

BGEM Test Card Specifications

Storage Stability



Cards must be stored in their card pouch at room temperature between 15 to 30°C (59 to 86°F) until expiration date. Do not fridge store or freeze.

Test Timing

The initiation of a test run starts with establishing a communications link between the host and reader. A card is removed from its pouch. The card should be inserted immediately into the card reader. During an approximately 165 second calibration period a blood sample is acquired. After calibration is complete the reader light indicates that the card is ready to receive the blood. The card is now in calibration, and the sample can be introduced at any time thereafter up to a period of five (5) minutes after which time the card's calibration times-out and the card is no longer available to accept a sample. Approximately half a minute after sample introduction into a calibrated card, the host computer displays the analytical results and the card can be removed from the EPOC Reader and discarded.

Sample Type

Fresh whole blood from arterial, venous or capillary sources, introduced to the card from a syringe or an EPOC Care-Fill Blood Collection Tube.

Sample Volume

>92µL, non-volumetric quantity

Sample Collection

Syringes or evacuated tubes without anticoagulant OR with lithium, sodium or balanced heparin anticoagulant.

EPOC Care-Fill Blood Collection Tubes with balanced heparin anticoagulant.

For a detailed description consult the sample collection procedures and cautions located in section "03– EPOC System Operation" of the EPOC System Manual.

Analysis time

Approximately 35 seconds after sample introduction for blood sample tests.

Approximately 44 seconds after sample introduction for aqueous control tests.

Measurement Range

Measured Parameters

pH	6.5 – 8.0	pH units
$p\text{CO}_2$	5 – 250	mm Hg
$p\text{O}_2$	5 – 750	mm Hg
Na	85 – 180	mmol/L
K	1.5– 12	mmol/L
iCa	0.25 – 4	mmol/L
Glucose	20 - 700	mg/dL
Hct	10 – 75	%PCV

Calculated Parameters

TCO_2	1 – 85	mmol/L
HCO_3	1 – 85	mmol/L
BE_{ecf}	-30 - +30	mmol/L
BE_b	-30 - +30	mmol/L
sO_2	0 – 100	%
Hb	3.3 – 25	g/dL

Interpretation of results

If the patient test results seem inconsistent with the clinical assessment, a fresh patient sample should be collected and tested on another card.

See further in this chapter for information on factors affecting the results of the various sensors. Certain substances, such as drugs, may affect the test results¹⁻⁴.

References

1. T.P.Moyer, L.M. Shaw, Chapter 33 of *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*-Fourth Edition, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
2. W.H.Porter, T.P.Moyer, Chapter 25 of *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*-Fourth Edition, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
3. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington DC, 1990.
4. N.W. Tietz, *Clinical Guide to Laboratory Tests*, 3rd Edition, W.B.Saunders Company, 1995.

Sodium Na

Sodium is measured by potentiometry using an ion selective membrane electrode. The concentration of sodium ions is obtained from the measured potential using the Nernst equation. The EPOC sodium measurement is an undiluted (direct) method. Values may differ from those obtained by dilutional (indirect) methods.¹

Indications for Use

The sodium test, as part of the EPOC Blood Analysis System is intended for use by trained medical professionals as an **in vitro diagnostic device** for the quantitative testing of samples of whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Measurement of sodium is used in diagnosis and treatment of diseases involving electrolyte imbalance.

Contents

Each test card incorporating a sodium test contains a sodium sensing electrode with a sodium selective membrane, a reference electrode and a calibrator fluid containing a known concentration of sodium salts.

Traceability

Values of sodium ion concentration assigned to controls and calibrator fluids are traceable to NIST standards.

Sample Type

Fresh whole blood from arterial, venous or capillary sources, introduced to the card from a syringe or an EPOC Care-Fill Blood Collection Tube.

Sample Volume

>92µL, non-volumetric quantity

Sample Collection

Syringes or evacuated tubes without anticoagulant OR with lithium, sodium or balanced heparin anticoagulant.

EPOC Care-Fill Blood Collection Tubes with balanced heparin anticoagulant.

For a detailed description consult the sample collection procedures and cautions located in section "03– EPOC System Operation" of the EPOC System Manual.

Analysis time

Approximately 35 seconds after sample introduction for blood sample tests.

Approximately 44 seconds after sample introduction for aqueous control tests.

Measurement Range

	Measurement range	Normal Range ^{2,3}
Na	85 – 180 mmol/L	138 – 146 mmol/L

Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the EPOC System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP9-A2⁴ for method comparison studies, CLSI EP7-A2⁵ for interference studies.

Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	113	0.9	0.8	1.2	1.1
Level 3	mmol/L	153	1.0	0.7	1.6	1.0

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study with 2 measurements each day per each control level. 4 manufactured lots, 6 different EPOC Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	115	0.6	0.5	0.8	0.7
Level 3	mmol/L	153	0.7	0.5	1.0	0.6

In-house Precision 3: whole blood samples run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mmol/L	147	0.9	0.6
Blood level 2	mmol/L	168	1.4	0.8

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the EPOC system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different EPOC Readers.

High sodium level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 1	mmol/L	158	1.3	0.8
Operator 2	mmol/L	155	0.8	0.5
Operator 3	mmol/L	157	1.3	0.8

Low sodium level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 4	mmol/L	109	0.6	0.5
Operator 5	mmol/L	109	1.0	0.9
Operator 6	mmol/L	108	0.8	0.8
Operator 7	mmol/L	109	0.5	0.5

Clinical Site Precision 2: 10 replicates of different whole blood patient samples run by different operators of the EPOC system at different point-of-care sites. Each precision study employed 5 different EPOC Readers.

	Units	Mean	SD _{WR}	%CV
Site 1 operator 1	mmol/L	142	0.5	0.3
operator 2	mmol/L	143	1.5	1.0
Site 2 operator 3	mmol/L	142	1.2	0.8
operator 4	mmol/L	143	0.8	0.6
operator 5	mmol/L	143	0.7	0.5
Site 3 operator 6	mmol/L	141	0.7	0.5
operator 7	mmol/L	140	1.0	0.7

Linearity Data

This study was performed in-house on multiple whole blood samples with sodium concentration spanning the reportable range. Linearity is reported versus an in-house standard ion selective electrode method with traceability to NIST standards.

	Test range	Units	Slope	Intercept	R ²
Na	80-190	mmol/L	0.973	3.8	0.999

Clinical Sites Method Comparison Data

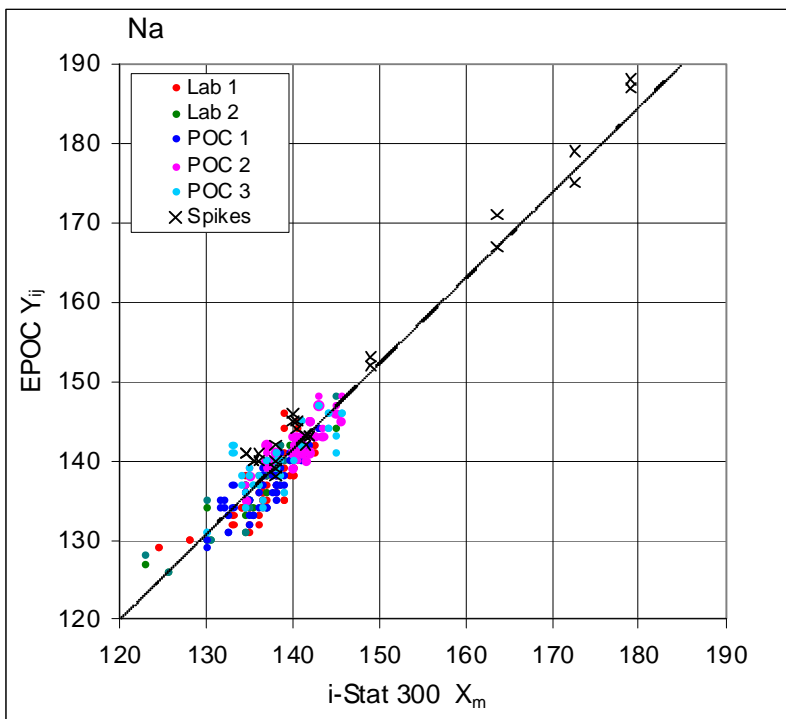
Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-2A⁴. In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and EPOC test methods respectively, Syx is the standard error and R is the correlation coefficient.

In one hospital study the EPOC was compared with the i-Stat 300⁶ in the lab (two test occasions) then in three point-of-care sites.

Method Comparison Summary Statistics: whole blood
 X: i-Stat 300 test
 Y: EPOC test

Na	Lab 1	Lab 2	POC 1	POC 2	POC 3	All	All*
N	34	24	35	27	22	142	156
Sxx	0.79	0.61	0.48	0.62	0.45	0.61	0.62
Syy	0.77	0.82	0.84	0.89	0.66	0.80	0.88
Intercept	22.2	8.4	5.3	27.9	28.9	8.8	-9.579
Slope	0.839	0.944	0.963	0.812	0.803	0.941	1.077
Syx	2.18	2.07	1.67	1.38	2.46	2.05	2.22
X min	125	123	130	135	130	123	123
X max	143	145	143	146	146	146	179
R	0.822	0.914	0.888	0.847	0.813	0.880	0.953

*data set includes patient samples spiked with NaCl for extended data range



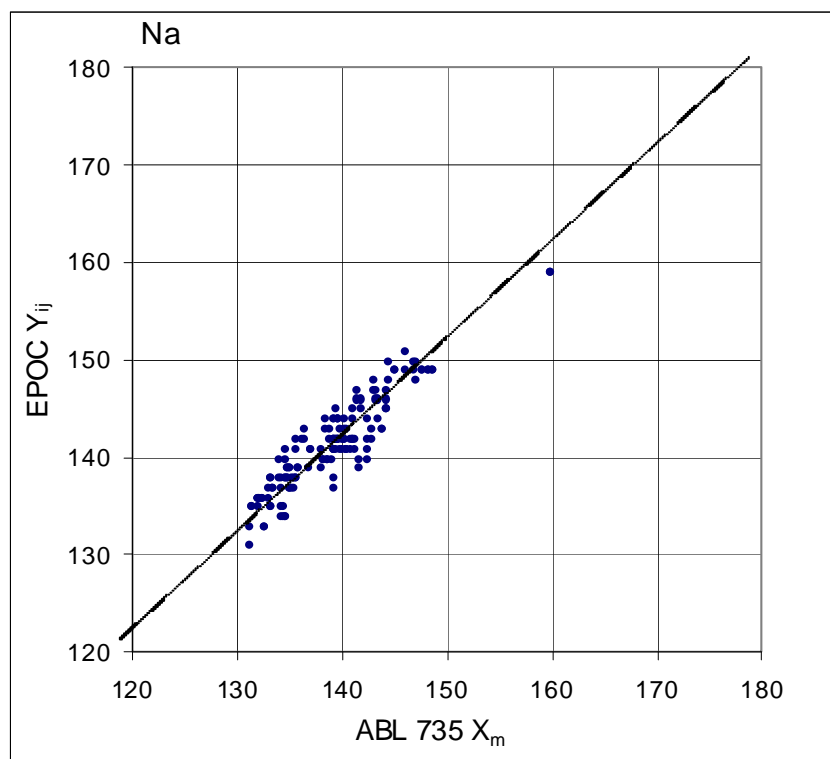
In another hospital study the EPOC was compared with the Radiometer ABL 735⁷ in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: EPOC test

Na	Lab
N	77
Sxx	0.78
Syy	0.79
Intercept	19.1
Slope	0.881
Syx	1.81
X min	131
X max	160
R	0.924



Limitations and Interferences

Similar to other dry reagent methods, a decrease (increase) of total protein will increase (decrease) Na by 1.3mM/(g/dL) versus a direct method. The EPOC Na result tracks the reading of an indirect (dilutional) method^{1,8,9}.

Concordant with direct methods, hyperlipidemia does not affect the Na measurement^{7,8}. The effect of Intralipid was tested up to 5% (lipid vol)/(plasma vol) and was found to be clinically insignificant.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results.

See section "03–EPOC System Operation" of the System Manual for proper sample collection procedures

Interference testing⁴ was performed in-house on the EPOC sodium sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of an interferent, while the control sample was spiked by the addition of the solvent of the interferent. The sodium bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Sodium heparin will give erroneously high Na results
- 20 mmol/L β -hydroxybutyrate will decrease Na by 3 mmol/L
- 20 mmol/L lactate will decrease Na by 4 mmol/L
- 16 mmol/L bromide will increase sodium by 5 mmol/L
- Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause significant elevation of sodium results¹⁰. For proper line-flushing procedures refer to CLSI H-11¹¹.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 0.7 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 10 mmol/L bromide, 3 μ mol/L dobutamide, 2.5 mmol/L tolbutamide.

The following levels of Endogenous Interferences were tested and found to be clinically insignificant: 8 mmol/L KCl, 3mmol/L CaCl₂, 10 to 120 mmHg pCO₂, pH 6.9 to 7.7, +20 mmol/L bicarbonate, 10 mmol/L lactate, +20% PCV Hct, 9.1 mmol/L cholesterol, 1 mmol/L cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

References

1. M.G. Scott, V.A. LeGrys and J.S. Klutts, Chapter 27 of *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*-Fourth Edition, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
2. *Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*-Fourth Edition, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
3. B.E. Statland, *Clinical Decision Levels for Lab Tests*, Medical Economic Books, Oradell, NJ, 1987.
4. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition*, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
5. CLSI. *Interference Testing in Clinical Chemistry; Approved Guideline*, CLSI document EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
6. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.
7. Radiometer ABL 735, Radiometer Medical Aps, Åkandevvej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical Aps.
8. G. Dimeski, R. J. Barnett, "Effects of Total Plasma Protein Concentration on Plasma Sodium, Potassium and Chloride Measurements by an Indirect Ion Selective Electrode Measurement System", *Critical Care and Resuscitation*, **7**, 12-15, 2005.
9. G.B. Levy, "Determination of Sodium with Ion-Selective Electrodes", *Clinical Chemistry*, **27**, 1435-1437, 1981.
10. CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*, CLSI document C46-A (ISBN 1-56238-444-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
11. CLSI. *Procedures for the Collection of Arterial Blood Specimens; Approved Standard*, CLSI document H11-A4 (ISBN 1-56238-545-3), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

Potassium K

Potassium is measured by potentiometry using an ion selective membrane electrode. The concentration of potassium ions is obtained from the measured potential using the Nernst equation. The EPOC potassium measurement is an undiluted (direct) method. Values may differ from those obtained by dilutional (indirect) methods.¹

Indications for Use

The potassium test, as part of the EPOC Blood Analysis System is intended for use by trained medical professionals as an **in vitro diagnostic device** for the quantitative testing of samples of whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Measurement of potassium is used in diagnosis and treatment of diseases involving electrolyte imbalance.

Contents

Each test card incorporating a potassium test contains a potassium sensing electrode with a potassium selective membrane, a reference electrode and a calibrator fluid containing a known concentration of potassium salts.

Traceability

Values of potassium ion concentration assigned to controls and calibrator fluids are traceable to NIST standards

Sample Type

Fresh whole blood from arterial, venous or capillary sources, introduced to the card from a syringe or an EPOC Care-Fill Blood Collection Tube.

Sample Volume

>92µL, non-volumetric quantity

Sample Collection

Syringes or evacuated tubes without anticoagulant OR with lithium, sodium or balanced heparin anticoagulant.

EPOC Care-Fill Blood Collection Tubes with balanced heparin anticoagulant.

For a detailed description consult the sample collection procedures and cautions located in section "03– EPOC System Operation" of the EPOC System Manual.

Analysis time

Approximately 35 seconds after sample introduction for blood sample tests.

Approximately 44 seconds after sample introduction for aqueous control tests.

Measurement Range

	Measurement range	Normal Range ²
K	1.5 – 12 mmol/L	3.5 – 4.5 mmol/L

Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the EPOC System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP9-A2³ for method comparison studies, CLSI EP7-A2⁴ for interference studies.

Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	2.2	0.02	0.9	0.03	1.5
Level 3	mmol/L	6.7	0.06	0.9	0.07	1.1

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study with 2 measurements each day per each control level. 4 manufactured lots, 6 different EPOC Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	2.2	0.02	1.0	0.03	1.2
Level 3	mmol/L	6.6	0.05	0.8	0.06	1.0

In-house Precision 3: whole blood samples run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mmol/L	4.3	0.04	1.0
Blood level 2	mmol/L	6.2	0.05	0.8

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the EPOC system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different EPOC Readers.

High potassium level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 1	mmol/L	6.8	0.05	0.7
Operator 2	mmol/L	6.7	0.06	0.9
Operator 3	mmol/L	6.7	0.09	1.3

Low potassium level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 4	mmol/L	2.0	0.01	0.6
Operator 5	mmol/L	2.0	0.03	1.6
Operator 6	mmol/L	2.0	0.05	2.5
Operator 7	mmol/L	2.0	0.02	1.0

Clinical Site Precision 2: 10 replicates of different whole blood patient samples run by different operators of the EPOC system at different point-of-care sites. Each precision study employed 5 different EPOC Readers.

	Units	Mean	SD _{WR}	%CV
Site 1 operator 1	mmol/L	4.0	0.05	1.3
operator 2	mmol/L	4.0	0.00	0.0
Site 2 operator 3	mmol/L	3.7	0.00	0.0
operator 4	mmol/L	3.8	0.03	0.8
operator 5	mmol/L	3.7	0.03	0.9
Site 3 operator 6	mmol/L	3.6	0.03	0.9
operator 7	mmol/L	4.1	0.05	1.2

Linearity Data

This study was performed in-house on multiple whole blood samples with potassium concentration spanning the reportable range. Linearity is reported versus an in-house standard ion selective electrode method with traceability to NIST standards.

	Test range	Units	Slope	Intercept	R ²
K	1.5-12	mmol/L	1.006	0.03	0.999

Clinical Sites Method Comparison Data

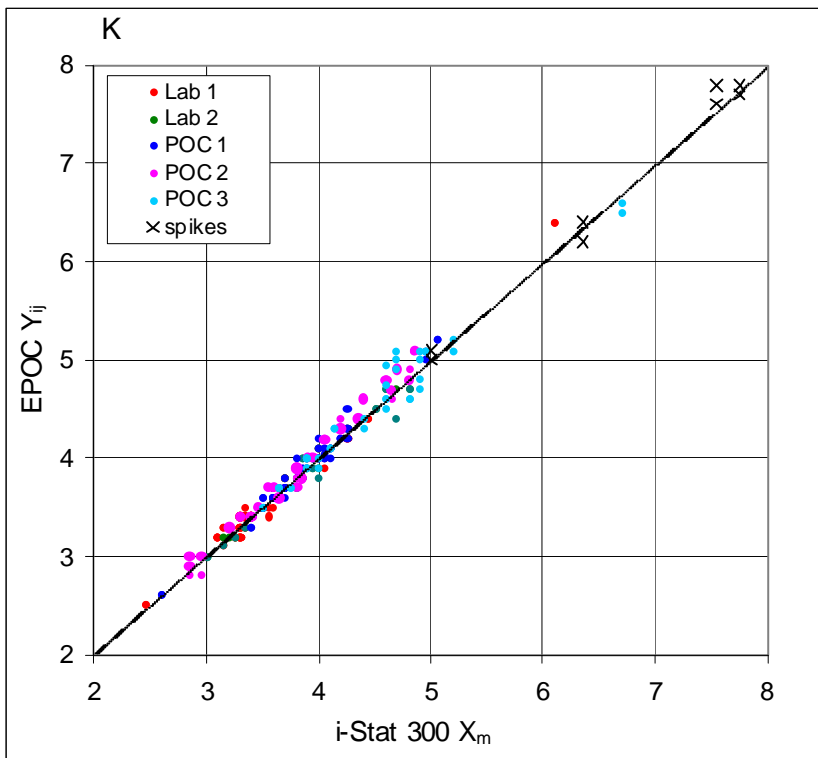
Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2³. In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and EPOC test methods respectively, Syx is the standard error and R is the correlation coefficient.

In one hospital study the EPOC was compared with the i-Stat 300⁵ in the lab (two test occasions) then in three point-of-care sites.

Method Comparison Summary Statistics: whole blood
 X: i-Stat 300 test
 Y: EPOC test

K	Lab 1	Lab 2	POC 1	POC 2	POC 3	All	All*
N	34	24	35	27	22	142	146
Sxx	0.040	0.061	0.040	0.061	0.030	0.047	0.048
Syy	0.043	0.052	0.045	0.045	0.045	0.046	0.049
Intercept	-0.164	-0.144	-0.171	-0.134	0.134	-0.044	-0.018
Slope	1.056	1.042	1.051	1.057	0.971	1.021	1.013
Syx	0.088	0.114	0.057	0.077	0.114	0.094	0.094
X min	2.5	3.0	2.6	2.9	3.3	2.5	2.5
X max	6.1	4.8	5.1	4.9	6.7	6.7	7.8
R	0.991	0.979	0.993	0.993	0.988	0.989	0.993

*data set includes patient samples spiked with KCl for extended data range



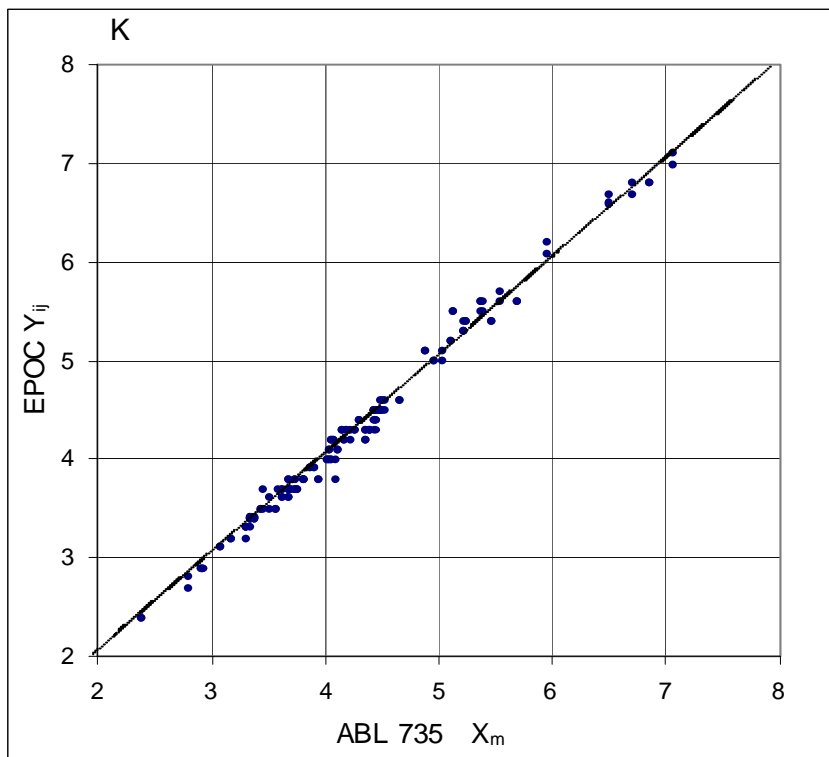
In another hospital study the EPOC was compared with the Radiometer ABL 735⁶ in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: EPOC test

K	Lab
N	77
Sxx	0.057
Syy	0.044
Intercept	-0.073
Slope	1.026
Syx	0.090
X min	2.4
X max	7.1
R	0.996



Limitations and Interferences

Sample hemolysis will cause elevated potassium values. Improper sample collection technique may cause variation in potassium values due to hemolysis¹.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results.

See section "03–EPOC System Operation" of the System Manual for proper sample collection procedures.

Interference testing⁴ was performed in-house on the EPOC potassium sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of an interferent, while the control sample was spiked by the addition of the solvent of the interferent. The potassium bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause significant elevation of potassium results⁷. For proper line-flushing procedures refer to CLSI H11-A4⁸.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 0.7 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 38 mmol/L bromide, 3 µmol/L dobutamide, 2.5mmol/L tolbutamide.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 3mmol/L CaCl₂, 10 to 120 mmHg pCO₂, pH 6.9 to 7.7, +20 mmol/L bicarbonate, 10 mmol/L lactate, +20% PCV Hct, 3% to 11% total protein, 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 1 mmol/L cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

References

1. M.G. Scott, V.A. LeGrys and J.S. Klutts, Chapter 27 of *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*-Fourth Edition, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
2. *Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*-Fourth Edition, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
3. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition*, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
4. CLSI. *Interference Testing in Clinical Chemistry; Approved Guideline*, CLSI document EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
5. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.
6. Radiometer ABL 735, Radiometer Medical Aps, Åkandevvej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical Aps.
7. CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*, CLSI document C46-A (ISBN 1-56238-444-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
8. CLSI. *Procedures for the Collection of Arterial Blood Specimens; Approved Standard*, CLSI document H11-A4 (ISBN 1-56238-545-3), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

Calcium iCa

Ionized calcium is measured by potentiometry using an ion selective membrane electrode. The concentration of calcium ions is obtained from the measured potential using the Nernst equation.

Indications for Use

The ionized calcium test, as part of the EPOC Blood Analysis System is intended for use by trained medical professionals as an **in vitro diagnostic device** for the quantitative testing of samples of whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Measurement of Ionized Calcium is used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Contents

Each test card incorporating an ionized calcium test contains a calcium ion sensing electrode with a calcium selective membrane, a reference electrode and a calibrator fluid containing a known concentration of calcium salts.

Traceability

Values of calcium ion concentration assigned to controls and calibrator fluids are traceable to NIST standards

Sample Type

Fresh whole blood from arterial, venous or capillary sources, introduced to the card from a syringe or an EPOC Care-Fill Blood Collection Tube.

Sample Volume

>92 μ L, non-volumetric quantity

Sample Collection

Syringes or evacuated tubes without anticoagulant OR with lithium, sodium or balanced heparin anticoagulant.

EPOC Care-Fill Blood Collection Tubes with balanced heparin anticoagulant.



Incomplete filling of anticoagulated tubes and syringes will cause higher heparin-to-blood ratios, which will decrease ionized calcium results.

For a detailed description consult the sample collection procedures and cautions located in section "03– EPOC System Operation" of the EPOC System Manual.

Analysis time

Approximately 35 seconds after sample introduction for blood sample tests.

Approximately 44 seconds after sample introduction for aqueous control tests.

Measurement Range

	Measurement range	Normal Range ¹
iCa	0.25 – 4 mmol/L	1.15 – 1.33 mmol/L

Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the EPOC System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP9-A2² for method comparison studies, CLSI EP7-A2³ for interference studies.

Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	2.18	0.03	1.4	0.04	1.7
Level 3	mmol/L	0.66	0.01	1.5	0.01	1.9

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study with 2 measurements each day per each control level. 4 manufactured lots, 6 different EPOC Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	2.20	0.02	1.0	0.03	1.3
Level 3	mmol/L	0.67	0.01	1.3	0.01	1.8

In-house Precision 3: whole blood samples run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mmol/L	1.35	0.02	1.4
Blood level 2	mmol/L	2.20	0.03	1.2

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the EPOC system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different EPOC Readers.

High ionized calcium level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 1	mmol/L	0.57	0.01	1.9
Operator 2	mmol/L	0.56	0.01	0.9
Operator 3	mmol/L	0.57	0.01	1.7

Low ionized calcium level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 4	mmol/L	1.53	0.02	1.3
Operator 5	mmol/L	1.53	0.02	1.5
Operator 6	mmol/L	1.55	0.03	1.7
Operator 7	mmol/L	1.56	0.02	1.2

Clinical Site Precision 2: 10 replicates of different whole blood patient samples run by different operators of the EPOC system at different point-of-care sites. Each precision study employed 5 different EPOC Readers.

	Units	Mean	SD _{WR}	%CV
Site 1 operator 1	mmol/L	1.20	0.02	1.5
operator 2	mmol/L	1.21	0.02	1.9
Site 2 operator 3	mmol/L	1.19	0.02	1.7
operator 4	mmol/L	1.21	0.03	2.1
operator 5	mmol/L	1.20	0.02	1.6
Site 3 operator 6	mmol/L	1.23	0.02	1.8
operator 7	mmol/L	1.24	0.02	1.9

Linearity Data

This study was performed in-house on multiple whole blood samples with ionized calcium concentration spanning the reportable range. Linearity is reported versus an in-house standard ion selective electrode method with traceability to NIST standards.

	Test range	Units	Slope	Intercept	R ²
iCa	0.6-3.7	mmol/L	1.017	-0.01	0.998

Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2². In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and EPOC test methods respectively, Syx is the standard error and R is the correlation coefficient.

In one hospital study the EPOC was compared with the i-Stat 300⁴ in the lab (two test occasions) then in three point-of-care sites.

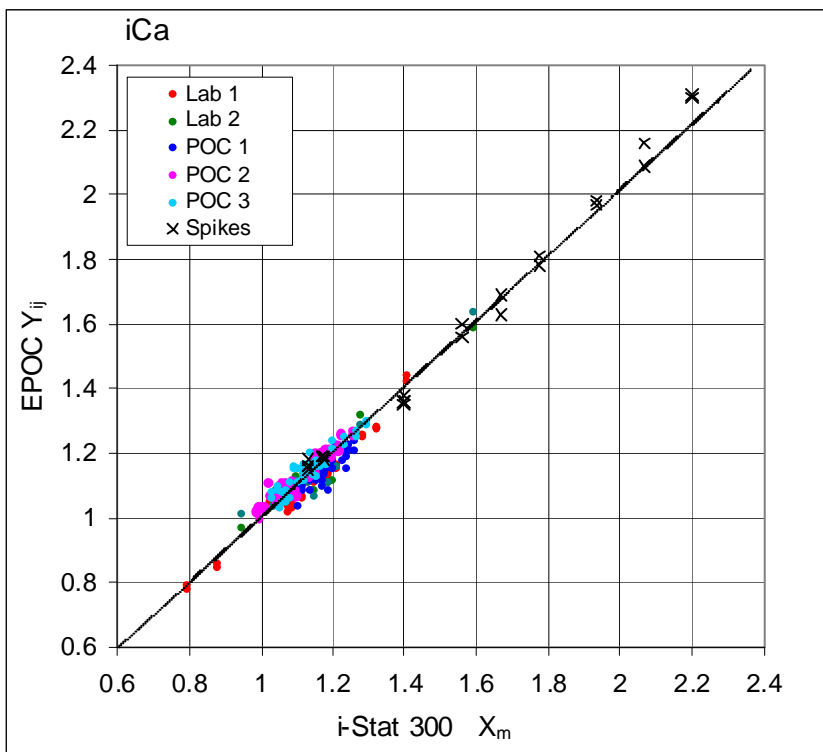
Method Comparison Summary Statistics: whole blood

X: i-Stat 300 test

Y: EPOC test

iCa	Lab 1	Lab 2	POC 1	POC 2	POC 3	All	All*
N	34	24	35	28	22	143	156
Sxx	0.016	0.019	0.014	0.017	0.015	0.016	0.016
Syy	0.011	0.014	0.017	0.014	0.015	0.014	0.015
Intercept	0.003	0.050	0.157	0.106	0.103	0.102	-0.026
Slope	0.980	0.953	0.851	0.925	0.923	0.908	1.021
Syx	0.025	0.033	0.020	0.016	0.024	0.029	0.031
X min	0.8	0.9	1.1	1.0	1.0	0.8	0.80
X max	1.4	1.6	1.3	1.3	1.3	1.6	2.20
R	0.974	0.961	0.891	0.978	0.939	0.943	0.985

*data set includes patient samples spiked with CaCl₂ for extended data range



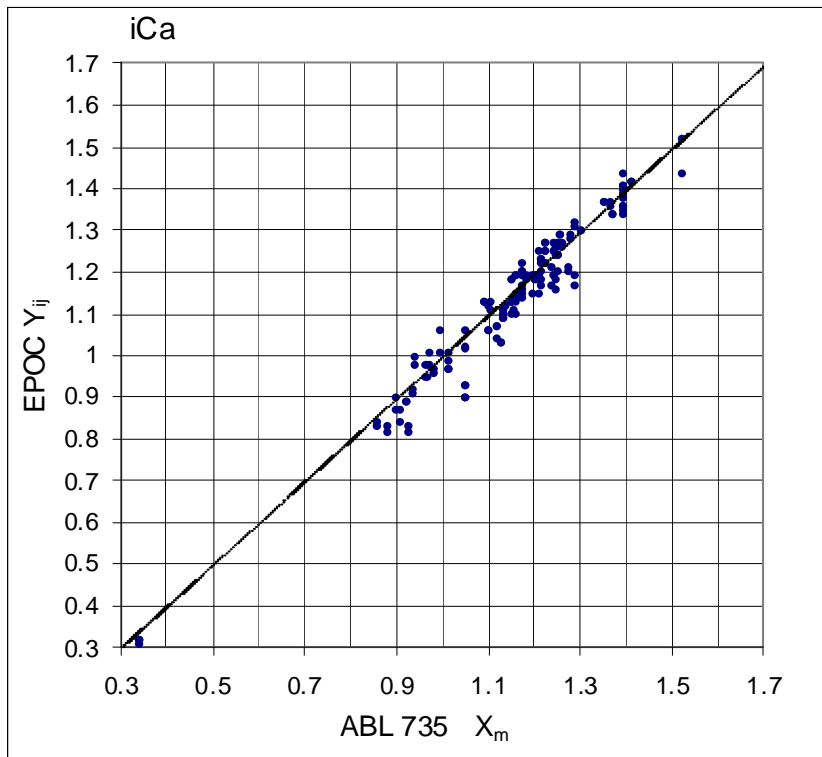
In another hospital study the EPOC was compared with the Radiometer ABL 735⁵ in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: EPOC test

iCa	Lab
N	77
Sxx	0.023
Syy	0.016
Intercept	-0.045
Slope	1.025
Syx	0.040
X min	0.34
X max	1.52
R	0.981



Limitations and Interferences

Specimen choice, collection technique, anti-coagulant type and level as well as sample handling will affect the concentration of ionized calcium⁶.

Exposure of the sample to air will affect pH, $p\text{CO}_2$, $p\text{O}_2$ and ionized calcium results due to the sample equilibration with the gas levels in the air, with pH affected by the $p\text{CO}_2$ change⁷ and ionized calcium affected by the pH change⁸. Air contains less than 1 mmHg $p\text{CO}_2$ and about 150-180 mmHg $p\text{O}_2$. Do not introduce air bubbles into a collection device. If present, air bubbles should be removed immediately after collection.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results.

See section "03-EPOC System Operation" of the System Manual for proper sample collection procedures.

Interference testing³ was performed in-house on the ionized calcium sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The ionized calcium bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- 20 mmol/L β -hydroxybutyrate will decrease iCa by 0.038 mmol/L
- 10 mmol/L lactate will decrease iCa by 0.04 mmol/L
- 4.3 mmol/L salicylate or acetyl salicylate will decrease iCa by 0.06 mmol/L
- 10 mmol/L bromide will increase iCa by 0.05 mmol/L
- Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause significant elevation of ionized calcium results⁹. For proper line-flushing procedures refer to CLSI H-11¹⁰.
- Highly heparinized samples will decrease the iCa⁶; balanced heparin or low heparin collection tubes/syringes are recommended.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 0.4 mmol/L ascorbate, 1 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 3 $\mu\text{mol/L}$ dobutamide, 2.5mmol/L tolbutamide.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 8 mmol/L KCl, 10 to 120 mmHg $p\text{CO}_2$, pH 6.9 to 7.7, +20 mmol/L bicarbonate, 7 mmol/L lactate, +20% PCV Hct, 0.8% lipids, 9.1 mmol/L cholesterol, 1 mmol/L cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

References

1. *Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-Fourth Edition*, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
2. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition*, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
3. CLSI. *Interference Testing in Clinical Chemistry; Approved Guideline*, CLSI document EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
4. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.
5. Radiometer ABL 735, Radiometer Medical Aps, Åkandevvej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical Aps.
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10. CLSI. *Procedures for the Collection of Arterial Blood Specimens; Approved Standard*, CLSI document H11-A4 (ISBN 1-56238-545-3), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

Hematocrit Hct and Calculated Hb

Measured values

Hematocrit is measured by ac conductometry using two gold electrodes. The conductance of the blood sample in the fluidic path between the two electrodes, after correction for variable plasma conductivity through the measurement of sodium concentration, is inversely proportional to the hematocrit value.

Calculated Values

Hemoglobin concentration is calculated from the measured hematocrit according to the relation^{1,2}

$$\text{Hb (g/dL)} = \text{Hct (decimal fraction)} \times 34$$

The relation above assumes a normal Mean Corpuscular Hemoglobin Concentration, MCHC of 34%^{1,2}.

Indications for Use

The Hct test, as part of the EPOC Blood Analysis System is intended for use by trained medical professionals as an **in vitro diagnostic device** for the quantitative testing of samples of whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Measurement of Hct distinguishes normal from abnormal states of blood volume, such as anemia and erythrocytosis.

Contents

Each test card incorporating a Hct test contains two gold sensing electrodes and a calibrator fluid containing a known concentration of dissolved electrolytes with a known conductivity.

Traceability

Hematocrit values assigned to controls and calibrator fluids are traceable to the standard method for measuring packed cell volume by the microhematocrit method – applicable standard CLSI H7-A3³

Sample Type

Fresh whole blood from arterial, venous or capillary sources, introduced to the card from a syringe or an EPOC Care-Fill Blood Collection Tube.

Sample Volume

>92µL, non-volumetric quantity

Sample Collection

Syringes or evacuated tubes without anticoagulant OR with lithium, sodium or balanced heparin anticoagulant.

EPOC Care-Fill Blood Collection Tubes with balanced heparin anticoagulant.

For a detailed description consult the sample collection procedures and cautions located in section "03– EPOC System Operation" of the EPOC System Manual.

Analysis time

Approximately 35 seconds after sample introduction for blood sample tests.

Approximately 44 seconds after sample introduction for aqueous control tests.

Measurement Range

	Measurement range	Normal Range ⁴
Hct	10 – 75 %	38 – 51 %
Hb	3.3 – 25 g/dL	12 – 17 g/dL

Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the EPOC System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP9-A2⁵ for method comparison studies, CLSI EP7-A2⁶ for interference studies.

Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial hematocrit controls run in a 20 day precision study with 2 measurements each day per each control level. 4 manufactured lots, 6 different EPOC Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	%PCV	25.3	0.4	1.5	0.4	1.6
Level 3	%PCV	46.1	0.7	1.5	0.7	1.5

In-house Precision 2: whole blood samples run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	%PCV	44.0	0.7	1.6
Blood level 2	%PCV	22.0	0.7	3.0

Clinical Site Precision: 10 replicates of whole blood patient samples run by different operators of the EPOC system at different point-of-care sites. Each precision study employed 5 different EPOC Readers.

	Units	Mean	SD _{WR}	%CV
Site 1 operator 1	%PCV	40	0.6	1.4
operator 2	%PCV	40	0.5	1.3
Site 2 operator 3	%PCV	39	0.6	1.6
operator 4	%PCV	41	0.5	1.2
operator 5	%PCV	40	0.6	1.4
Site 3 operator 6	%PCV	40	0.8	2.0
operator 7	%PCV	38	0.7	1.9

Linearity Data

This study was performed in-house on multiple whole blood samples with hematocrit level spanning the reportable range. Linearity is reported versus an in-house standard spun hematocrit method.

	Test range	Units	Slope	Intercept	R ²
Hct	0-75	% PCV	1.005	-0.58	0.999

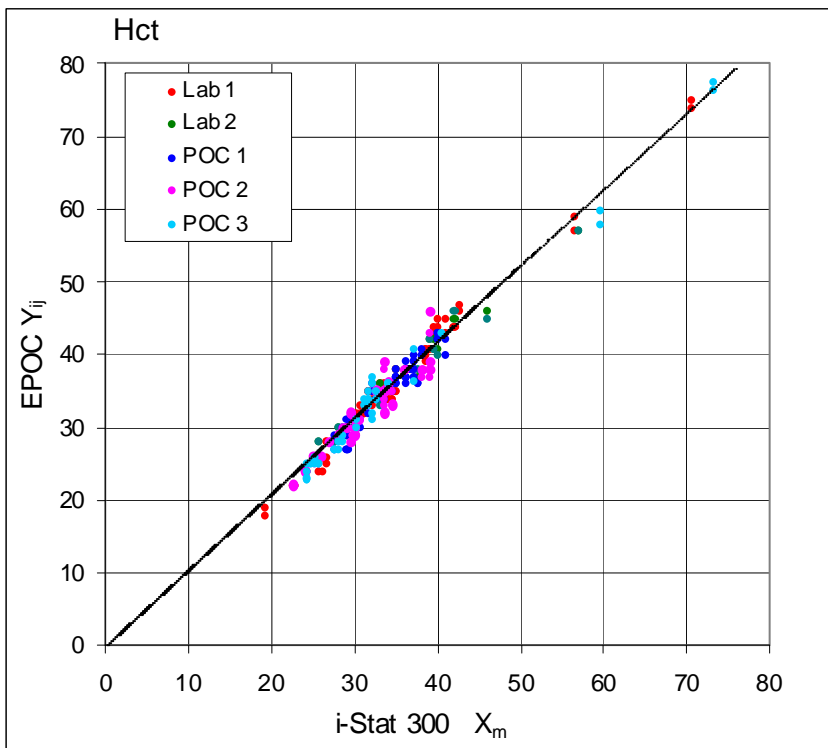
Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2. In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and EPOC test methods respectively, Syx is the standard error and R is the correlation coefficient.

In one hospital study the EPOC was compared with the i-Stat 300⁷ in the lab (two test occasions) then in three point-of-care sites.

Method Comparison Summary Statistics: whole blood
 X: i-Stat 300 test
 Y: EPOC test

Hct	Lab 1	Lab 2	POC 1	POC 2	POC 3	All
N	34	23	35	28	22	142
Sxx	0.49	0.66	0.46	0.67	0.69	0.58
Syy	0.69	0.42	0.65	0.57	0.80	0.64
Intercept	-1.5	1.3	0.0	-0.4	-0.4	-1.1
Slope	1.086	1.006	1.034	1.027	1.051	1.066
Syx	1.28	1.17	1.05	1.48	1.82	1.36
X min	19	24	28	23	24	19
X max	73	57	41	39	60	73
R	0.995	0.990	0.964	0.955	0.976	0.987



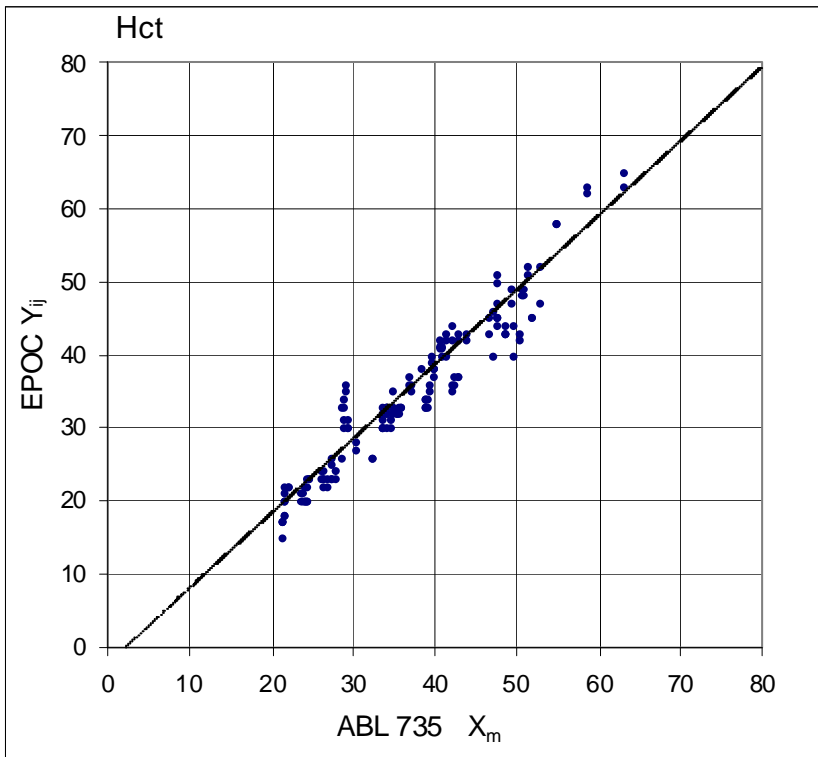
In another hospital study the EPOC was compared with the Radiometer ABL 735⁸ in the lab. (The ABL 735 hematocrit value is calculated from the measured hemoglobin.)

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: EPOC test

Hct	Lab
N	77
Sxx	1.42
Syy	1.16
Intercept	-2.3
Slope	1.006
Syx	2.84
X min	21
X max	63
R	0.964



Limitations and Interferences

Blood samples must be well mixed in order to obtain accurate hematocrit results. The best way to ensure this is to test the sample immediately after collection. For samples where testing delays of greater than one minute occur, cells should be thoroughly re-mixed by rolling the sample between the hands for several rotations in both directions. *Note* – Thin diameter collection devices (for example, 1cc syringes or epoc Care-Fill Capillary Tubes) may be difficult to re-mix. Therefore, it is recommended that testing from these devices not be delayed.

See section “03–EPOC System Operation” of the System Manual for proper sample collection procedures.

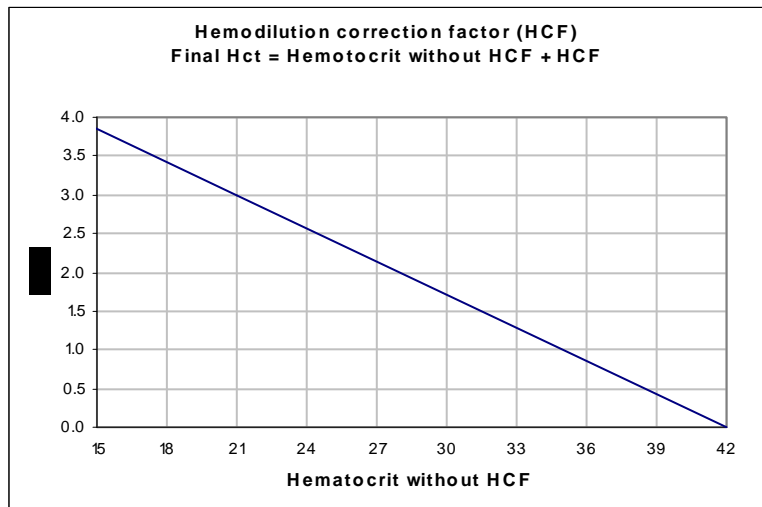
Interference testing⁶ was performed in-house on the EPOC hematocrit sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The hematocrit bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Total protein content will affect the hematocrit results as follows: an increase (decrease) of 1 g/dL of total protein will increase (decrease) the hematocrit value by approximately 1% PCV. Total protein levels vary with the clinical populations⁴. Low total protein values may be found in neonates, burned patients, patients receiving large volumes of IV fluids and patients undergoing cardiopulmonary bypass (CPB) and extra-corporeal membrane oxygenation (ECMO).

In these cases, the user should activate the hemodilution correction factor, HCF, in the Epoc Host (see sections 6 and 7 for details). The HCF algorithm assumes that the IV fluids contain no albumin, no colloid and no red blood cells. There is no HCF applied for Hct over 42%. The differences between no HCF and HCF algorithm are illustrated in the figure below.

It is recommended that each practice verify the use of the HCF algorithm as well as the time interval that the HCF should be selected during the recovery period.



- A significant increase in white blood cell count may increase the hematocrit result.
- Abnormally high lipids may increase hematocrit results.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 1 mmol/L iodide, 2.2 mmol/L ibuprofen, 4 mmol/L lithium, 19 mmol/L bromide.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β -hydroxybutyrate, 1 mmol/L cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

References

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2. J.D. Bower, P.G. Ackerman and G. Toto, Eds., *Clinical Laboratory Methods*, Chapter 5: Evaluation of formed elements in blood, St. Louis, The C.V. Mosby Company, 1974.
3. CLSI. *Procedure for determining Packed Cell Volume by the Microhematocrit method; Approved Standard-Third Edition*, CLSI document H7-A3 (ISBN 1-56238-413-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.
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6. CLSI. *Interference Testing in Clinical Chemistry; Approved Guideline*, CLSI document EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
7. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.
8. Radiometer ABL 735, Radiometer Medical Aps, Åkandevvej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical Aps.

pH

pH is measured by potentiometry using an pH selective membrane electrode. The concentration of hydrogen ions is obtained from the measured potential using the Nernst equation.

Indications for Use

The pH test, as part of the EPOC Blood Analysis System is intended for use by trained medical professionals as an **in vitro diagnostic device** for the quantitative testing of samples of whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Measurement of pH, pCO_2 , pO_2 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

Contents

Each test card incorporating a pH test contains a hydrogen ion sensing electrode with a hydrogen ion selective membrane, a reference electrode and a calibrator fluid containing a known concentration of pH buffer salts.

Traceability

Values of pH assigned to controls and calibrator fluids are traceable to NIST standards

Sample Type

Fresh whole blood from arterial, venous or capillary sources, introduced to the card from a syringe or an EPOC Care-Fill Blood Collection Tube.

Sample Volume

>92 μ L, non-volumetric quantity

Sample Collection

Syringes or evacuated tubes without anticoagulant OR with lithium, sodium or balanced heparin anticoagulant.

EPOC Care-Fill Blood Collection Tubes with balanced heparin anticoagulant.

For a detailed description consult the sample collection procedures and cautions located in section "03– EPOC System Operation" of the EPOC System Manual.

Analysis time

Approximately 35 seconds after sample introduction for blood sample tests.

Approximately 44 seconds after sample introduction for aqueous control tests.

Measurement Range

	Measurement range	Normal Range ¹
pH	6.5 – 8.0	7.35 – 7.45 arterial 7.32 – 7.43 venous

Temperature Correction

pH is a temperature dependent quantity, measured at 37°C on the EPOC System. The pH value can be corrected to the patient's temperature. Patient temperature is entered on the Test Information Page of the Reader Tab on the EPOC Host (see EPOC System Operation section of System Manual).

The pH at the patient's temperature (T) is calculated as follows²

$$\text{pH (T)} = \text{pH} - 0.0147(\text{T} - 37) + 0.0065(7.4 - \text{pH})(\text{T} - 37)$$

Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the EPOC System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP9-A2³ for method comparison studies, CLSI EP7-A2⁴ for interference studies.

Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	pH units	6.992	0.007	0.10	0.010	0.15
Level 3	pH units	7.673	0.007	0.09	0.011	0.14

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study with 2 measurements each day per each control level. 4 manufactured lots, 6 different EPOC Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	pH units	6.986	0.006	0.09	0.008	0.11
Level 3	pH units	7.676	0.005	0.07	0.006	0.08

In-house Precision 3: whole blood samples run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	pH units	7.200	0.007	0.09
Blood level 2	pH units	7.700	0.009	0.12

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the EPOC system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different EPOC Readers.

High pH level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 1	pH units	7.679	0.004	0.05
Operator 2	pH units	7.672	0.005	0.07
Operator 3	pH units	7.685	0.009	0.12

Low pH level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 4	pH units	7.101	0.005	0.07
Operator 5	pH units	7.094	0.006	0.08
Operator 6	pH units	7.088	0.013	0.18
Operator 7	pH units	7.079	0.006	0.08

Clinical Site Precision 2: 10 replicates of different whole blood patient samples run by different operators of the EPOC system at different point-of-care sites. Each precision study employed 5 different EPOC Readers.

	Units	Mean	SD _{WR}	%CV
Site 1 operator 1	pH units	7.365	0.006	0.08
operator 2	pH units	7.368	0.005	0.07
Site 2 operator 3	pH units	7.322	0.005	0.07
operator 4	pH units	7.335	0.006	0.08
operator 5	pH units	7.303	0.009	0.12
Site 3 operator 6	pH units	7.266	0.006	0.08
operator 7	pH units	7.381	0.004	0.05

Linearity Data

This study was performed in-house on multiple whole blood samples with pH values spanning the reportable range. Linearity is reported versus an in-house standard ipH electrode method with traceability to NIST standards.

	Test range	Units	Slope	Intercept	R ²
pH	6.4-7.9	pH units	1.021	-0.15	0.998

Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-2A³. In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and EPOC test methods respectively, Syx is the standard error and R is the correlation coefficient.

In one hospital study the EPOC was compared with the i-Stat 300⁶ in the lab (two test occasions) then in three point-of-care sites.

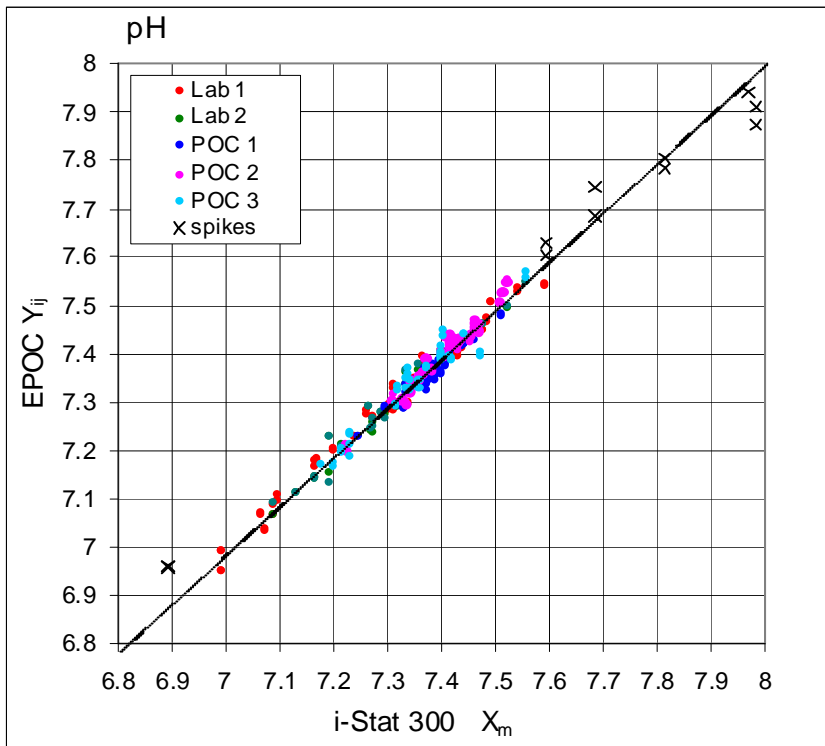
Method Comparison Summary Statistics: whole blood

X: i-Stat 300 test

Y: EPOC test

pH	Lab 1	Lab 2	POC 1	POC 2	POC 3	All	All*
N	34	24	35	27	22	142	149
Sxx	0.016	0.012	0.010	0.010	0.015	0.013	0.014
Syy	0.005	0.006	0.006	0.006	0.008	0.006	0.007
Intercept	0.152	0.006	0.448	-0.772	-0.367	0.029	0.251
Slope	0.978	0.999	0.938	1.104	1.050	0.995	0.966
Syx	0.019	0.021	0.013	0.015	0.024	0.018	0.020
X min	6.991	7.085	7.243	7.223	7.174	6.991	6.770
X max	7.592	7.557	7.507	7.522	7.557	7.592	7.982
R	0.993	0.985	0.961	0.981	0.985	0.987	0.991

*data set includes patient samples spiked with NaOH for extended data range



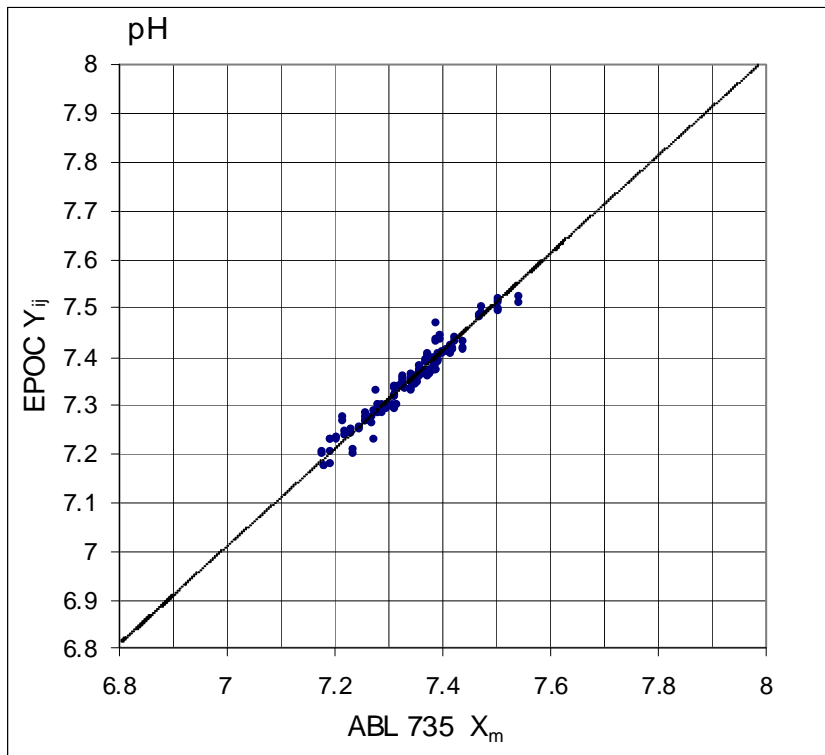
In another hospital study the EPOC was compared with the Radiometer ABL 735⁷ in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: EPOC test

pH	Lab
N	77
Sxx	0.011
Syy	0.010
Intercept	0.366
Slope	0.952
Syx	0.017
X min	7.175
X max	7.542
R	0.975



Limitations and Interferences

Exposure of the sample to air will affect pH, $p\text{CO}_2$, $p\text{O}_2$ and ionized calcium results due to the sample equilibration with the gas levels in the air, with pH affected by the $p\text{CO}_2$ change⁹ and ionized calcium affected by the pH change⁸. Air contains less than 1 mmHg $p\text{CO}_2$ and about 150-180 mmHg $p\text{O}_2$. Do not introduce air bubbles into a collection device. If present, air bubbles should be removed immediately after collection.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results.

See section "03–EPOC System Operation" of the System Manual for proper sample collection procedures.

Interference testing⁴ was performed in-house on the EPOC pH sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The pH bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause lower pH results². For proper line-flushing procedures refer to CLSI H11-A4⁵.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 1 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 35 mmol/L bromide.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 8 mmol/L KCl, 3 mmol/L CaCl_2 , 10 to 120 mmHg $p\text{CO}_2$, pH 6.9 to 7.7, +20 mmol/L bicarbonate, 10 mmol/L lactate, +20% PCV Hct, 3% to 11% total protein, 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β -hydroxybutyrate, 1 mmol/L cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

References

1. *Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-Fourth Edition*, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
2. CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*, CLSI document C46-A (ISBN 1-56238-444-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
3. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition*, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
4. CLSI. *Interference Testing in Clinical Chemistry; Approved Guideline*, CLSI document EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
5. CLSI. *Procedures for the Collection of Arterial Blood Specimens; Approved Standard*, CLSI document H11-A4 (ISBN 1-56238-545-3), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.
6. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.
7. Radiometer ABL 735, Radiometer Medical Aps, Åkandevej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical Aps.
8. D.B. Endres and R.K. Rude, Chapter 49 (p. 1901) of *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-Fourth Edition*, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
9. M.G. Scott, V.A. LeGrys and J.S. Klutts, Chapter 27 of *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-Fourth Edition*, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.

Measured values

$p\text{CO}_2$ is measured by potentiometry using a membrane covered pH sensing electrode^{9,10}. The electrode voltage is proportional to the dissolved carbon dioxide concentration through the Nernst equation.

Calculated Values¹

$$\text{LOG } \text{HCO}_3^- = \text{pH} + \text{LOG } p\text{CO}_2 - 7.608$$

$$\text{TCO}_2 = \text{HCO}_3^- + 0.0307p\text{CO}_2$$

$$\text{BE}_{\text{ecf}} = \text{HCO}_3^- - 24.8 + 16.2(\text{pH} - 7.4)$$

$$\text{BE}_b = (1 - 0.014\text{Hb}) * (\text{HCO}_3^- - 24.8 + (1.43 * \text{Hb} + 7.7) * (\text{pH} - 7.4))$$

Applicable standards: CLSI C46-A¹.

Indications for Use

The $p\text{CO}_2$ test, as part of the EPOC Blood Analysis System is intended for use by trained medical professionals as an **in vitro diagnostic device** for the quantitative testing of samples of whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Measurement of pH, $p\text{CO}_2$, $p\text{O}_2$ (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

Contents

Each test card incorporating a $p\text{CO}_2$ test contains a pH sensing electrode overlaid with a bicarbonate containing membrane, a carbon dioxide permeable membrane, a reference electrode and a calibrator fluid containing a known concentration of dissolved carbon dioxide.

Traceability

Dissolved carbon dioxide concentration values assigned to controls and calibrator fluids are traceable to NIST standards via commercially available certified medical gas standards.

Sample Type

Fresh whole blood from arterial, venous or capillary sources, introduced to the card from a syringe or an EPOC Care-Fill Blood Collection Tube.

Sample Volume

>92 μL , non-volumetric quantity

Sample Collection

Syringes or evacuated tubes without anticoagulant OR with lithium, sodium or balanced heparin anticoagulant.

EPOC Care-Fill Blood Collection Tubes with balanced heparin anticoagulant.

For a detailed description consult the sample collection procedures and cautions located in section "03– EPOC System Operation" of the EPOC System Manual.

Analysis time

Approximately 35 seconds after sample introduction for blood sample tests.

Approximately 44 seconds after sample introduction for aqueous control tests.

Measurement Range

	Measurement range	Normal Range ²	
		Arterial	Venous
$p\text{CO}_2$	5 – 250 mm Hg (0.67 – 33.3 kPa)	35 – 48 mm Hg (4.7 – 6.4 kPa)	41 – 51 mm Hg (5.4 – 6.8 kPa)
HCO_3^-	1 – 85 mmol/L	21-28 mmol/L	22-29 mmol/L
TCO_2	1 – 85 mmol/L	22-29 mmol/L	23-30 mmol/L
BE	-30 – 30 mmol/L	-2 – +3 mmol/L	-2 - +3 mmol/L

Temperature Correction

$p\text{CO}_2$ is a temperature dependent quantity, measured at 37°C on the EPOC System. The $p\text{CO}_2$ value can be corrected to the patient's temperature. Patient temperature is entered on the Test Information Page of the Reader Tab on the EPOC Host (see EPOC System Operation section of System Manual).

The $p\text{CO}_2$ at the patient's temperature (T) is calculated as follows¹

$$p\text{CO}_2 (T) = p\text{CO}_2 \times 10^{0.019(T - 37)}$$

Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the EPOC System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP9-A2⁴ for method comparison studies, CLSI EP7-A2⁷ for interference studies.

Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_{T} denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_{T}	%CV
Level 1	mm Hg	86.2	1.9	2.2	2.4	2.8
Level 3	mm Hg	24.1	0.5	2.1	0.7	3.0

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study with 2 measurements each day per each control level. 4 manufactured lots, 6 different EPOC Readers

	Units	Mean	SD _{WR}	%CV	SD _T	%CV
Level 1	mm Hg	80.6	1.9	2.4	2.4	2.9
Level 3	mm Hg	22.5	0.4	1.6	0.6	2.5

In-house Precision 3: whole blood samples run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD _{WR}	%CV
Blood level 1	mm Hg	65.0	1.5	2.3
Blood level 2	mm Hg	90.0	2.9	3.2

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the EPOC system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different EPOC Readers.

Low $p\text{CO}_2$ level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 1	mm Hg	21.2	0.4	1.9
Operator 2	mm Hg	21.2	0.5	2.3
Operator 3	mm Hg	20.5	1.1	5.2

High $p\text{CO}_2$ level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 4	mm Hg	69.0	1.2	1.7
Operator 5	mm Hg	70.2	1.2	1.7
Operator 6	mm Hg	68.2	1.3	1.8
Operator 7	mm Hg	67.2	1.3	1.9

Clinical Site Precision 2: 10 replicates of different whole blood patient samples run by different operators of the EPOC system at different point-of-care sites. Each precision study employed 5 different EPOC Readers.

	Units	Mean	SD _{WR}	%CV
Site 1 operator 1	mm Hg	52.3	2.0	3.8
operator 2	mm Hg	49.9	0.9	1.9
Site 2 operator 3	mm Hg	56.9	0.9	1.5
operator 4	mm Hg	55.4	1.4	2.5
operator 5	mm Hg	58.9	1.1	1.9
Site 3 operator 6	mm Hg	61.7	1.8	2.9
operator 7	mm Hg	41.5	0.9	2.1

Linearity Data

This study was performed in-house on multiple whole blood samples with $p\text{CO}_2$ values spanning the reportable range. Linearity is reported versus an in-house standard blood gas method with traceability to NIST standards.

	Test range	Units	Slope	Intercept	R ²
$p\text{CO}_2$	10-230	mm Hg	1.058	-3.6	0.998

Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2⁴. In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and EPOC test methods respectively, Syx is the standard error and R is the correlation coefficient.

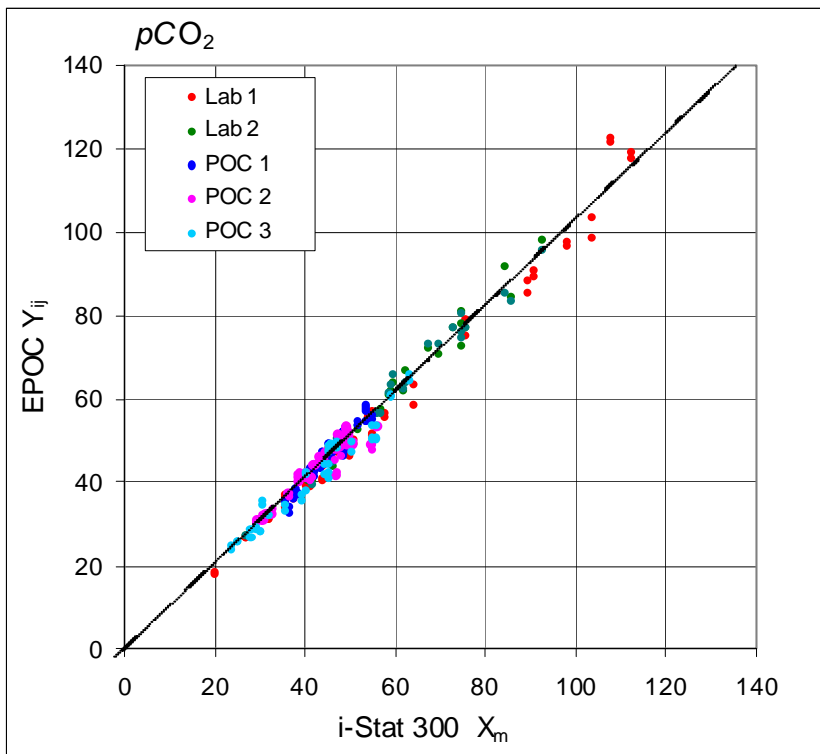
In one hospital study the EPOC was compared with the i-Stat 300⁵ in the lab (two test occasions) then in three point-of-care sites.

Method Comparison Summary Statistics: whole blood

X: i-Stat 300 test

Y: EPOC test

$p\text{CO}_2$	Lab 1	Lab 2	POC 1	POC 2	POC 3	All
N	34	24	35	28	22	143
Sxx	1.4	2.1	0.6	1.5	1.7	1.5
Syy	1.3	1.3	0.6	1.1	1.2	1.1
Intercept	-2.0	-1.2	-6.1	5.0	1.0	-0.9
Slope	1.048	1.055	1.167	0.911	0.983	1.041
Syx	3.1	2.3	1.6	2.3	2.4	2.4
X min	19.7	26.7	35.6	29.1	23.6	19.7
X max	112.2	92.5	54.4	55.6	63.0	112.2
R	0.993	0.991	0.967	0.949	0.978	0.990



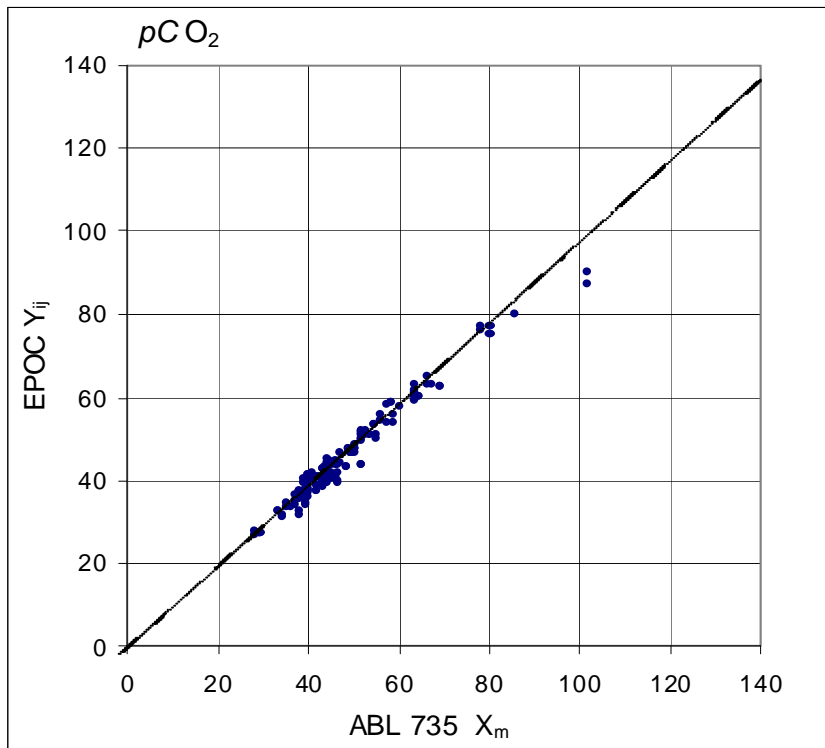
In another hospital study the EPOC was compared with the Radiometer ABL 735⁶ in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: EPOC test

$p\text{CO}_2$	Lab
N	77
Sxx	1.5
Syy	0.8
Intercept	1.6
Slope	0.924
Syx	1.97
X min	27.6
X max	101.5
R	0.987



Limitations and Interferences

Exposure of the sample to air will affect pH, $p\text{CO}_2$, $p\text{O}_2$ and ionized calcium results due to the sample equilibration with the gas levels in the air, with pH affected by the $p\text{CO}_2$ change³ and ionized calcium affected by the pH change⁸. Air contains less than 1 mmHg $p\text{CO}_2$ and about 150-180 mmHg $p\text{O}_2$. Do not introduce air bubbles into a collection device. If present, air bubbles should be removed immediately after collection.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results.

See section "03–EPOC System Operation" of the System Manual for proper sample collection procedures.

Interference testing⁷ was performed in-house on the EPOC $p\text{CO}_2$ sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The $p\text{CO}_2$ bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Bromide will increase the $p\text{CO}_2$ by 0.19 mmHg/mM bromide

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 0.4 mmol/L iodide, 25 mmol/L bromide.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 8 mmol/L KCl, 3 mmol/L CaCl_2 , pH 6.9 to 7.7, +20 mmol/L bicarbonate, 10 mmol/L lactate, +20% PCV Hct, 3% to 11% total protein, 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β -hydroxybutyrate, 1 mmol/L cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

References

1. CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*, CLSI document C46-A (ISBN 1-56238-444-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
2. *Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-Fourth Edition*, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
3. M.G. Scott, V.A. LeGrys and J.S. Klutts, Chapter 27 of *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-Fourth Edition*, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.
4. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition*, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
5. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.
6. Radiometer ABL 735, Radiometer Medical Aps, Åkandevvej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical Aps.
7. CLSI. *Interference Testing in Clinical Chemistry; Approved Guideline*, CLSI document EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
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9. Stow, R.W, Baer, R.F., Randall, B.F., Rapid measurement of the tension of carbon dioxide in blood, *Arch.Phys.Med.and Rehabil.*, **39**, 646-650, 1957.
10. Severinghaus, J.W. and Bradley, A.F., Electrodes for blood pO₂ and pCO₂ determination, *J.Appl.Pysiol.*, **13**, 515-520, 1958.

Measured values

pO_2 is measured by amperometry using a membrane covered oxygen sensing cathode electrode. The oxygen reduction current is proportional to the dissolved oxygen concentration¹⁰

Calculated Values¹

$$sO_2 = 100(X^3 + 150X) / (X^3 + 150X + 23400)$$

$$X = pO_2 * 10^{(0.48(pH-7.4)-0.0013(HCO_3-25))}$$

Because oxygen saturation also depends on the level of carbon monoxide and 2,3 diphosphoglycerate in the blood, as well as the effects of dysfunctional hemoglobins (carboxy-, met- and sulfhemoglobin), the above equation does not account for variations in these values, the oxygen saturation that is reported should only be used as an estimate of the actual value^{2, 3}. Clinically significant errors can result from incorporation of such an estimated sO_2 value for oxygen saturation in further calculations, such as shunt fraction, or by assuming the value obtained is equivalent with fractional oxyhemoglobin.

Oxygen saturation is a useful predictor of the amount of oxygen that is available for tissue perfusion. Some causes for decreased values of sO_2 include low pO_2 or impaired ability of hemoglobin to carry oxygen.

Indications for Use

The pO_2 test, as part of the EPOC Blood Analysis System is intended for use by trained medical professionals as an **in vitro diagnostic device** for the quantitative testing of samples of whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Measurement of pH, pCO_2 , pO_2 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

Contents

Each test card incorporating a pO_2 test contains a sensing electrode with a oxygen permeable membrane, a reference electrode, a counter electrode and a calibrator fluid containing a known concentration of dissolved oxygen.

Traceability

Dissolved oxygen concentration values assigned to controls and calibrator fluids are traceable to NIST standards via commercially available certified medical gas standards.

Sample Type

Fresh whole blood from arterial, venous or capillary sources, introduced to the card from a syringe or an EPOC Care-Fill Blood Collection Tube.

Sample Volume

>92 μ L, non-volumetric quantity

Sample Collection

Syringes or evacuated tubes without anticoagulant OR with lithium, sodium or balanced heparin anticoagulant.

EPOC Care-Fill Blood Collection Tubes with balanced heparin anticoagulant.

For a detailed description consult the sample collection procedures and cautions located in section "03– EPOC System Operation" of the EPOC System Manual.

Analysis time

Approximately 35 seconds after sample introduction for blood sample tests.

Approximately 44 seconds after sample introduction for aqueous control tests.

Measurement Range

	Measurement range	Normal Range ⁴
		Arterial
pO_2	5 - 750 mm Hg (0.7 – 100 kPa)	83 – 108 mm Hg (11.04 – 14.36 kPa)
sO_2	0 – 100 %	94 – 98 %

Temperature Correction

pO_2 is a temperature dependent quantity, measured at 37°C on the EPOC System. The pO_2 value can be corrected to the patient’s temperature. Patient temperature is entered on the Test Information Page of the Reader Tab on the EPOC Host (see EPOC System Operation section of System Manual).

The pO_2 at the patient’s temperature (T) is calculated as follows²

$$pO_2 (T) = pO_2 \times 10^{\frac{5.49 \times 10^{-11} pO_2^{3.88} + 0.071}{9.71 \times 10^{-9} pO_2^{3.88} + 2.30} (T-37)}$$

Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the EPOC System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP9-A2⁵ for method comparison studies, CLSI EP7-A2⁶ for interference studies.

Precision Data

In the precision data tables below, SD_{wr} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{wr}	%CV	SD_T	%CV
Level 1	mm Hg	74.9	2.4	3.1	2.8	3.8
Level 3	mm Hg	140.1	2.4	1.7	2.8	2.0

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study with 2 measurements each day per each control level. 4 manufactured lots, 6 different EPOC Readers

	Units	Mean	SD _{WR}	%CV	SD _T	%CV
Level 1	mm Hg	78.4	1.9	2.5	2.6	3.3
Level 3	mm Hg	141.2	1.8	1.3	2.2	1.6

In-house Precision 3: whole blood samples run on 20 sequential manufactured lots using at least 8 different EPOC Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD _{WR}	%CV
Blood level 1	mm Hg	38.0	2.2	5.9
Blood level 2	mm Hg	70.0	2.4	3.5

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the EPOC system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different EPOC Readers.

High pO_2 level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 1	mm Hg	136.3	4.1	3.0
Operator 2	mm Hg	139.8	2.0	1.4
Operator 3	mm Hg	138.1	3.1	2.2

Low pO_2 level commercial aqueous blood gas control

	Units	Mean	SD _{WR}	%CV
Operator 4	mm Hg	67.5	2.3	3.5
Operator 5	mm Hg	67.4	3.3	4.9
Operator 6	mm Hg	70.1	3.2	4.6
Operator 7	mm Hg	70.8	4.0	5.6

Clinical Site Precision 2: 10 replicates of different whole blood patient samples run by different operators of the EPOC system at different point-of-care sites. Each precision study employed 5 different EPOC Readers.

	Units	Mean	SD _{WR}	%CV
Site 1 operator 1	mm Hg	28.6	1.7	6.0
operator 2	mm Hg	32.9	1.8	5.5
Site 2 operator 3	mm Hg	33.9	1.2	3.5
operator 4	mm Hg	30.0	1.5	5.0
operator 5	mm Hg	40.1	1.2	3.1
Site 3 operator 6	mm Hg	61.8	3.5	5.6
operator 7	mm Hg	74.6	2.9	3.9

Linearity Data

This study was performed in-house on multiple whole blood samples with pO_2 values spanning the reportable range. Linearity is reported versus an in-house standard blood gas method with traceability to NIST standards.

	Test range	Units	Slope	Intercept	R ²
pO_2	10-750	mm Hg	1.022	-3.9	0.999

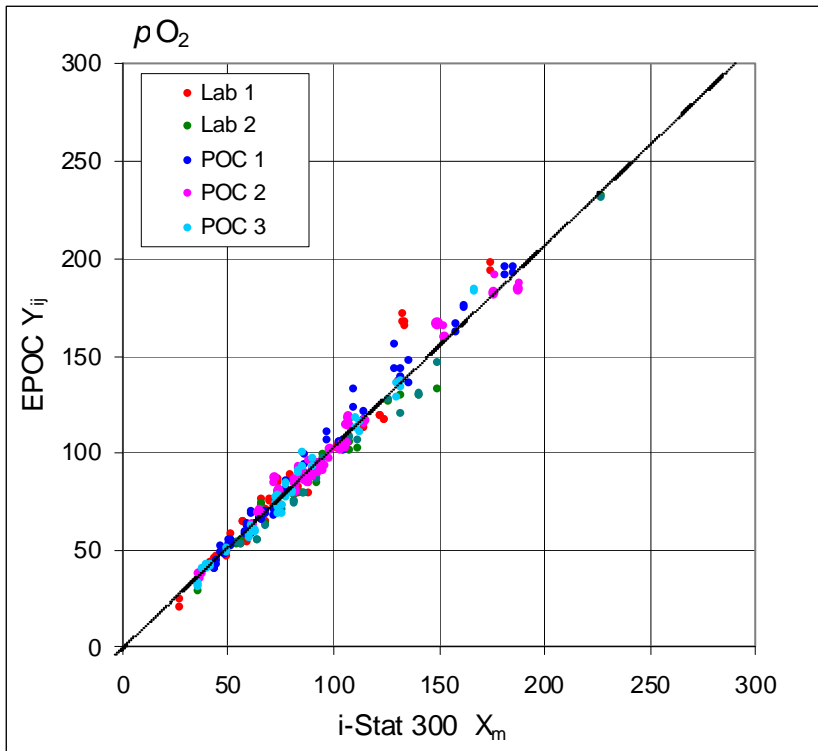
Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-2A⁵. In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and EPOC test methods respectively, Syx is the standard error and R is the correlation coefficient.

In one hospital study the EPOC was compared with the i-Stat 300⁶ in the lab (two test occasions) then in three point-of-care sites.

Method Comparison Summary Statistics: whole blood
 X: i-Stat 300 test
 Y: EPOC test

pO_2	Lab 1	Lab 2	POC 1	POC 2	POC 3	All
N	34	23	35	28	22	142
Sxx	2.6	4.3	3.2	6.2	2.7	4.6
Syy	1.7	3.5	3.0	2.9	2.6	2.7
Intercept	-6.5	-3.1	-1.3	0.3	-3.9	-1.7
Slope	1.142	1.006	1.083	1.041	1.090	1.053
Syx	8.5	4.5	4.5	4.9	4.2	6.6
X min	26.0	35.0	43.5	36.0	35.5	26.0
X max	174.5	226.5	185.0	187.5	166.0	226.5
R	0.977	0.995	0.995	0.990	0.994	0.978



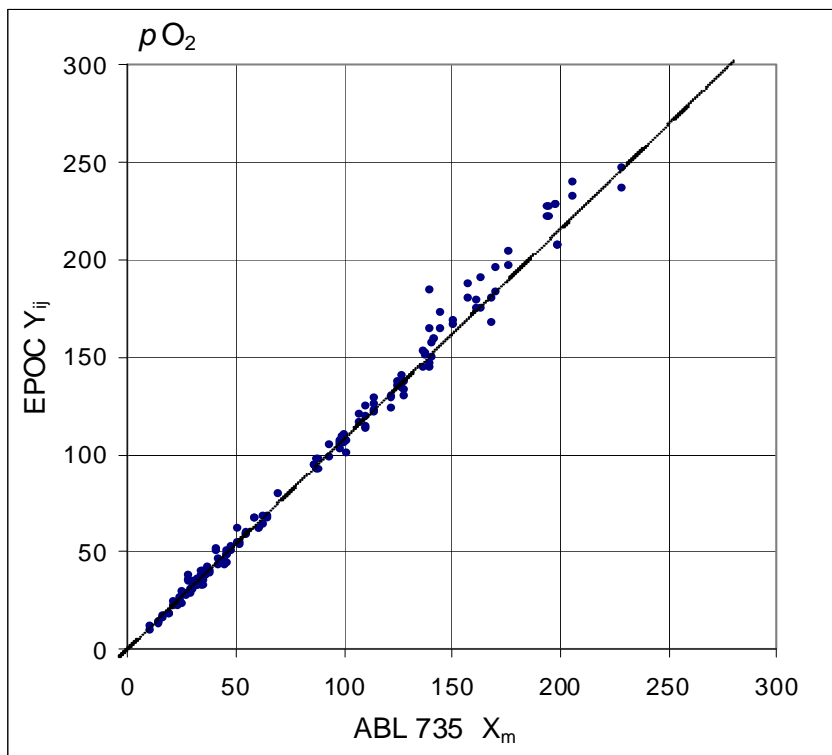
In another hospital study the EPOC was compared with the Radiometer ABL 735⁷ in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: EPOC test

pO_2	Lab
N	77
Sxx	3.4
Syy	3.7
Intercept	-0.8
Slope	1.117
Syx	5.1
X min	10.2
X max	278.5
R	0.997



Limitations and Interferences

Exposure of the sample to air will affect pH, $p\text{CO}_2$, $p\text{O}_2$ and ionized calcium results due to the sample equilibration with the gas levels in the air, with pH affected by the $p\text{CO}_2$ change² and ionized calcium affected by the pH change⁹. Air contains less than 1 mmHg $p\text{CO}_2$ and about 150-180 mmHg $p\text{O}_2$. Do not introduce air bubbles into a collection device. If present, air bubbles should be removed immediately after collection.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results.

See section "03–EPOC System Operation" of the System Manual for proper sample collection procedures.

Interference testing⁸ was performed in-house on the EPOC $p\text{O}_2$ sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The $p\text{O}_2$ bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- None identified.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 1 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 37.5 mmol/L bromide, 2.7% halothane.

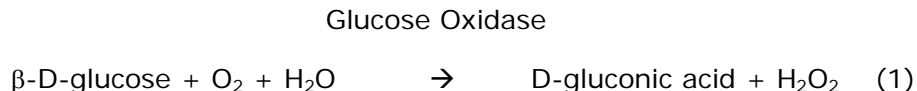
The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 8 mmol/L KCl, 3 mmol/L CaCl_2 , 10 to 120 mmHg $p\text{CO}_2$, pH 6.9 to 7.7, +20 mmol/L bicarbonate, 10 mmol/L lactate, +20% PCV Hct, 3% to 11% total protein, 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β -hydroxybutyrate, 1 mmol/L cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

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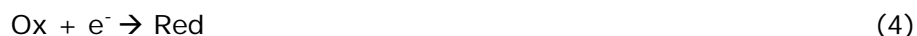
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Measured values

Glucose is measured by amperometry¹. The sensor comprises an immobilized enzyme first layer coated onto a gold electrode of the electrode module, with a diffusion barrier second layer. The glucose oxidase enzyme is employed to convert glucose to hydrogen peroxide,



and then uses an amperometric sensor to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox mediated (ABTS (2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonic acid) diammonium salt), horseradish peroxidase (HRP) catalyzed, reduction on a gold electrode.



The reduction current is proportional to the concentration of glucose in the test fluid.

Indications for Use

The *Glucose* test, as part of the EPOC Blood Analysis System is intended for use by trained medical professionals as an **in vitro diagnostic device** for the quantitative testing of samples of whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia, and of pancreatic islet cell tumors.

Contents

Each test card incorporating a *Glucose* test contains a sensing electrode with a redox mediated enzymatic membrane covered with an oxygen permeable diffusion layer, a reference electrode, a counter electrode and a calibrator fluid containing a known concentration of glucose.

Traceability

Glucose concentration values assigned to controls and calibrator fluids are traceable to NIST standards.

Sample Type

Fresh whole blood from arterial or venous sources, introduced to the card from a syringe.

Sample Volume

>92 μ L, non-volumetric quantity

Sample Collection

Syringes or evacuated tubes without anticoagulant OR with lithium, sodium or balanced heparin anticoagulant.

For a detailed description consult the sample collection procedures and cautions located in section "03– EPOC System Operation" of the EPOC System Manual.

Analysis time

Approximately 35 seconds after sample introduction for blood sample tests.

Approximately 44 seconds after sample introduction for aqueous control tests.

Measurement Range

	Measurement range	Normal Range ²
<i>Glucose</i>	20 - 700 mg/dL (1.1 – 38.5 mM)	74 – 100 mg/dL (4.1 – 5.6 mM)

Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the EPOC System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP9-A2³ for method comparison studies, CLSI EP7-A2⁴ for interference studies and CLSI EP5-A⁵ for precision studies.

Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 5 sequential manufactured lots using at least 8 different EPOC Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 3	mg/dL	51.1	1.2	2.3	1.6	3.1
Level 1	mg/dL	242.6	5.5	2.3	6.0	2.5

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study with 2 measurements each day per each control level for each of 4 manufactured lots using 6 different EPOC Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 3	mg/dL	50.2	1.1	2.2	1.2	2.3
Level 1	mg/dL	241.9	4.7	2.0	5.5	2.3

In-house Precision 3: whole blood samples run on 5 sequential manufactured lots using at least 8 different EPOC Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mg/dL	80.0	1.2	1.5
Blood level 2	mg/dL	210.0	5.8	2.7

In-house Precision 4: whole blood samples were spiked at five levels of glucose and were tested with 100 replicates per each blood sample; each sample was tested within 12 minutes in two runs; each run was performed simultaneously on 50 different EPOC Readers; a mix of four manufactured lots were included in this test.

	Units	Mean	mean SD	%CV
Blood level 1	mg/dL	22.5	1.2	5.4
Blood level 2	mg/dL	123.7	3.0	2.4
Blood level 3	mg/dL	215.9	8.5	3.9
Blood level 4	mg/dL	311.8	13.1	4.2
Blood level 5	mg/dL	548.3	17.6	3.2

Clinical Site Precision 1: 12 replicates of venous blood where glycolysis was allowed for a certain period of time was run by four different operators of the EPOC system in a clinical environment. Each precision study employed 6 different EPOC Readers.

Low glucose level blood

	Units	Mean	SD _{WR}	%CV
Operator 1	mg/dL	42.8	1.9	4.4
Operator 2	mg/dL	43.2	1.8	4.3
Operator 3	mg/dL	41.6	1.6	3.8
Operator 4	mg/dL	50.0	1.1	2.2

Clinical Site Precision 2: 12 replicates of venous blood spiked with glucose was run by four different operators of the EPOC system in a clinical environment. Each precision study employed 6 different EPOC Readers.

High glucose level blood

	Units	Mean	SD _{WR}	%CV
Operator 5	mg/dL	242.8	6.6	2.7
Operator 6	mg/dL	229.0	5.3	2.3
Operator 7	mg/dL	233.4	6.8	2.9
Operator 8	mg/dL	228.5	7.0	3.1

Clinical Site Precision 3: 10-12 replicates of commercial aqueous blood gas, electrolytes and metabolites controls were run by operators of the EPOC system at 2 different point-of-care sites. Each precision study employed 5-6 different EPOC Readers.

Low glucose level commercial aqueous blood gas electrolyte and metabolite control

	Units	Mean	SD _{WR}	%CV
Operator 1	mg/dL	48.0	1.5	3.2
Operator 2	mg/dL	46.6	1.0	2.1

Medium glucose level commercial aqueous blood gas electrolyte and metabolite control

	Units	Mean	SD _{WR}	%CV
Operator 3	mg/dL	109.7	3.6	3.3
Operator 4	mg/dL	106.8	1.8	1.7

High glucose level commercial aqueous blood gas electrolyte and metabolite control

	Units	Mean	SD _{WR}	%CV
Operator 5	mg/dL	258.9	9.0	3.5
Operator 6	mg/dL	256.9	2.3	0.9

Linearity Data

This study was performed in-house on multiple whole blood samples with *Glucose* values spanning the reportable range. Three types of samples were considered, i.e. normal hematocrit-normal venous blood pO_2 , normal hematocrit- hypoxic blood sample and elevated hematocrit-normal venous blood pO_2 . Linearity is reported versus two in-house standard whole blood glucose method with traceability to NIST standards.

Type of blood sample	Test range	Units	Slope	Intercept	R ²
43% Hct, 30mmHg pO_2	20-700	mg/dL	1.022	-3.32	0.9997
62% Hct, 30mmHg pO_2	20-700	mg/dL	1.018	-4.04	0.9996
43% Hct, <20mmHg pO_2	20-700	mg/dL	0.955	+0.33	0.9995

Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-2A. In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and EPOC test methods respectively, Syx is the standard error and R is the correlation coefficient.

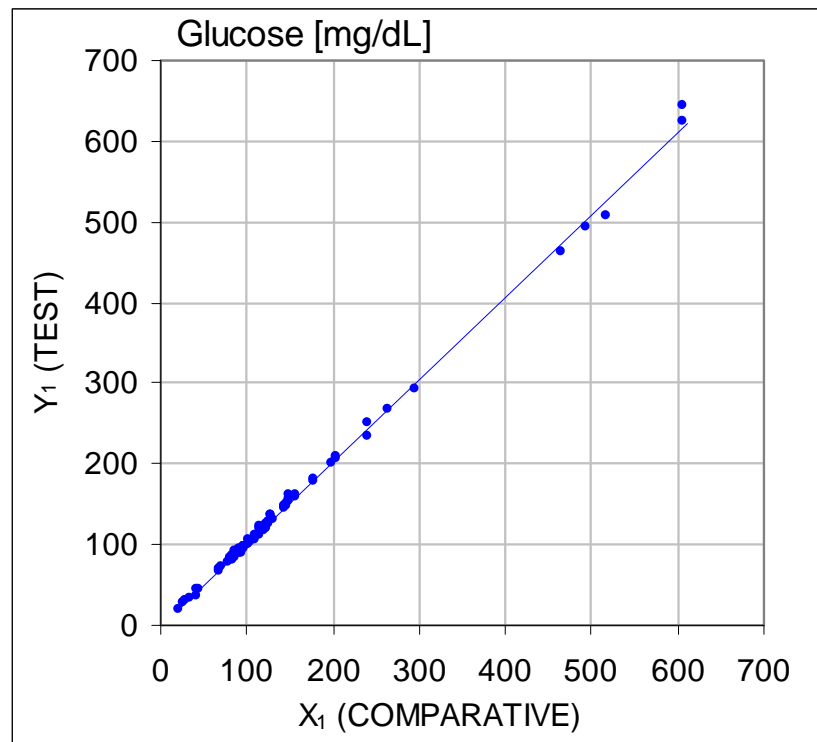
In one hospital study the EPOC was compared with the i-Stat 300⁵ in the lab and in one point-of-care site.

Method Comparison Summary Statistics: whole blood

X: i-Stat 300 CG8 cartridges test

Y: EPOC test

Glucose [mg/dL]	All
N	80
Sxx	0.93
Syy	3.4
intercept	-2.2
slope	1.031
Syx	5.6
X min	20.0
X max	605.5
R	0.999



Glucose Scatter Plot versus i-Stat 300 CG8 cartridges

The precision in whole blood was assessed from the pooling of within method pairs from the method comparison data. This is shown in the table below.

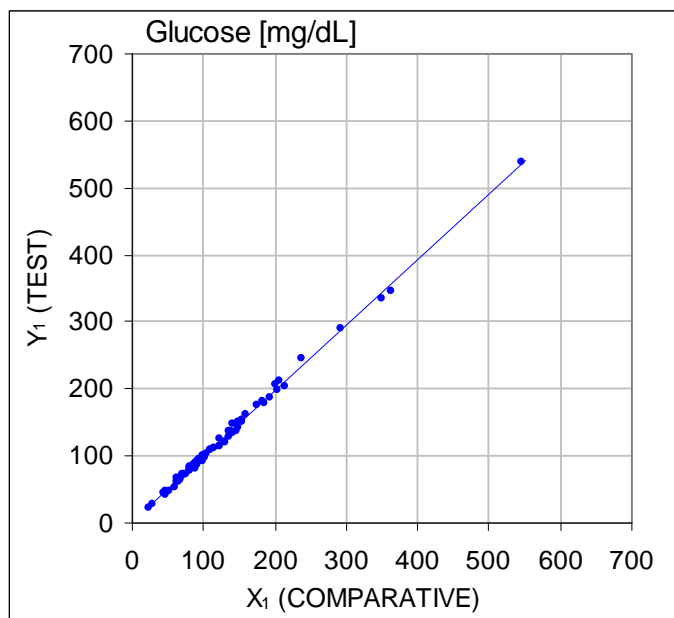
	Glucose [mg/dL]		
Range	20-70	70-200	200-700
N	10	59	11
Average reading	44.8	116.4	383.8
Pair Precision (SD)	0.80	2.44	7.08
%CV	1.8%	2.1%	1.8%

In another hospital study the EPOC was compared simultaneously with the Roche-Hitachi⁷ instrument in the lab and with iSTAT 300⁶. The summaries are presented in the tables below. The correlation plots are illustrated on the next page.

Method Comparison Summary Statistics: whole blood

X: Roche-Hitachi P800-D2400 test
Y: EPOC test

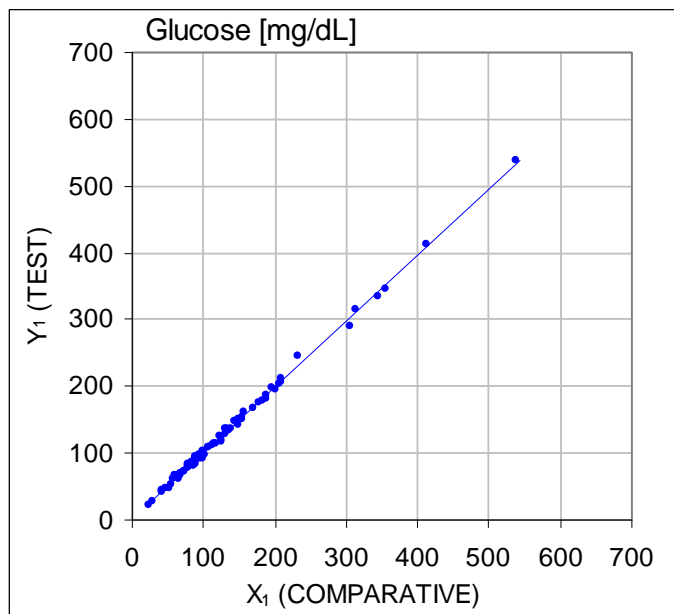
Glucose [mg/dL]	All
N	73
Sxx	
Syy	3.6
intercept	-0.2
slope	0.971
Syx	3.0
X min	23.0
X max	546.0
R	0.998



Method Comparison Summary Statistics: whole blood

X: i-Stat 300 G cartridges test
Y: EPOC test

Glucose [mg/dL]	All
N	80
Sxx	3.25
Syy	4.25
intercept	-1.33
slope	1.003
Syx	4.45
X min	22.5
X max	517.5
R	0.999



The precision in whole blood was assessed from the pooling of within method pairs from the method comparison data. This is shown in the table below.

	Glucose [mg/dL]		
Range	20-70	70-200	200-700
N	16	53	11
Average reading	53.5	113.4	299.0
Pair Precision (SD)	1.32	3.18	8.73
%CV	2.47%	2.81%	2.92%

Consolidated Method Comparison Study Focusing on Low End Glucose Range

We evaluated the performance of the new EPOC glucose sensor in the low end range of glucose concentrations on patient samples in clinical settings including at the point of care at several different hospitals. The results shown below include method comparison data against iSTAT (whole blood method), ABL 800 Flex (whole blood method), Roche-Hitachi (plasma method) and J&J (plasma method).

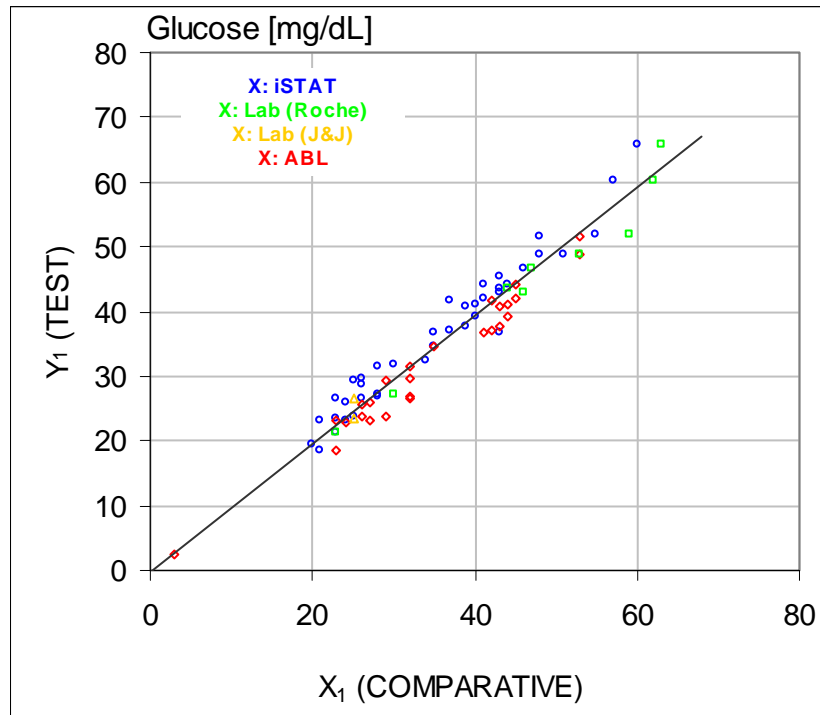
We supplemented the above mentioned clinical results with an in-house full duplicate method comparison³ against iSTAT⁶ and ABL705⁸. In this study high hematocrit blood samples were prepared by removing half of the plasma volume from a venous sample that was allowed to glycolyse. The hematocrit of these specimens was tested by micro-centrifugation method¹⁰ and found to be ~62%, i.e. characteristic to the upper range of the neonatal blood⁹. After the glucose reached ~20mg/dL, it was spiked to cover uniformly the low range glucose, i.e. 20-80 mg/dL specific to neonatal population⁹. One sample was treated with Hexokinase, NADH-β and ATP in order to obtain a zero glucose concentration.

The data was processed as per CLSI EP9-A2 recommendations. The correlation plot and bias plot are presented in the figures below. The test results versus the various reference instruments (X) are color coded.

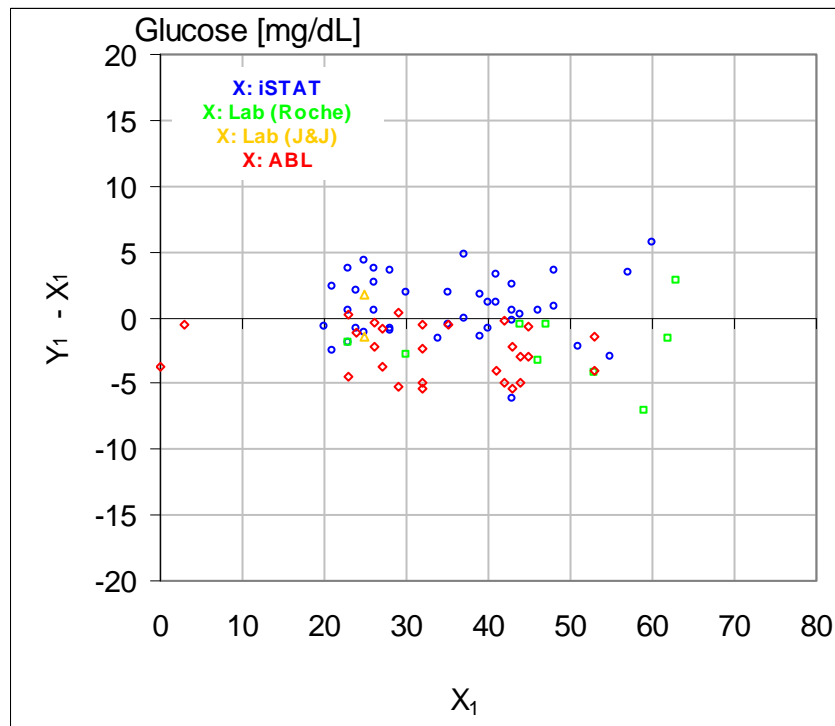
EPOC Low End Study	All points	Lab (plasma)	iSTAT	ABL	Roche	J&J
N	78	11	40	27	9	2
Sxx	1.0		0.6	1.6		
Syy	1.1	1.4	1.1	1.0	1.5	0.7
intercept	-0.2	1.1	1.0	-2.2	0.8	
slope	0.984	0.936	0.992	0.990	0.942	
Syx	2.9	2.1	2.55	2.16	2.21	
X min	1.5	23.0	20	1.5	23	25
X max	63.0	63.0	60	53	63	25
R²	0.947	0.960	0.948	0.971	0.946	
Decision Level⁹	40	40	40	40	40	
Bias	-0.8	-1.4	0.7	-2.6	-1.52	
Bias 95% Conf. Hi	-0.3	-0.5	1.3	-1.9	-0.18	
Bias 95% Conf. Lo	-1.3	-2.3	0.1	-3.3	-2.86	

Method Comparison Summary Statistics: whole blood

- X (blue circles): i-Stat 300 G cartridges (whole blood) test
- X (green squares): Roche Hitachi Lab (plasma) test
- X (red diamonds): ABL 705 (whole blood) test
- X (yellow triangles): J&J Lab (plasma) test
- Y: EPOC test



Low end glucose range, correlation plot versus various comparative instruments



Low end glucose range, bias plot versus various comparative instruments

Limitations and Interferences

The EPOC glucose sensor has not been evaluated in neonates.

Tests were performed on blood samples sharing two primary characteristics with neonatal blood⁹, i.e. high hematocrit and glucose under 80mg/dL, see the previous section for details.

Interference testing⁴ was performed in-house on the EPOC *glucose* sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The *glucose* bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Anticoagulants:
 - Citrate will have no significant effect up to 15mM (441mg/dL), after which it will decrease the glucose reading by $-0.28\%/mM_{\text{Citrate}}$, i.e. $-0.01\%/(\text{mg/dL}_{\text{Citrate}})$; therefore we do not recommend using collection devices containing citrate as additive.
 - Na fluoride will have no significant effect up to 10mM (42mg/dL), after which it will decrease the glucose reading by $-0.1\%/mM_{\text{NaF}}$, i.e. $-0.024\%/(\text{mg/dL}_{\text{NaF}})$; therefore we do not recommend using collection devices containing Na fluoride as additive.
 - Oxalate will have no significant effect up to 20mM (128mg/dL), after which it will decrease the glucose reading by $-0.29\%/mM_{\text{Oxalate}}$, i.e. $-0.045\%/(\text{mg/dL}_{\text{Oxalate}})$; therefore we do not recommend using devices tubes containing oxalate as additive.
- Iodide will have no significant effect up to 28 μ M (0.47mg/dL_{KI}), after which it will decrease the glucose reading by as much as $(-0.16\text{mg/dL})/\mu\text{M}_{\text{I}^-}$, i.e. $(-9.5\text{mg/dL})/(\text{mg/dL}_{\text{KI}})$. Iodide concentrations higher than 0.4mM_{I⁻} (6.7mM_{KI}) will trigger iQC.
- Bromide will have no significant effect up to 28mM (224mg/dL_{NaBr}), after which it will decrease the glucose reading by $(-0.23 \text{ mg/dL})/mM_{\text{Br}^-}$, i.e. $(-0.029\text{mg/dL})/(\text{mg/dL}_{\text{NaBr}})$.
- N-acetyl cysteine will have no significant effect up to 500 μ M (8mg/dL), after which it will trigger iQC.
- L-cysteine will have no significant effect up to 750 μ M (9mg/dL), after which it will trigger iQC.
- Gallamine triethiodide (Flaxedil) will have no significant effect up to 11 μ M (1mg/dL), after which it will decrease the glucose reading by $(-0.27\text{mg/dL})/\mu\text{M}_{\text{gallamine triethiodide}}$, i.e. $(-3\text{mg/dL})/(\text{mg/dL}_{\text{gallamine triethiodide}})$.
- Thiocyanate will have no significant effect up to 1mM (5.9mg/dL_{KSCN}), after which it will decrease the glucose reading with $-1.7\%/mM_{\text{SCN}^-}$, i.e. $(-0.29\text{mg/dL})/(\text{mg/dL}_{\text{KSCN}})$.
- Uric acid will have no significant effect up to 700 μ M (11.8mg/dL), after which it will decrease the glucose reading by $(-3.5\text{mg/dL})/mM_{\text{Uric Acid}}$, i.e. $(-0.21\text{mg/dL})/(\text{mg/dL}_{\text{Uric Acid}})$.
- Mannose will have no significant effect up to 3.5mM (63mg/dL), after which it will increase the glucose reading by $+3.8\%/mM_{\text{Mannose}}$, i.e. $(+0.21\%)/(\text{mg/dL}_{\text{Mannose}})$.
- Xylose will have no significant effect up to 3mM (45mg/dL), after which it will increase the glucose reading by $+7.5\%/mM_{\text{Xylose}}$, i.e. $(+0.5\%)/(\text{mg/dL}_{\text{Xylose}})$.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 1.66mM (25mg/dL) acetaminophen, 0.09mmol/L (10mg/dL) anidulafungin, 500 μ mol/L (8.2mg/dL) N-acetyl cysteine, 3.3mmol/L (60mg/dL) acetyl salicylate, 630 μ mol/L (12.5mg/dL) Na ascorbate, 28mmol/L (224mg/dL) bromide, 15mmol/L (441mg/dL) citrate, 89.2 μ mol/L (4.5mg/dL) clindamycin hydrochloride, 0.1mmol/L (0.65mg/dL) K cyanide, 6.15nmol/L (507ng/dL) digoxin, 66 μ mol/L (2.2mg/dL) dobutamine, 100 μ mol/L (1.9mg/dL) dopamine HCl, 50 μ mol/L (~1mg/dL) L-dopa, 9mmol/L (263mg/dL) EDTA, 12 μ mol/L (0.2mg/dL) ephedrine, 87mM (400mg/dL) ethanol, 4.84mmol/L (30mg/dL) ethylene glycol, 1.78 μ mol/L (60 μ g/dL) famotidine, 10mmol/L (42mg/dL) Na fluoride, 1mmol/L (18mg/dL) fructose, 181 μ mol/L (6mg/dL) furosemide, 3.3mmol/L (59mg/dL) galactose, 11 μ mol/L (1mg/dL) gallamine triethiodide (flaxedil), 238 μ mol/L (10mg/dL) gentamicin, 4.5 μ mol/L (200 μ g/dL) glipizide, 1.1mmol/L (28.5mg/dL) glu-

cosamine, 2.55mmol/L_{RBC} oxidized glutathione, 2.55mmol/L_{RBC} reduced glutathione, 400µmol/L (5mg/dL) guaiacol, 80U/ml heparin, 0.4mmol/L (14.5mg/dL) hydrocortisone, 2.5mmol/L (19mg/dL) hydroxyurea, 292µmol/L (4mg/dL) isoniazide (hydrazid), 48.6µmol/L (1.76mg/dL) levofloxacin, 1mmol/L (34mg/dL) linezolid, 13.3mmol/L (479mg/dL) maltose, 3.5mmol/L (90mg/dL) mannose, 71µmol/L (1.7mg/dL) methyl dopa, 77.4µmol/L (2.9mg/dL) 6α-methyl prednisolone, 0.7mM (12mg/dL) metronidazole, 17.4µM (0.6mg/dL) omeprazole, 102µmol/L (2.4mg/dL) procainamide, 4.22µmol/L (0.12mg/dL) promethazine hydrochloride, 37µmol/L (1.2mg/dL) quinidine, 1.67µmol/L (40µg/dL) salbutamol (albuterol), 4.34mmol/L (60mg/dL) salicylic acid, 1.96µmol/L (60µg/dL) sertaline, 1mmol/L (5.8mg/dL) thiocyanate, 413µmol/L (10mg/dL) sodium pentotal, 1mmol/L (31mg/dL) tolazamide (tolinase), 2.37mmol/L (64mg/dL) tolbutamide, 69µmol/L (10mg/dL) vancomycin, 21.3µmol/L (1mg/dL) vitamin K1, 3mmol/L (45mg/dL) xylose.

The following levels of endogenous interferences were tested and found to be clinically insignificant: +20mmol/L (168mg/dL) Na bicarbonate, +86µmol/L (+7.3mg/dL) bilirubin conjugated, +510 µmol/L (+30mg/dL) bilirubin unconjugated, +13mmol/L (+298mg/dL) cholesterol, 15 to 140 mmHg pCO₂, +500µmol/L (+6mg/dL) L-cysteine, +20mmol/L (+256mg/dL) Na β-hydroxybutyrate, +20mmol/L (+180mg/dL) Na L-lactate, +0.8% lipids, +59.2µmol/L (+1.9mg/dL) norepinephrine, pH 6.7 to 7.7, +20% PCV Hct, 3.4% to 10.4% total protein, +11.2mmol/L (+1g/dL) triglycerides, +500µmol/L (+8.4mg/dL) uric acid.

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8. Radiometer ABL 705, Radiometer Medical Aps, Åkandevvej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical Aps.
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