97
pO <sub>2</sub> (mmHg)	30.2–689.4 (18.0–65.0)	36.2 (12.86)	5–750 (18.0–55.6)	34.69 (12.72)	0.886	–1.51 (–4.26)	6.11
Na <sup>+</sup> (mmol/L)	107.3–179.7 (137–142)	138.8 (1.6)	85–180 (136–142)	137.9 (2.1)	0.7982	–0.9 (–0.7)	1.3
K <sup>+</sup> (mmol/L)	2.1–19.0 (3.6–4.6)	4.06 (0.35)	1.5–12.0 (3.5–4.3)	3.94 (0.28)	0.9851	–0.12 (–3.0)	0.09
Ca <sup>++</sup> (mmol/L)	0.44–4.25 (1.17–1.27)	1.217 (0.035)	0.25–4.0 (1.12–1.25)	1.178 (0.044)	0.385	–0.039 (–3.257)	0.044
Cl <sup>-</sup> (mmol/L)	63–158 (99–109)	104.5 (2.9)	65–140 (101–112)	104.8 (3.5)	0.7707	0.3 (0.3)	2.2
Glucose (mg/dL)	44–685 (80–183)	112.2 (27.7)	20–700 (81–183)	111.5 (26.9)	0.9872	–0.7 (–0.6)	4.4
Lactate (mmol/L)	1.0–17.0 (0.9–3.0)	1.57 (0.65)	0.30–20.00 (1.0–2.9)	1.65 (0.58)	0.9788	0.08 (4.97)	0.15
Hematocrit (% PCV)	19–72 (25–50)	42.5 (6.9)	10–75 (39–51)	42.7 (3.7)	0.6807	0.2 (0.5)	5.1
Hemoglobin (g/dL)	6.0–22.5 (8.1–15.6)	13.62 (2.23)	3.3–25 (13.2–17.3)	14.48 (1.26)	0.6598	0.86 (6.12)	1.69
Creatinine (mg/dL)	0.05–14.0 (0.56–0.96)	0.744 (0.129)	0.30–15.00 (0.44–0.93)	0.719 (0.168)	0.9313	–0.025 (–3.418)	0.067

Deming regression correlation coefficients, average absolute and percent bias, and SD differences are shown in Table 1. All correlation coefficients were above 0.65 except for ionized Ca<sup>2+</sup>. Excellent correlation (> 0.90) between methods was observed for K<sup>+</sup>, glucose, lactate and creatinine.

Paired capillary and venous blood (n = 8) was tested on epoc and ABL800 respectively for the correlation of Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>2+</sup>, glucose, lactate, hematocrit, hemoglobin, pCO<sub>2</sub>, and pH. The correlation data are shown in Table 2. All correlation coefficients are above 0.65, and excellent correlations were found in K<sup>+</sup> and Cl<sup>-</sup>.

### 3.2. Accordance of reference range

Capillary blood from 23 apparently healthy subjects between 18 and 65 years were tested on the epoc system to examine the concordance to reference ranges used locally (Table 3). Outliers based on fasting states (for fasting glucose) or genders (for gender-specific reference ranges) were excluded from the analyses. The results of pO<sub>2</sub> and Cl<sup>-</sup> were not presented due to poor agreement with TCH reference ranges. The test result distribution of pH, pCO<sub>2</sub>, hematocrit, hemoglobin, creatinine and major electrolytes including Na<sup>+</sup>, K<sup>+</sup> showed good concordance to the TCH reference ranges (accordance > = 90%).

## 4. Discussion

This study evaluated the performance of capillary blood testing on the epoc Point of Care Blood Analysis System. Acceptable

**Table 2**

Correlation of epoc capillary tests with ABL800 tests (n = 8). Reference method is venous whole blood testing on ABL800. Comparison method is capillary blood tested on epoc. AMR: Analytical Measurement Range. SD: Standard Deviation. R: Correlation coefficient of Deming regression.

Analyte	Reference method		Comparison method		R	Mean bias (% Bias)	SD differences
	AMR (Result range)	Result mean (SD)	AMR (Result range)	Result mean (SD)			
pH	6.300–8.000 (7.36–7.43)	7.39 (0.022)	6.5–8.0 (7.39–7.46)	7.42 (0.022)	0.7894	0.03 (0.44)	0.01
pCO <sub>2</sub> (mmHg)	5.0–250.0 (37.1–53.3)	44.29 (5.37)	5–250 (36.0–47.5)	40.31 (3.30)	0.6509	–3.97 (–9.4)	4.12
Na <sup>+</sup> (mmol/L)	7.0–350.0 (139–144)	141.8 (1.7)	85–180 (139–144)	142.5 (1.8)	0.7242	0.8 (0.5)	1.3
K <sup>+</sup> (mmol/L)	0.5–25.0 (3.7–4.5)	4.01 (0.25)	1.5–12.0 (3.9–4.9)	4.30 (0.31)	0.9023	0.29 (6.92)	0.14
Ca <sup>++</sup> (mmol/L)	0.2–9.99 (1.17–1.24)	1.206 (0.027)	0.25–4.0 (1.06–1.28)	1.159 (0.067)	0.8003	–0.047 (–4.017)	0.048
Cl <sup>-</sup> (mmol/L)	7–350 (103–108)	105.9 (1.7)	65–140 (102–108)	105.3 (2.0)	0.9286	–0.6 (–0.6)	0.7
Glucose (mg/dL)	0–1081 (94–113)	105.5 (6.1)	20–700 (94–127)	105.5 (10.8)	0.7748	0 (0)	7.2
Lactate (mmol/L)	0.0–30.0 (0.80–2.30)	1.213 (0.473)	0.30–20.00 (0.85–1.72)	1.164 (0.322)	0.8156	–0.049 (–4.103)	0.281
Hematocrit (% PCV)	0–81.5 (42.0–48.3)	45.35 (2.17)	10–75 (38.0–47.0)	43.13 (3.00)	0.7385	–2.22 (–5.03)	2.02
Hemoglobin (g/dL)	0.0–27.7 (13.7–15.8)	14.82 (0.78)	3.3–25 (13.0–15.9)	14.67 (0.98)	0.6563	–0.15 (–1.02)	0.75

**Table 3**  
Concordance of capillary blood reference ranges on the epoc system.

Analyte	N	Reference range	Mean (SD)	Median (range)	% of Accordance
pH	17 (female)	7.36–7.44 (female) 7.35–7.45 (male)	7.41 (0.02)	7.41 (7.37–7.46)	92
pCO <sub>2</sub> (mmHg)	17 (female)	33–43 (female) 36–46 (male)	37.9 (2.6)	38.8 (32.6–41.5)	93
Na <sup>+</sup> (mmol/L)	23	136–145	141.5 (1.6)	142 (137–144)	100
K <sup>+</sup> (mmol/L)	23	3.5–5.5	4.4 (0.5)	4.3 (3.9–5.6)	95
Ca <sup>++</sup> (mmol/L)	23	1.10–1.30	1.17 (0.06)	1.17 (1.06–1.28)	89
Glucose (mg/dL)	19	70–100 (fasting)	93.3 (6.6)	94 (80–102)	87
Lactate (mmol/L)	23	0.2–1.7	1.1 (0.4)	1.0 (0.6–1.8)	87
Creatinine (mg/dL)	23	0.12–1.06	0.86 (0.16)	0.84 (0.64–1.29)	90
Hematocrit (% PCV)	17 (female)	36–46 (female) 41–53 (male)	41.3 (3.1)	42 (37–49)	94
Hemoglobin (g/dL)	17 (female)	12.0–16.0 (female) 13.5–17.5 (male)	14.1 (1.1)	14.3 (12.6–16.7)	94

correlations with other chemistry analyzers were found for all analytes except for ionized calcium. Accordance to the TCH reference ranges of greater than 85% were observed with the exception of pO<sub>2</sub> and chloride. Our data supports the implementation of the capillary blood tests on the epoc system with cautions needed for calcium. Chloride and pO<sub>2</sub> tests are not suitable for capillary blood sampling.

Blood gas and other critical laboratory tests on capillary blood are particularly preferred in the transport of children, for whom vascular collection of blood could be challenging and posing great impact on the total blood volume (in neonates). Compared to venous blood, capillary blood shows closer correlation to the reference arterial blood samples [4], and the practice of capillary blood collection for blood gas analysis has been recommended by CLSI [1,8] and IFCC [2]. The capillary bed of the targeted collection skin site can be dilated with heat or a topical vasodilator before the puncture, in order to obtain the arterialized capillary blood, which is a mixture of capillary blood, arteriolar blood, venular blood, interstitial fluid, and intracellular fluid [3,4].

Our results, in consensus with previous findings [5,6], suggest that majority of the analytes available on the epoc system have comparable results to other chemistry analyzers. With further analyses on reference range accordance, our study showed that capillary blood tests on the epoc system can be considered for these analytes: Na<sup>+</sup>, K<sup>+</sup>, glucose, lactate, creatinine, hematocrit, hemoglobin, pH and pCO<sub>2</sub>. However, our study has the following limitations: 1) The correlation study shown in Table 1 tested venous blood on capillary mode of epoc, while the paired capillary and venous blood correlation data shown in Table 2 are from healthy people and therefore may not be generalized to patients in critical conditions; 2) The correlation study result range did not represent the entire AMR; 3) Additionally, our study did not have sufficient number of paired comparison of capillary blood and venous blood on creatinine measurement. In summary, this study demonstrates that the epoc Point of Care Blood Analysis System may be one of options of blood gas analyses and other critical tests using capillary blood in patient transport.

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