Department Of Pathology
POC.526.08 Epocal Blood Gas Analyzer - LBH
Version#8

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1. **Purpose**
   1.1. To test for blood analytes quantitatively using smartcard technology. The analyzer transmits results via wireless communication. This presents to caregivers quick and quality blood gas, electrolyte, and metabolite results at the patient bedside.
   1.2. For Sinai: all analytes on the EPOC card have been approved to be run on certain units in the hospital: Sodium, potassium, ionized calcium, lactate, creatinine, hematocrit, chloride, glucose, pH, pCO2 and pO2.
   1.3. For Levindale: the following analytes have been approved to be run on certain units in the hospital: pH, pCO2 , pO2 and potassium
2. **Specimen**
   2.1. The Epoc system use specimen of heparinized anticoagulated arterial, venous or capillary whole blood.
   2.2. For capillary whole blood testing, see attachment for instructions on using Epoc Care-Fill capillary tube.
   2.3. Syringes without anticoagulant must be run within 3-5 minutes. Use 1 or 3ml syringes and Li or Na Heparin anticoagulant. Plastic syringes without anticoagulant must be tested immediately.
   2.4. Use of evacuated tubes that contain Li or Na heparin anticoagulant is recommended.
   2.5 If testing for lactate, must test within 5 minutes to avoid glycolysis.
3. **Specimen Collection:**
   3.1 In-Dwelling line:
   Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: three to six times the volume of the catheter connector and needle.
   3.2 Arterial specimens:
   Fill blood gas syringe to the recommended capacity or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under-filling syringes containing liquid heparin will decrease results due to dilution. Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds and then inverting the syringe repeatedly for at least 5 seconds. Avoid or remove

immediately any air drawn into syringe to maintain anaerobic conditions. A blood sample should be tested within 10 minutes after it has been obtained. (re-mix before testing).

3.3 Venous specimens:
If a card cannot be dosed immediately, collect sample into an evacuated blood collection tube or a syringe containing lithium heparin anticoagulant. Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds and then inverting the syringe repeating for at least 5 seconds.

3.4 Blood gas testing:
Follow usual anaerobic procedure for drawing blood gases. After specimen has been obtained, mix sample by rolling syringe between palms for at least 5 seconds then inverting the syringe repeatedly for at least 5 seconds.
Discard the first drop of blood which has been exposed to air; dose card when meter is ready.

4. Equipment And Materials

4.1. Epoc Blood Gas Analyzer
4.2. Epoc Test card
4.3. Sample collection devices
4.4. Tube/syringe: venous/arterial sample
4.5. Lancet: fingerstick/capillary
4.6. 2x2 gauze
4.7. Latex gloves
4.8. Alcohol swabs
4.9. Latex gloves

5. Calibration

5.1. Internal Calibration verification is automatically performed as part of the test cycle of each card. Each EPOC test card contains calibration fluid that is released over the sensors prior to sample application. When the card calibration process completes successfully, the message "Calibration finished, insert sample" appears on the host.

5.2. Liquid Calibration Verification is to be performed when a new instrument is received, after software updates and every six months for AMR validation. Five levels of the calibration verification solutions are performed one time. See POC.523.03 QC/QA for moderate complex testing-LBH

6. Quality Control

6.1. Electronic Control

Electronic quality control is performed automatically upon reader initialization and at least every 8 hours of patient testing

6.2. Liquid Control

6.2.1. Two levels of blood gas, electrolyte, and lactate controls will be performed at least weekly on each analyte and lot number used for patient testing. For Levindale 3 levels will be performed until, Levindale lab is switched over to CAP.

6.2.2. Two levels of hematocrit controls will be performed at least weekly on each analyte and lot number used for patient testing.

6.2.3. Quality control will also be performed if the epoc analyzer undergoes maintenance, repair or environmental exposure that could affect the accuracy and reliability of test results.

6.2.4. Target values for controls are available at alere-epoc.com. The manufacturer has established target values with multiple card lots and control ampules for each level. The month end QC reports are evaluated by the Point of Care Coordinator for significant changes. Noted problems and corrective action will be documented on the monthly QC report.
New shipment lot numbers will be compared to previous lot numbers.

6.2.5. Equilibrate the ampules to room temperature (20-25ºC) for a minimum of four hours for a full box, and one hour for single ampules outside of the box.

6.2.6 Results must pass before patient testing can be performed.

6.2.7 To complete a QA test, the following steps are required.
-Turn "ON" the epoc Reader and epoc Host.
-Start and log in to epoc Host software application.
-Connect wirelessly to the epoc Reader from the epoc Host.
-Select Tools and select Switch to QA test from drop down menu.
-After the Reader configuration is completed, remove a new Test card from the pouch and immediately insert it into the epoc Reader. This will start the calibration period for the Test Card (the Reader will be flashing the green light, and the Host will display the message, "Calibrating..DO NOT INJCECT SAMPLE").
-Use the 165-second calibration period to enter the QC lot number (may scan barcode provided by lab) and select tests (if applicable).
-Immediately before use, shake the ampule vigorously for at least fifteen seconds to re-equilbrate gases with the solution. When shaken, the ampule should be held between the thumb and forefinger to avoid warming the solution. Swirl the ampule gently to return the solution to the bottom of the ampule.
-Allow the bubble to rise between shaking and before opening the ampule. Protect the fingers with gauze, tissue or gloves.
-In order to preserve the gases in the control fluid, immediately transfer the fluid from the ampule into a plain syringe by slowly aspirating it through a large-bore needle or blunt tip.
-After the calibration is complete, the green light on the Ready will turn steady and the Host will display "Inject Sample". Inject sample as you would a patient.

6**.3 Thermal QA test (verification of thermal control system) must be performed every 6 months.**

6.3.1 Reader must be off for at least one hour (Device may be plugged in with battery light "on" orange light).

6.3.2 Reader must be in open clam shell position during this 1 hour period.

6.3.3 Turn the reader on. Using a epoc host, discover, then press and hold the reader icon for about one second.

6.3.4 Select **Run Thermal QA** from the dropdown menu. Measurements are

displayed, including “Pass” or “Fail”.

6.3.5 When testing for PASS/Fail, if device fails on 1st attempt, perform 2 additional attempts, in an effort for device to pass. Observe heater temps, with each failure.

6.3.6 If device fails, unplug reader for at least 1 hour, repeating steps 2 and 3.

6.3.7 If this procedure fails, device may be defective, call Alere hotline.

6.3.8 What is being tested:

1. Top vs bottom heaters: These heaters need to be no more than 0.3 degrees apart.

2. Top and bottom heater vs. ambient temp: The amount of difference between either heater and ambient temp. can be no more than 1 degree.

7. Procedure (Stepwise) for patient testing.

7.1. The initiation of a test starts with establishing a communications link between the host and the reader.

7.2. Turn on the epoc Reader and epoc Host. The power button will turn solid green. The reader must be turned on to communicate with host.

7.3. Scan the operator ID into the host. Only certified personnel can operate the epoc instrument.

7.4. Select the patient test mode using the stylus connected to the reader.

7.5. Obtain the patient ID by scanning the patient’s wristband. The patient ID appears on the patient field. Verify the patient ID scanned is the correct ID for the particular patient.

7.6. Select the ‘patient information’ tab to enter patient’s information and all other related information. Selection of specimen type is a mandatory field.

7.7. Obtain a test card from the card pouch; this should only be done when ready to perform testing. Cards are for single use only and should NEVER be reused.

7.8. Insert the test card into the card insertion slot into the reader with the blue label facing upwards. As the card enters the reader, the scanner will turn on and the barcode will be read. Push the card past a minimal degree of resistance to lock it into place. The Reader acknowledges the barcode was read and begins the calibration process.

7.9. The calibration process takes approximately 165 seconds to complete. When calibration process is complete, the Reader indicates by a solid green light that the card is ready to receive blood.

7.10. The epoc host will display the message ‘please insert sample’. The sample has to be introduced within seven minutes. Introducing the sample too soon will result in an error message. If seven minutes elapse without introducing sample into the well, the calibration times out and the card is no longer available to accept sample.

7.11. To introduce sample, ensure the sample is well-mixed and discard a small amount of sample onto an absorbent material.

7.12. Hold the syringe barrel vertically between fingertips and thumb then place the syringe onto the opening on the test card and twist slightly to ensure a complete seal.

7.13. Using slight downward pressure, use index finger to steadily depress the syringe plunger with a single, smooth and continuous motion until an audible beep is heard. The test status indicator flashes green to indicate enough sample for analysis was received.

7.14. Remove the syringe from the test card immediately after the audible sound.

7.15. Add patient and test information into the host. Information can also be added during calibration period and after test results. If entered after the test results appear, a prompt to save each field will appear.

Specimen type is required, select correct type from the drop down list.

- Arterial
- Venous
- Capillary

Verify that the correct tests ordered are selected in the host.

7.16. Approximately half a minute after sample introduction into the calibrated test card, the host computer displays the analytical results. Verify the results and patient information is correct.

7.17. Once verified, select the 'X' to send results to the electronic health record.

7.18. Remove the test card from the Epoc reader and discard it.

8. Calculations

8.1. Results will automatically be uploaded via a wireless connection and interfaced to Cerner. Test results are available in 3 sub-tabs: "measured", "Calculated", and "Corrected".

8.2. Hematocrit and Hemoglobin results should be used with caution. Send specimen to the lab to verify H&H results. Blood transfusion should not be carried out based on epoc's H&H results. Patients undergoing bi-pass surgery should be tested under "Hemodilution Yes" for accurate results. H&H results may be falsely decreased due to dilution factor if "Hemodilution Yes" is not selected.

9. OPERATOR COMPETENCY

All operators will be required to:

- Complete initial training with a unit trainer and six months thereafter.
- Complete annual competency module on Health stream.
- Complete direct observation by a unit trainer, supervisor (if trained) or POCC.
- Perform proficiency testing using the CAP AQ Survey or CAP Quality cross checks when required.
- Perform quality control procedure using at least one level of quality control material.
- Complex all 6 elements of competency assessments addressed in training procedure.

10. Reporting Results

10.1 After completion of a test, additional analytes may be selected. Once results are displayed analytes may NOT be de-selected. Any result that conflict with the clinical assessment of the patient should be repeated.

10.2 Once results are completed and closed, the patient information cannot be changed. Once the results are "X' out, the information will wirelessly transmit to the Data management system into Cerner.

10.3 **See** POC.525.04 Analytical Measurement Range (AMR) for Point-of Care Testing - LBH **to obtain the measurement ranges for each analyte.**

11.0 CRITICAL RESULTS

11.1 Critical values are programmed into the epoc system. Critical values are represented by red arrows pointing upwards or downwards depending on the result. Critical high results are indicated by an upward arrow and critical low are indicated by a downward arrow.

11.2 When a critical result is obtained press the critical action bar and select the appropriate action taken. The clinical provider should be notified of the critical result immediately. Based on the clinical presentation of the patient, the provider will determine if follow-up specimen is to be ordered for repeat. Repeat test can be done at the bedside or sample collected and sent to the main laboratory for analysis.

11.3Critical value notification should be documented electronically by charting a note on patients' medical record in adhoc power chart including the critical result value, date and time test was performed, provider notified and the date/time provider was notified. The user can also fill out the notification screen on the EPOC meter if the provider is present at time of testing.

Adult Reference and Critical Ranges for EPOC meter

Test	Critical Range Low	Reference Range	Critical Range High
Sodium, mmol/L	<120	138-146	>155
Potassium,mmol/L	<2.8	3.5-49	>6.0
Chloride, mmol/L	<76	98-109	>125
Glucose, mg/dL	<51	70-105	>399
Hematocrit% PCV	<21	38-51	>60
pH (arterial) (venous)	<7.20 NA	7.35-7.45 7.34-7.41	>7.55 NA
pCO2(arterial) (venous)	<20 NA	35-45 41-51	>50 NA
pO2 mmHg arterial (venous)	<50 NA	80-105 NA	>600 NA
Ionized calcium mmol/L	<0.80	1.12-1.32	>1.55
Creatinine, mg/dL	NA	0.5-1.3	Not defined
Lactate, mmol/L	NA	0.5-2.8	>4.0
O2 Sat, %	NA	95-98	NA
TCO2 mmol/L art Venous	NA NA	23-27 23-30	NA NA
HCO3mmol/L art Venous	<10 NA	22-26 23-28	>40 NA
Base ex, mmol/Lart Venous	NA NA	(-2)-(+3) (-2)-(+3)	NA NA
Hemoglobin g/dL	<7.0	Female: 11.7-15.7 Male: 13.0-17.0	>25.0

EPOC Point-of-Care Reference and Critical Ranges for Neonates, 0-28 days

Analyte	Critical Range(low)	Reference Range	Critical Range(high)
Sodium, mmol/L	≤121	133-145	> 154
Potassium, mmol/L	<2.6	3.2-6.0	>6.8
Chloride, mmol/L	<81	96-108	>119
Glucose, mg/dL age 0-4 hours old	<25	30-99	>200
Glucose, mg/dL age > 4-24 hours old	<35	35-99	>200
Glucose, mg/dL >24-48 hours old	<40	50-99	>200
Glucose, mg/dL >48 hrs to 28 days	<50	50-99	>200
pH (arterial) pH (venous/cap)	<7.21 <7.20	7.30-7.45 7.31-7.41	>7.49 >7.55
pCO2, mmHg(arterial) pCO2, mmHg(venous/cap	<26 Not defined	35-45 41-51	>69 Not defined
pO2 mmHg arterial pO2mmHg venous/cap	<41 Not defined	50-100 Not defined	N/A Not defined
HCO3, mmol/L arterial HCO3,mmol/L venous/cap	<13 Not defined	18-24 23-28	N/A Not defined
TCO2 mmol/L arterial TCO2mmol/L venous/cap	Not defined Not defined	18-24 23-30	Not defined Not defined
BE mmol/L art BEmmol/L venous/cap	Not defined Not defined	(-2)-(+2) (-2)-(+3)	Not defined Not defined
Hematocrit %	<26	Scale below	>69
Hemoglobin, g/dL	<7.1	Scale below	N/A
O2 sat, %	N/A	95-98	N/A
Ionized Ca, mmol/L	<1.0	1.0-1.32	>1.4
Creatinine, mg/dL	Not defined	0.6-1.3	>1.9
Lactate mmol/L	N/A	0.5-2.0	>4.0

Age Based Reference Range for Hemoglobin and Hematocrit

Age	Hemoglobin g/dL	Hematocrit %
0-1 day	13.5-19.5	42.-60
1 day-1 week	14.5-22.5	45-67
1 week- 1 month	13.4-19.8	41-65
1 month-2 months	10.7-17.1	33-55
2 months-6 months	9.4-13.0	28-42

Values outside the reportable range should be repeated in the Main laboratory when possible. Reference ranges apply to whole blood sample tested on the EPOC analyzer and may not exactly match those performed in the main laboratory.

Critical values are adapted from multiple sources and reflect LifeBridge Health historical data.

Sources: Pediatric Reference Ranges, 2nd Ed, Soldin, Brugnara, Gunter, and Hicks (eds), and Harriet Lane Handbook.

Critical values are also determined by Sinai Pediatrics faculty.

EPOC Point-of-Care Reference and Critical Ranges for PICU/PEDS

Analyte	Critical Range(low)	Reference Range	Critical Range(high)
Sodium, mmol/L	<126	133-145	> 154
Potassium, mmol/L	<2.6	3.5-5.5	>5.9
Chloride, mmol/L	<81	96-108	>119
Glucose, mg/dL **>28 days to 18 years**	<50	70-105	>300*
>18 years	≤50	70-105	≥400
pH (arterial) **pH (venous/cap)**	<7.21 <7.20	7.35-7.45 7.31-7.41	>7.54 >7.55
pCO2, mmHg(arterial) **pCO2, mmHg(venous/cap**	<21 Not defined	35-45 41-51	>49 Not defined
pO2 mmHg arterial **pO2mmHg venous/cap**	<51 Not defined	83-108 Not defined	Not defined Not defined
HCO3, mmol/L arterial **HCO3,mmol/L venous/cap**	<13 Not defined	18-24 23-28	N/A Not defined
TCO2 mmol/L arterial **TCO2mmol/L venous/cap**	Not defined Not defined	18-24 23-30	Not defined Not defined
BE mmol/L art **BEmmol/L venous/cap**	Not defined Not defined	(-2)-(+2) (-2)-(+3)	Not defined Not defined
Hematocrit %	<21	Scale below	>64
Hemoglobin, g/dL	<8	Scale below	N/A
O2 sat, %	N/A	95-98	N/A
Ionized Ca, mmol/L	<1.0	1.0-1.32	>1.4
Creatinine, mg/dL	Not defined	0.6-1.3	Not defined
Lactate mmol/L	N/A	0.5-2.0	>4.0

***Glucose results >300 in Peds/PICU DKA patients will be called/documented following their DKA protocol.**

Age Based Reference Range for Hemoglobin and Hematocrit

Age	Hemoglobin g/dL	Hematocrit %
1 month-2 months	10.7-17.1	33-55
2 months-6 months	9.4-13.0	28-42
6 months- 2years	10.5-13.5	33-39
2 years-12 years	11.5-15.5	34-45
>12 years male	13.0-17.0	40-50
>12 years female	11.7-15.7	37-47

Values outside the reportable range should be repeated in the Main laboratory. Reference ranges
apply to whole blood sample tested on the EPOC analyzer and may not exactly match those performed
in the main laboratory.
Critical values are adapted from multiple sources and reflect LifeBridge Health historical data.
Sources: Pediatric Reference Ranges, 2nd Ed, Soldin, Brugnara, Gunter, and Hicks (eds), and Harriet Lane Handbook.
Critical values are determined by Sinai Pediatrics faculty.
Document approved by Dr. Diana Molavi

12.0 RESULTS CORRECTION

Erroneous results released and reported onto patient's chart must be amended in the Cerner system. The erroneous result must be reported to the clinical provider in charge of the patient and a documentation of error form filled out and sent to pathology department. To obtain this from on the intranet, go to:

- On the left panel select 'Departments'
- Click 'pathology'
- Under Point of care testing, select 'result form for Result error'
- Fill out the form entirely and fax it to the correct facility. Fax numbers are provided at the bottom of the form.

Once the form is received the incorrect results will be amended.
A repeat test should be performed using the correct way to identify the patient so as the correct results can transmit to the correct patient's medical record.

ALTERNATIVE PROCEDURE

If the epoc system proves inoperable for any reason, a sample of blood should be collected and sent to the main laboratory for analysis.

13.0Limitation of Procedure

13.1The epoc Host is intended for use with only Blood analysis system. The Host should not be used as a general computing device.

13.2Never install "off the shelf" software without written authorization from Epocal inc. Unauthorized software may impact the operation of the epoc system.

13.3 The epoc should not be synchronized with other computing devices except RALS.

13.4 The Wi-Fi capabilities are factory disabled; they should be enabled and configured for use only with epoc device or printer.

14. CARE AND MAINTENANCE

14.1 Use and store the epoc Reader and Host in areas that are secure, free of moisture or excessive heat and vibration.

14.2 Clean the epoc system between each patient testing using the Super Sani wiped Cleaner.

14.3 Dry the host display screen with a soft cloth after cleaning.

14.4 Avoid using excessive fluids while cleaning as the fluid may penetrate through the reader and the host causing damage.

14.5 Do not clean the inside of the Reader's card insertion slot.

14.6 Do not expose electrical contacts to fluids.

15. INTERFERRING SUBSTANCES

15.1 Exposing the blood sample to air will affect the pH, PCO2, pO2 and ionized calcium results due to sample equilibration with the gas levels in the air. Change in PC02 will affect the Ph, and the change in pH will affect the ionized calcium results. Whole blood specimens should not be over-diluted with liquid anti-coagulants or any other solution as this may alter results.

15.2 Operators should be aware of the following list of interfering substances:

-Contamination w/ Benzalkonium salts (indwelling line coating) increases Na+ &K+
-20 mmol/L b-hydroxybutyrate (ketone) decreases Na+ by 3 mmol/L
-20 mmol/L b-hydroxybutyrate (ketone) decreases iCa++ by 0.038 mmol/L
-b-hydroxybutyrate (ketone) >8.27 mM (85.2 mg/dL) increases Cl by up to 0.37 mM/mM b-hydroxybutyrate
-Bromide increases pCO2 by 0.19 mmHg/mM bromide
-Bromide > 1.63 mM increases Cl by up to 2.75 mM/mM bromide
-10 mmol/L bromide increases iCa++ by 0.05 mmol/L
-16 mmol/L bromide will increase Na+ by 5 mmol/L
-Citrate >2.79 mM increases Cl by up to 1.13 mM/mM citrate
-Creatine >0.10 mmol/L will increase creatinine by up to 2.17 mg/dL creatinine per mmol/L creatine
-Iodide > 0.45 mmol/L will increase creatinine by up to 0.49 mg/dL creatinine per mmol/L iodide
-20% or greater hemodilution with saline, Ringer', or dextrose will cause Na+ errors.
-N-acetyl cysteine > 0.47 mmol/L increases creatinine by up to 0.72 mg/dL creatinine per mmol/L N-acetyl cysteine

-N-acetyl cysteine > 5.55 mM or greater will decrease Cl by up to 0.79 mM/mM N-acetyl cysteine
-Metronidazole causes average bias of +4 mmHg pO2/100 uL metronidazole
-Sodium heparin: erroneously high Na+ by 1-2 mmol/L
-4.3 mmol/L salicylate or acetyl salicylate decreases iCa++ by 0.06 mmol/L N-acetyl cysteine
-Salicylic acid > 1.67 mM/mM increases Cl by up to 2.94 mM/mM salicylic acid
-1 mmol/L sodium perchlorate will decrease iCa++ by 0.23 mmol/L
-Thiocyanate > 0.89 mM/mM increases Cl by up to 5.62 mM/mM thiocyanate

16. References

Epoc System Standard Operating procedure. CLSI Procedure Manual. Received from Alere 2014.

17.Attachment

14.1 Instructions for Epoc Care-Fill Capillary Tube use
14.2 Screen shot of patient testing

Departments: POCT