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Radiometer ABL 800 Series Operator Procedure

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. The Radiometer ABL 800 Series analyzers utilize Potentiometric measuring principles to measure pH, pCO_2, and electrolytes.

B. The Radiometer ABL 800 Series analyzers utilize Amperometric measuring principles to measure pO_2, Glucose (cGlu), Lactate (cLac), and Creatinine (cCrea).

C. The Radiometer ABL 800 Series analyzers utilize Optical measuring principles to measure total Hemoglobin (ctHb), Oxygen saturation (sO_2), Fraction of Oxyhemoglobin (FO_2Hb), Fraction of Carboxyhemoglobin (FCOHb), Fraction of Methemoglobin (FMetHb).

D. In addition, HCO_3^-, Base Excess, tCO_2, O_2 content, and P50 may be calculated using these measurements.

E. The Radiometer ABL 800 Series systems are designed for use on undiluted whole human blood, serum, and expired air. The Radiometer ABL 800 Series systems may also be used for pleural fluid pH. The FLEXQ module can accommodate up to three samplers simultaneously. It records a sample barcode, mixes the sample, and transports the sample to the inlet for aspiration and analysis without any further assistance from the operator.

II. CLINICAL SIGNIFICANCE:

A. Refer to Attachment A for Clinical Significance.

III. SPECIMEN COLLECTION AND HANDLING:

A. **Collection Requirements**

1. A 1 mL or 3 mL plastic blood gas syringe (coated with dry electrolyte-balanced heparin) should be used for blood gas analysis specimen collection. Air bubbles must be expelled by the collector immediately after collection.
2. Samples collected in evacuated tubes are not acceptable for blood gas analysis.
3. Samples collected in dark green heparinized evacuated tubes are only accepted for FCOHb, FMetHb, venous pH, cLac, cGlu, cNa^+, cK^+, cCl^-, and Crea.
4. Follow all usual precautions for collecting blood by venipuncture to avoid specimen hemolysis. See Respiratory procedure.
5. Verify the correct specimen type is used. The Radiometer system does not verify specimen type.
6. Specimens collected in a heparinized syringe or an evacuated tube must be placed on ice immediately following collection and sent to lab. Samples for Ionized Calcium, Glucose, Sodium, Potassium, Chloride, and Creatinine do not need to be sent to the laboratory on ice. Samples not tested within one hour of collection should be canceled.

IV. SPECIMEN PREPARATION AND STORAGE:

A. Sample Type

1. Plastic heparinized blood gas syringe: Inspect samples with the LIS collection label affixed to sure that there are no air bubbles present in sample, collection time is within 1 hour of receipt, and sample is received in the lab on crushed ice. Syringes with air bubbles should be canceled. To expel air bubbles at the bench is inappropriate because gas exchange would have already occurred during specimen transportation, causing falsely elevated pO2.
2. Green Heparinized evacuated tube: Samples transported to laboratory with Laboratory Information System (LIS) label affixed within one hour of collection. Specimens must remain capped until analysis. Clotted samples should be canceled.
3. Lithium Heparin: Acceptable tests include pH, Venous; Methemoglobin, Arterial; Methemoglobin, Whole Blood; Carboxyhemoglobin, Arterial, Carboxyhemoglobin, Whole Blood; Sodium, Whole Blood; Potassium, Whole Blood; Chloride, Whole Blood; Glucose, Whole Blood; Lactate, Whole Blood; Creatinine, Arterial; Creatinine, Whole Blood.
4. Sodium Heparin: Acceptable tests include pH, Venous; Methemoglobin, Arterial; Carboxyhemoglobin, Arterial; Carboxyhemoglobin, Whole Blood; Lactate, Whole Blood.
5. Methemoglobin, Carboxyhemoglobin, Whole Blood Lactate, and pH must be received on ice.
6. Serum separator tube (SST): Ionized calcium samples must remain capped until analysis.

B. **Sample Volume**

1. Optimum sample volume when performing an arterial or venous blood gas is 195 µL.

The minimum volume required is 95 µL. The optimum sample volume when performing a capillary blood gas is 95 µL, and the minimum required is 55 µL.

2. When performing a venous pH, pleural pH, ionized calcium, or lactic acid, the optimum sample volume is 195 µL. The minimum required volume is 95 µL.

C. **Specimen Handling**

1. For any unlabeled blood gas specimen: Analyze the specimen immediately upon receipt, print a copy of the results, and put the specimen back into the iced biohazard bag. If the specimen is eventually identified by the collector and a redraw is either inconvenient or not possible (e.g., Cord blood gases, cardiac arrest), report these results in the LIS.
2. It is recommended to analyze capillary blood gas samples within ten minutes of receipt.
3. For North sites, see Correction of Information on Specimen Labels: Proper Handling of Unlabeled/Mislabeled Specimens for specifics. For South sites, see Acceptable Laboratory Specimen Criteria-Inpatient and Laboratory Specimen Acceptance and Rejection Criteria-Outreach.

D. **Specimen Stability**

1. See Attachment H for a detailed list of specimen stability guidelines.

E. **Unacceptable Specimens**

1. EDTA, sodium citrate, potassium oxalate and sodium fluoride anticoagulants are unacceptable.
2. Pediatric microtainer tubes are unacceptable.
3. Specimens containing large air bubbles are unacceptable.
4. Clotted whole blood samples are unacceptable.
5. Lithium Heparin tubes are unacceptable for ALL Blood Gas orders.
6. Specimens for ALL blood gas orders, Methemoglobin, Carboxyhemoglobin, Whole blood Lactic Acid, and pH not received on ice are unacceptable.
7. Specimens received past one hour from the collection time are unacceptable.
8. Specimens received with a needle present are not acceptable. In these instances, a Quality and Safety Report (QSR) must be filled out.

V. REAGENTS:

A. **Reagent Handling**

1. Do not use reagents beyond their expiration date
2. Do not replace the same reagent that has been removed for any reason
3. Do not pool reagents
4. To avoid contamination, wear clean gloves when preparing or uncapping reagent bottles

B. All pertinent information, including composition, lot number, and expiration date are contained in the barcode on all reagents.

C. Note: Refer to Attachment B for a detailed list of reagent preparation and storage requirements.

VI. EQUIPMENT COMPONENTS:

A. The Radiometer ABL 800 Series consists of three primary components: The FLEXQ Modue, the Inlet Module, and the Measuring Section.

B. When using Pico syringes, the FLEXQ Module transports the sample to the inlet for automatic sampling.

C. Laser barcode reader reads the sample barcode.

D. The Pico syringe sample is mixed by the mixer tray.

E. The Inlet Module accepts sample from a syringe, test tube, or capillary tube.

F. The Measuring Section controls and contains the transport of the aspirated sample and reagents to measure the analyte.

VII. MAINTENANCE:

A. Maintenance is performed Daily, Weekly, Bi-Weekly, Monthly, Quarterly and As Needed. Refer to the onboard system maintenance tutorials for details and instructions. The maintenance schedule can be accessed by selecting Analyzer Status and touching the soft key for Electrodes and Other.

B. See Radiometer 800 Series Maintenance Procedure for maintenance details.

VIII. CALIBRATION:

A. The Calibration process determines and checks the accuracy with which the analyzer measures its parameters. The process is therefore important in ensuring the reliability of results. Calibrations are performed using solutions and gases of known concentration for each of the measured parameters. The calibration values are contained in the barcode on each calibration solution and gas cylinder. The values are updated when reagents are replaced.

B. Calibrations are scheduled as follows:

1. 1 Point Calibration: Every 4 hours
    a. Measures each parameter on one solution and/or gas of known composition, giving one value per parameter
    b. Relates the measured values to the theoretical values of a solution and/or gas of the same composition
    c. Gives the Drift 1 and status value of the electrode
2. 2 Point Calibration: Every 8 hours
    a. Measures each parameter on two different solutions and/or gases, both of known composition, giving two values per parameter

b. Relates the measured values to the theoretical values of solutions and/or gases of the same composition

c. Gives the Drift 1 and Drift 2 values and the status or zero point, sensitivity of the electrodes (two sensitivity values are given for the Crea B electrode and one for the Crea A electrode).

3. 1 Point pH/blood gas: Every 30 minutes (pH, pCO2, pO2)

a. Measures pCO_2 and pO_2 on one gas mixture of known composition and pH on a known solution, giving one value per parameter

b. Relates the measured values to the theoretical values of mixture/solution of the same composition

c. Gives the Drift 1 of the electrodes

4. tHb:

a. Performed manually every 3 months or as needed (See Radiometer 800 Series Maintenance procedure)

b. Calibrates the spectrophotometer

C. To perform an unscheduled calibration, select Analyzer Status > Calibrations and select the desired calibration button on the bottom of the screen.

D. Calibration Verification is performed manually every six months using the Radiometer Calibration Verification/Linearity kit. Follow instructions included in the kit.

E. Calibration Review and Storage

1. Calibrations can be viewed as soon as the calibration is complete. Results from the most recent calibration can be viewed via Analyzer Status > Calibration > Result screen.

2. Previous calibrations can be viewed via Data Log > Calibration Log and picking the calibration to be viewed. Calibrations are stored for a month and then are archived into the machine. It is possible to recall older calibrations by searching the archive.

F. If a calibration is unacceptable, troubleshoot the problem first by repeating the calibration followed by more extensive troubleshooting measures including replacing the membranes. See the Radiometer 800 Series Maintenance procedure.

IX. QUALITY CONTROL (QC):

A. At least three levels of AutoCheck QC material are used dail and assigned to specific work times. One level of High Creatinine Check is used at sites where creatinine is tested. After a manual calibration or an unscheduled calibration (i.e., including those triggered by a maintenance or troubleshooting procedure that include but not limited to an electrode or a membrane change), all three levels of control must be run. Patient results should not be reported when QC limits are exceeded unless approved by supervisory staff.

B. Scheduled QC

1. QC is automatically run from the carousel at its scheduled time

2. Each shift runs a specified level of QC on each analyzer
3. Any pending calibration will be performed before the scheduled AutoCheck measurement
4. Results are displayed and printed after the measurement is complete

C. Unscheduled QC
    1. To start an unscheduled AutoCheck measurement, press Analyzer Status > Quality Control
    2. Highlight the appropriate solution
    3. Press Run AC Ampoule to start the measurement
    4. Results are displayed and printed after measurement is complete

D. AutoCheck Module holds twenty vials of QC material. The QC material is loaded into an AutoCheck carousel, which is manually loaded.
    1. QC will automatically run at selected timed intervals
    2. Once QC is complete, a printout of results will follow
    3. The QC will automatically be entered in QC review
    4. QC that has an error or is marked with "?" will not cross into the QC review program
    5. Verify/Save the QC and enter actions for QC failures
    6. A parameter that is out of QC range will flag as a failure or warning in the QC program
    7. Either manually rerun the QC or it can be repeated via autorun if QC is out of range
    8. Troubleshoot if QC is still out of range

E. Manually initiate a QC program using the AutoCheck Module.
    1. Select Analyzer Status > Quality Control
    2. Select the QC level to run
    3. Choose Run AC Ampoule
    4. QC will automatically run
    5. Verify QC results in the QC review program

F. Manual QC measurement
    1. Place the QC vial fully into the H700 adapter and press down on the top of the H700 adapter to break open the QC vial.
    2. Open the syringe inlet flap
    3. Place the adapter tip up into the syringe inlet
    4. Press Ampoule QC to select the measuring program
    5. Press Start
    6. When prompted by the analyzer, remove the adapter and close the syringe inlet flap

7. Press results
8. Press QC ID
9. Select the lot number of QC that was tested. Once the lot number is assigned, it will transmit to the QC program
10. Press Back
11. The results do not print automatically, but press "Print" to manually print out the QC report
12. Accept QC and answer any QC failures

G. Troubleshooting Radiometer Controls

1. Check traffic lights for any messages and resolve any problems
2. Initiate a 1-point calibration (if necessary, initiate a 2-point calibration)
3. If calibration is successful, run all levels of QC. If the controls are successful, proceed with patient testing. If controls fail again, continue to troubleshoot. (Contact service if necessary). DO NOT USE for patient testing.
4. Document any corrective action on the troubleshooting or QC log as needed

X. SPECIAL SAFETY PRECAUTIONS:

Universal precautions are indicated when handling patient specimens and quality control materials. Spills and accidents should be addressed immediately. Refer to appropriate online safety data sheet (SDS) for specific reagent information.

XI. PROCEDURE:

A. **Start-up/Shut down Analyzer**

1. Start up
    a. To turn on power – flip switch at back of analyzer to the on position and instrument will start up automatically
    b. The instrument will begin to initialize on its own
    c. The instrument takes about 20 minutes to equilibrate
    d. The analytes at the top of the screen will turn green when the instrument is ready to use
2. Shut down
    a. If you need to turn off the Radiometer ABL 800 Series, DO NOT use the ON/OFF switch that is located on the back of the instrument. Use the Shutdown procedure as follows:
    b. Powering down the instrument is used for troubleshooting techniques
        i. Choose Menu > Utilities > Power Down
        ii. Confirm Power Down, wait until screen displays, "It is safe to

turn off computer."

iii. Turn the power switch to OFF, which is located on the back of the instrument

iv. Wait one minute, turn instrument back on

B. **Loading Bulk Reagents**

1. See Radiometer 800 Series Maintenance procedure

C. **Sample Analysis**

1. Blood Gas syringe - Pico syringe
    a. Check sample for air bubbles and sufficient sample. If there is at least 195 µL, it can be run on the FLEXQ module when using the SafePico syringe.
    b. Make sure the barcode is facing the barcode scanner to the left and place in the FLEXQ sample slot
    c. The sample barcode will appear on the screen
    d. Select the panel to be run and select Start
    e. The sample will be mixed and then move to the inlet to be aspirated
    f. Follow the prompts when the instrument instructs to remove the sample
    g. Results will print when completed and will identify whether Sulfhemoglobin (SulfHgb) is detected. When detected, it will print present for SulfHgb. In Beaker, if SulfHgb is detected, select positive and the comment will be generated, "Sulfhemoglobin may interfere with quantitation of total hemoglobin, oxyhemoglobin, or dyshemoglobins in this sample. Sulfhemoglobin can be detected but not accurately quantified by this method."

2. Blood Gas Syringe - Run Manually
    a. Check sample for air bubbles and sufficient volume (at least 95 µL)
    b. Scan the sample barcode
    c. Sample information and patient demographics will appear on the screen
    d. Mix sample to ensure homogeneity by inverting the sample several times and then rolling the sample between the palms of hands
    e. Lift up the blue syringe inlet
    f. Choose appropriate panel by sample volume and test requested. Do not change sample type from "arterial". All sample types will be correct in the LIS based on the test code ordered.
    g. Remove syringe cap. Expel any air in tip and wipe off blood overspills. Expel a small amount of sample onto a small absorbent pad and assess for clots.
    h. Pull back on syringe barrel until air fills syringe tip
    i. Attach syringe to open inlet port

j. Hit the Start button to begin sample aspiration
k. Follow the prompts when the instrument instructs to remove sample
l. Results will print when completed to check for the presence of SulfHgb

3. Heparin Tube or SST - Manually
    a. Check the sample for clots
    b. Scan the sample barcode
    c. Sample information and patient demographics will appear on the screen
    d. Heparin samples: Mix the sample to ensure homogeneity and again observe for the presence of clots
    e. Lift up the blue syringe inlet
    f. Select the pane to be run
    g. An aliquot of sample can be poured into a cup to verify no clots are aspirated into the inlet
    h. Hit the Start button to begin sample aspiration
    i. Hold tube or cup carefully while the sample is being aspirated. The probe can easily be bent.
    j. Wait for the sample probe to retract before removing the sample
    k. Result will print when completed to check for the presence of SulfHgb
4. Capillary Tube
    a. Check sample for air bubbles, clots and for sufficient sample volume (at least 55 µL)
    b. Use magnet to move flea inside capillary tube to mix sample
    c. Remove the flea
    d. Scan the sample barcode
    e. Sample information and patient demographics will appear on the screen
    f. Attach clot catcher to capillary tube
    g. LIft inlet flap on the right side
    h. Select panel to run and hit Start
    i. Attach capillary tube to right side inlet
    j. Sample will aspirate
    k. Follow prompts to remove sample after completion
    l. Results will print when completed to check for the presence of SulfHgb

D. Tutorials for the Radiometer ABL 800 FLEX can be accessed directly from the instrument screen. To do so:
    1. Select Help? in the top right corner

2. Select Tutorials from the bottom right of the screen (next to the "Back" button)

E. NOTE: After running cord blood gas samples, run a clean cycle to clear out any offending material.

XII. CALCULATIONS AND INTERPRETATIONS:

A. All valid patient results are automatically uploaded to the LIS and control results are automatically uploaded to the QC review program. Patient results are reviewed for the presence of SulfHgb prior to release.

B. Samples that generate an error code are held at the instrument. These results have red text and a question mark (?). The error code is defined at the bottom of the result printout.

1. These results may not be released to the pateint chart. The parameters must be repeated if allowable.
2. Repeat measurement(s) for pH, pO2, pCO2 are allowed only if the specimen is verified to be free of air bubbles and remained capped in the first measurement.
3. See the chart below for some common error messages that result in parameters with "?".

Error Message	Issue	Operator Corrective Action
374, 467, 468, 521, 593, 719, 720, 721	Homogeneity issue or insufficient sample	Repeat the measurements(s) on the same analyzer. A lower test volume may be selected. If the parameter marked with "?" is still present, repeat measurement(s) on another analyzer.
378, 379, 386, 408, 512, 963, 964	Instrumentation or analytical issues	Repeat the measurement(s) on another analyzer.

4. If a parameter is repeatedly flagged with the "?" error and the rest of the results are consistently not flagging on more than one instrument, then it is likely the specimen issue is only affecting one of the analytical methods. The same holds true if tow or three parameters are consistently flagged. Do not report the result with the "?" error but do report the results without any errors.

a. Do not report TCO2 and HCO3 if pCO@ is marked by "?"

b. Do not report GFR if creatinine is marked by "?"

C. Critical results are communicated according to each site's critical call policies.

D. The "Notes" section appears at the bottom of each result or QC printout. This will give more information related to the results that may have flagged or have problems. Examples include denoting when a result is above or below the reportable range, calculated values, or parameters out of range.

E. Blood gas linearity materials for Analytical Measurement Range (AMR) verification are used according to instructions from the manufacturer. For some analytes, these materials do not cover the entire range of vallues reported. For example, the highest level of pCO2 reaches approximately 60% of the upper limit of the reportable range; based on historical patient data, high pCO2 results up to 180 mmHg correlated well with low pO2 results. The AMRs of COHb and MetHb are extended up to 70% because ranges above the highest linearity material are clinically relevant. Medical and technical directors have approved the indicated reportable ranges to provide clinical benefit in cases of extreme acid-base disorders, methemoglobinemia and carboxyhemoglobinemia. These benefits outweigh the relatively small risk of not formally verifying the full reportable range. This approach is consistent with CAP instructions indicating: *"It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations or activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion. the method manufacturer's instructions for verifying the AMR must be followed, when available."* (Chemistry and Toxicology Checklist 09.22.2021, p. 8)

XIII. REFERENCE RANGES:

Refer to Attachment D for a list of reference ranges

XIV. REPORTABLE RANGE:

Refer to Attachment E for a list of reportable ranges

XV. LIMITATIONS:

A. Assay results MUST be used with other clinical data, including, but not limited to: patient symptoms, other test results, patient history, clinical impressions, information available from clinical evaluation, and other diagnostic procedures. All data MUST be considered for patient care management.

B. If assay results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

C. The Radiometer System has been validated for its intended use. However, errors can occur due to potential operator errors and Radiometer System technology limitations.

XVI. INTERFERING SUBSTANCES:

A. Halothane use in anesthesia causes unreliable pO_2 results due to reduction of halothane by

the pO_2 electrode.

B. Hemolysis should be avoided as it may falsely elevate potassium levels.

C. Anions: Br^-, I^-, S^{2-}, and ClO_4^-, used in drugs will erroneously elevate Cl^- results.

D. Anticoagulants that contain Sodium Fluoride or Sodium Citrate will interfere with Na^+, K^+, and Glucose results.

E. Thiocyanic acid, which is a degradation product from nitroprusside and thiosulphate treatment, may cause erroneously high glucose measurements.

F. Lipid therapy and protamine sulphate used in treatments may interfere with oximetry measurements.

G. Methylene Blue used as medication may interfere with oximetry measurements.

H. Consult the Package Inserts accompanying each test for specific information on interferences with endogenous substances and drugs.

I. Refer to Attachment F for potential causes of error.

XVII. REFERENCES:

1. Radiometer Medical A/S, ABL 800 Series Operator's Manual, 2017
2. Radiometer Medical A/S, ABL 800 Series Reference Manual, 2008
3. Radiometer ABL Calibrator for Automated Systems package insert sheet

Attachments

Attachment A - Radiometer ABL 800 FLEX Clinical Significance.pdf

Attachment B - Radiometer ABL 800 FLEX Reagent Guide.pdf

Attachment C - Radiometer ABL 800 FLEX Solutions and Calibrators.pdf

Attachment E ABL Radiometer Reportable Range.pdf

Attachment F - Radiometer ABL 800 FLEX Potential Causes of Error.pdf

Attachment G - Radiometer ABL 800 FLEX Tests by Campus.pdf

Attachment H - Radiometer ABL 800 FLEX Sample Storage Stability.pdf

Radiometer Attachments D_Reference Ranges.pdf

Approval Signatures

Step Description	Approver	Date

Medical Directors	Vaishali Pansare: Chief, Pathology	1/17/2023
Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	1/13/2023
Medical Directors	Muhammad Arshad: Physician	1/11/2023
Medical Directors	Jeremy Powers: Chief, Pathology	1/10/2023
Medical Directors	Ryan Johnson: OUWB Clinical Faculty	1/9/2023
Medical Directors	John Pui: Chief, Pathology	1/9/2023
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr, Division Laboratory	1/6/2023
Policy and Forms Steering Committee Approval (if needed)	Ilene Hirsch: Project Mgr Policy	1/6/2023
	Caitlin Schein: Staff Physician	1/6/2023
	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	1/5/2023
	Qian Sun: Tech Dir, Clin Chemistry, Path	1/5/2023
	Elzbieta Wystepek: Dir, Lab Operations B	1/4/2023
	Kimberly Geck: Dir, Lab Operations B	1/4/2023
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	Colette Kessler: Mgr, Division Laboratory	1/4/2023
	Colette Kessler: Mgr, Division Laboratory	1/4/2023

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Arterial Blood Gas	Used in the evaluation of oxygen and carbon dioxide exchange and acid-base status. Arterial blood gases are also used in the assessment of asthma, chronic obstructive pulmonary disease (COPD) and other types of lung disease, pulmonary embolism, carbon monoxide poisoning, methemoglobinemia, sulfhemoglobinemia and in cardio-pulmonary bypass cases.
Venous Blood Gas	Used to evaluate acid-base status but are less useful in assessment of blood oxygenation. Results are used to assess pH in infants, children, and adults in whom oxygen parameters are not needed. In many metabolic situations a venous pH is adequate to assess acid-base status, and arterial puncture is unnecessary. In cases of severe hypoperfusion central venous blood better detects hypercapnia and acidemia. The pH, PCO_2, and PO_2 from pulmonary arterial samples correlate with central venous specimens.
Critical Care Panel	This panel provides rapid information on blood oxygenation, acid-base status, electrolyte and glucose balance in critically-ill patients, particularly if diabetic, and in patients where results are needed quickly, e.g. in cardiopulmonary bypass patients.
Methemoglobin	This assay aids in the diagnosis of methemoglobinemia. Methemoglobinemia, with or without sulfhemoglobinemia, is most commonly encountered as a result of administration of such medications as phenacetin, phenazopyridine, sulfonamides, local anesthetics, dapsone, or following ingestion of nitrites or nitrates. Congenital methemoglobinemias are rare. In congenital methemoglobinemia, the methemoglobin concentration in blood is about 15-20% of total hemoglobin. These patients are mildly cyanotic and asymptomatic. In acquired (toxic) methemoglobinemia, the Met Hgb concentration may be much higher. Symptoms may be severe when methemoglobin is greater than 40% of hemoglobin. Very high methemoglobin concentrations may be fatal.
Oxyhemoglobin	This test is used to evaluate blood oxygenation and aids in the diagnosis of hypoxia. It is also used to monitor a patient's respiratory function during mechanical ventilation.
Carboxyhemoglobin	This assay aids in the diagnosis of carbon monoxide poisoning. CO Hb (%) Symptoms/Signs of Carbon Monoxide Poisoning 10 No appreciable effect; may have tightness across forehead. 20 Short of breath on moderate exertion; occasional headaches. 30 Headache, irritable, easily fatigued. 40-50 Headache, confusion, collapse. 60-70 Unconscious, convulsions, respiratory failure. 80+ Rapidly fatal. Carbon monoxide combines with the heme Fe^{2+} of hemoglobin to form carboxyhemoglobin. The binding affinity is about 250 times greater than that of oxygen. In addition to this increased binding affinity with subsequent decreased oxygen content of blood, there is a shift of the hemoglobin oxygen dissociation curve to the left, causing a decrease in release of oxygen from hemoglobin.
Sulfhemoglobin	Sulfhemoglobin is a moiety of normal hemoglobin with a sulfur atom incorporated into the porphyrin ring. Because of this change the hemoglobin is unable to bind oxygen. Sulfhemoglobinemia may be induced by drugs (e.g., flutamide, acetanilide, diapason), exposure to sulfur dioxide, hydrogen sulfide, trinitrotoluene and severe air pollution. Sulfhemoglobin often accompanies drug induced methemoglobinemia and is also associated with cyanosis. In contrast to methemoglobinemia that responds to treatment with methylene blue or ascorbic acid, sulfhemoglobin persists until the erythrocytes containing it are destroyed. The blood level of sulfhemoglobin declines gradually over a period of weeks. Patients with sulfhemoglobinemia often also have methemoglobinemia. Therapy is directed at reversing the methemoglobinemia present.
Lactic Acid, Whole Blood	This assay aids in the evaluation of metabolic acidosis, regional or diffuse tissue hypoperfusion, hypoxia, shock, congestive heart failure, dehydration, complicated postoperative state, ketoacidosis or nonketotic acidosis in diabetes mellitus, patients with infections, inflammatory states, certain myopathies, acute leukemia and other neoplasia, enzyme defects, glycogen storage disease (type1), thiamine deficiency and hepatic failure.
Venous pH, Whole Blood	Venous pH is used to assess acid-base status when a complete arterial blood gas panel is not considered necessary. It is frequently used to monitor patients who are being treated for diabetic ketoacidosis. A decreased pH is consistent with acidosis and an increased pH is consistent with alkalosis. A normal pH may indicate that the patient has a normal pH or has a mixed acid-base disturbance. Appropriate assessment in the latter case requires arterial blood gas testing.
Glucose, Whole Blood	This assay is appropriate when rapid turn around time is important for patient management. If serum or heparinized plasma is left in contact with blood cells for extended periods, glucose will be metabolized. Glucose levels decrease by about 5-7 mg/dl per hour at room temperature in normal specimens containing normal numbers of RBC's and WBC's.
Sodium, Chloride, Postassium, Whole Blood	This assay is appropriate when rapid turnaround time is important for patient management.
Pleural Fluid pH	An abnormally low pleural fluid pH helps to identify patients with effusions due to pneumonia or lung abscesses. Exudates with a pH lower than 7.3 can indicate the need for chest tube drainage in addition to antibiotics. A pH value as low as 6.0 may indicate esophageal rupture.
Ionized Calcium	Ionized calcium is useful for the assessment of calcium status in patients with acid-base or plasma protein abnormalities and those in whom the total calcium result does not correlate with clinical finding. The ionized calcium assay provides useful information during liver transplantation surgery, cardiopulmonary bypass, or any procedure requiring rapid transfusion of whole blood.
Ionized Calcium, Post Filter CRRT	For patients in the ICU receiving regional citrate anticoagulation with continuous renal replacement therapy, citrate infusion rate titrations are determined by post-filter ionized calcium levels (mg/dL), drawn from the return (Afferent) line of the CRRT filter set.

Ionized Calcium, Systemic CRRT	For patients in the ICU receiving regional citrate anticoagulation with continuous renal replacement therapy, calcium chloride is infused into the Afferent line (blood going back into patient) to normalize the patient's systemic calcium level, after chelation with citrate, and intentional hypocalcemia regionally in the CRRT circuit. Calcium chloride infusion rate titrations are determined by systemic ionized calcium levels (mg/dL).
Total CO2	The CO_2 assay aids in the evaluation of acid-base balance.
P50	The P50 is defined as the oxygen tension at which 50% of the hemoglobin is saturated when the blood is at 37°C , has a PCO_2 value of 40 mm Hg and has a pH of 7.40. The concept was designed to evaluate factors, other than temperature, pH, and PCO_2 that change hemoglobin-oxygen affinity.
Creatinine	This assay is appropriate when rapid turnaround time is important for patient management.

Assay	Method	Sample Type	Membrane On-board Stability	Membrane Prep	Membrane Storage
MEMBRANES					
pH	Potentiometric	Heparinized Whole Blood	Changed by PM		RT
pCO2	Potentiometric	Heparinized Whole Blood	3 Months		RT
K+	Potentiometric	Heparinized Whole Blood	3 Months		RT
Na+	Potentiometric	Heparinized Whole Blood	3 Months		RT
Ca2+	Potentiometric	Heparinized Whole Blood or SST	3 Months		RT
Cl-	Potentiometric	Heparinized Whole Blood	3 Months		RT
ctHb	Optical	Heparinized Whole Blood			
sO2	Optical	Heparinized Whole Blood			
FO2HB	Optical	Heparinized Whole Blood			
FCOHB	Optical	Heparinized Whole Blood			
FMetHb	Optical	Heparinized Whole Blood			
pO2	Amperometric	Heparinized Whole Blood	3 Months		RT
cGlucose	Amperometric	Heparinized Whole Blood	1 Month	Empty electrolyte solution into electrode jacket	2-25 C
cLactate	Amperometric	Heparinized Whole Blood	1 Month	Empty electrolyte solution into electrode jacket	2-8 C
Crea A - Measures creatine	Amperometric	Heparinized Whole Blood	14 Days	Empty electrolyte solution into electrode jacket	2-10 C
Crea B - Measures creatine and creatinine	Amperometric	Heparinized Whole Blood	14 Days	Empty electrolyte solution into electrode jacket	2-10 C
Reference		Heparinized Whole Blood	1 Month		RT

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Solutions and Calibrators

Calibrator	Preparation	Open Stability (Days)	Storage Temp after opening
Cal 1 Solution		4 Weeks	Room Temperature
Cal 2 Solution		8 Weeks	Room Temperature
Cal Gas 1		Expiration date on bottle	Room Temperature
Cal Gas 2		Expiration date on bottle	Room Temperature
Rinse Solution		4 Weeks	Room Temperature
Hypochlorite Solution		Expiration date on bottle	2-8 C
Cleaning Solution	a. Remove the foil from the DosiCapZip. b. Turn the DosiCapZip upside down and screw it onto the container again. c. Invert the container at least 20 times to dissolve the additive. d. Place the container horizontally so that the solution may enter the DosiCapZip and leave it for 3 minutes. e. Invert the container again at least 20 times to fully dissolve the additive.	2 Months	Room Temperature
Cal 1 Solution (ABL827)	a. Remove the foil from the DosiCapZip. b. Turn the DosiCapZip upside down and screw it onto the container again. c. Invert the container at least 20 times to dissolve the additive. d. Place the container horizontally so that the solution may enter the DosiCapZip and leave it for 3 minutes. e. Invert the container again at least 20 times to fully dissolve the additive.	4 Weeks	Room Temperature
Cal 2 Solution (ABL827)	a. Remove the foil from the DosiCapZip. b. Turn the DosiCapZip upside down and screw it onto the container again. c. Invert the container at least 20 times to dissolve the additive. d. Place the container horizontally so that the solution may enter the DosiCapZip and leave it for 3 minutes. e. Invert the container again at least 20 times to fully dissolve the additive.	8 Weeks	Room Temperature

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Reference Ranges

12/1/2022
Attachment D

	Age	Reference Range		Units
ARTERIAL BLOOD GAS				
pH	0-4 d	7.27	7.47	
	5 d +	7.35	7.45	
pCO2	0-5 d	27	40	mm Hg
	6 d - 23 m	27	41	mm Hg
	24 m+	32	45	mm Hg
pO2	0-1 d	54	95	mm Hg
	2 d +	80	100	mm Hg
HCO3	0-4 d	16	23	mmol/L
	5 d- 12y	19	27	mmol/L
	13y +	20	29	mmol/L
TCO2	0-11 m	20	28	mmol/L
	1-12 y	17	28	mmol/L
	13y +	20	29	mmol/L
BE	0+	-3	3	mmol/L
O2Hb	0+	95	98	%
COHb	0+	Comment on all reports: Non Smoker: Less than 1.5% Heavy Smoker: Less than 9% Toxic: Greater than 20%		%
MetHb	0+	0	2	%
tHgb	1 d	14.6	22.7	g/dL
	2-14 d	13.2	21.3	g/dL
	15 d - 3 m	9.8	12.9	g/dL
	4-6 m	10.4	14.7	g/dL
	7-12 m	10.2	14.7	g/dL
	13-24 m	11.1	13.7	g/dL
	25 m - 5 y	11.1	14.1	g/dL
	6-9 y	11.4	14.7	g/dL
	10-12 y	11.0	15.1	g/dL
	13-17 y	11.7	15.6	g/dL
Male	18 + y	13.5	17.0	g/dL
Female	18 + y	12.1	15.0	g/dL
ctO2	0+	18	21	Vol%

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Reference Ranges

12/1/2022
Attachment D

	Age	Reference Range		Units
VENOUS BLOOD GAS				
pH	0 +	7.32	7.42	
pCO2	0 +	41	51	mm Hg
HCO3	0 +	19	27	mmol/L
TCO2	0-11 m	20	28	mmol/L
	1-12 y	17	28	mmol/L
	13y +	20	29	mmol/L
BE	0+	-5	5	mmol/L
O2Hb	0+	95	98	%
COHb	0+	Comment on all reports: Non Smoker: Less than 1.5% Heavy Smoker: Less than 9% Toxic: Greater than 20%		%
MetHb	0+	0	2	%
tHgb	1 d	14.6	22.7	g/dL
	2-14 d	13.2	21.3	g/dL
	15 d - 3 m	9.8	12.9	g/dL
	4-6 m	10.4	14.7	g/dL
	7-12 m	10.2	14.7	g/dL
	13-24 m	11.1	13.7	g/dL
	25 m - 5 y	11.1	14.1	g/dL
	6-9 y	11.4	14.7	g/dL
	10-12 y	11.0	15.1	g/dL
	13-17 y	11.7	15.6	g/dL
Male	18 + y	13.5	17.0	g/dL
Female	18 + y	12.1	15.0	g/dL

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Reference Ranges

12/1/2022
Attachment D

	Age	Reference Range		Units
MIXED VENOUS BLOOD GAS				
pH	0 +	7.32	7.42	
pCO2	0 +	41	51	mm Hg
pO2	0 +	25	40	mm Hg
HCO3	0 +	19	27	mmol/L
TCO2	0-11 m	20	28	mmol/L
	1-12 y	17	28	mmol/L
	13y +	20	29	mmol/L
BE	0+	-5	5	mmol/L
O2Hb	0+	60	80	%
COHb	0+	Comment on all reports: Non Smoker: Less than 1.5% Heavy Smoker: Less than 9% Toxic: Greater than 20%		%
MetHb	0+	0	2	%
tHgb	1 d	14.6	22.7	g/dL
	2-14 d	13.2	21.3	g/dL
	15 d - 3 m	9.8	12.9	g/dL
	4-6 m	10.4	14.7	g/dL
	7-12 m	10.2	14.7	g/dL
	13-24 m	11.1	13.7	g/dL
	25 m - 5 y	11.1	14.1	g/dL
	6-9 y	11.4	14.7	g/dL
	10-12 y	11.0	15.1	g/dL
	13-17 y	11.7	15.6	g/dL
Male	18 + y	13.5	17.0	g/dL
Female	18 + y	12.1	15.0	g/dL
ctO2	0+	18	21	Vol%

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Reference Ranges

12/1/2022
Attachment D

	Age	Reference Range		Units
CAPILLARY BLOOD GAS				
pH	0-4 d	7.27	7.47	
	5 d +	7.35	7.45	
pCO2	0-5 d	27	40	mm Hg
	6 d - 23 m	27	41	mm Hg
	24 m+	35	45	mm Hg
pO2	0-1 d	54	95	mm Hg
	2 d +	80	100	mm Hg
HCO3	0-4 d	16	23	mmol/L
	5 d- 12y	19	27	mmol/L
	13y +	20	29	mmol/L
TCO2	0-11 m	20	28	mmol/L
	1-12 y	17	28	mmol/L
	13y +	20	29	mmol/L
BE	0+	-2	2	mmol/L
O2Hb	0+	95	98	%
COHb	0+	Comment on all reports: Non Smoker: Less than 1.5% Heavy Smoker: Less than 9% Toxic: Greater than 20%		%
MetHb	0+	0	2	%
tHgb	1 d	14.6	22.7	g/dL
	2-14 d	13.2	21.3	g/dL
	15 d - 3 m	9.8	12.9	g/dL
	4-6 m	10.4	14.7	g/dL
	7-12 m	10.2	14.7	g/dL
	13-24 m	11.1	13.7	g/dL
	25 m - 5 y	11.1	14.1	g/dL
	6-9 y	11.4	14.7	g/dL
	10-12 y	11.0	15.1	g/dL
	13-17 y	11.7	15.6	g/dL
Male	18 + y	13.5	17.0	g/dL
Female	18 + y	12.1	15.0	g/dL
ctO2	0+	18	21	Vol%

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Reference Ranges

12/1/2022
Attachment D

	Age	Reference Range		Units
ARTERIAL CORD BLOOD GAS				
pH		7.18	7.38	
pCO2		32	66	mm Hg
pO2		6	30	mm Hg
HCO3		17	27	mmol/L
BE		-10	-2	mmol/L
O2Hb		none	none	%
COHb		none	none	%
MetHb		none	none	%
tHgb	1 d	14.6	22.7	g/dL
	2-14 d	13.2	21.3	g/dL
	15 d - 3 m	9.8	12.9	g/dL
	4-6 m	10.4	14.7	g/dL
	7-12 m	10.2	14.7	g/dL
	13-24 m	11.1	13.7	g/dL
	25 m - 5 y	11.1	14.1	g/dL
	6-9 y	11.4	14.7	g/dL
	10-12 y	11.0	15.1	g/dL
	13-17 y	11.7	15.6	g/dL
Male	18 + y	13.5	17.0	g/dL
Female	18 + y	12.1	15.0	g/dL

VENOUS CORD BLOOD GAS				
pH		7.25	7.45	
pCO2		27	49	mm Hg
pO2		17	41	mm Hg
HCO3		12	28	mmol/L
BE		-10	-2	mmol/L
O2Hb		none	none	%
COHb		none	none	%
MetHb		none	none	%
tHgb	1 d	14.6	22.7	g/dL
	2-14 d	13.2	21.3	g/dL
	15 d - 3 m	9.8	12.9	g/dL
	4-6 m	10.4	14.7	g/dL
	7-12 m	10.2	14.7	g/dL
	13-24 m	11.1	13.7	g/dL
	25 m - 5 y	11.1	14.1	g/dL
	6-9 y	11.4	14.7	g/dL
	10-12 y	11.0	15.1	g/dL
	13-17 y	11.7	15.6	g/dL
Male	18 + y	13.5	17.0	g/dL
Female	18 + y	12.1	15.0	g/dL

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Reference Ranges

12/1/2022
Attachment D

	Age	Reference Range		Units
Ionized Ca	0-1 d	4.20	5.48	mg/dL
	2-3 d	4.40	5.68	mg/dL
	4-5 d	4.80	5.92	mg/dL
	6 d +	4.48	5.28	mg/dL
Lactate	Arterial	0.0	1.3	mmol/L
	Venous	0.0	2.2	mmol/L
Creatinine				
Male	0 - 14 d	0.32	0.92	mg/dL
	15 d - 2 y	0.10	0.36	mg/dL
	2 - 5 y	0.20	0.43	mg/dL
	5 - 12 y	0.31	0.61	mg/dL
	12- 15 y	0.45	0.81	mg/dL
	15-19 y	0.62	1.08	mg/dL
	19 - Adult	0.60	1.30	mg/dL
Female	0 - 14 d	0.32	0.92	mg/dL
	15 d - 2 y	0.10	0.36	mg/dL
	2 - 5 y	0.20	0.43	mg/dL
	5 - 12 y	0.31	0.61	mg/dL
	12- 15 y	0.45	0.81	mg/dL
	15 - 19 y	0.49	0.84	mg/dL
	19 y - Adult	0.50	1.10	mg/dL
Chloride		98	111	mmol/L
Potassium	0 - 1 d	5.0	7.5	mmol/L
	2 d - 3 m	4.0	6.0	mmol/L
	4 m - Adult	3.5	5.2	mmol/L
Sodium	0 - 1 d	126	166	mmol/L
	2 - 29 d	134	144	mmol/L
	30 d - 1 y	139	146	mmol/L
	2 - 12 y	138	145	mmol/L
	13 y - Adult	135	145	mmol/L

		LOW	HIGH
pH		6.600	7.800
pH(Pleural Mode)		7.000	7.500
PCO2	mm Hg	8	180
PO2	mm Hg	0	650
ctHb	g/dL	0.0	23.0
sO2	%	0	100
FO2Hb	%	0.0	100
FCOHb	%	0.0	70
FMetHb	%	0	70
Na+	mmol/L	82	180
K+	mmol/L	1.0	14.0
Cl-	mm	43	150.0
Ca++	mg/dL	0.9	8.8
cGlucose	mg/dL	3	1081
cLactate	mmol/L	0	27

Potential causes of error	Major affected parameters
Air bubbles in sample	pO2*
Clot in sample**	pH
Sedimented samples	ctHb, pO2, pCO2
Hemolysis	cK+, cCa2+, cCl-, cNa+
Arterial blood mixed with venous blood	pH, pO2, sO2
Leakage from red blood cells	cK+
Infusion solution given in the same arm	Electrolytes and metabolites

** WARNING/CAUTION: Always remove air bubbles from a sample before introducing it into the analyzer. Air bubbles may result in erroneous pO2 values.*

***WARNING/CAUTION: When measurements are flagged always conduct the operator actions required by the troubleshooting program to prevent possible clots from remaining in the sample path. Fluid path clots may cause erroneous measurement results.*

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Tests by Campus

5/27/2022
Attachment G

Assay	Dearborn	Royal Oak	Grosse Pointe	Troy	Canton	Taylor	Trenton	Wayne	Farmington Hills	Lenox	Livonia
pH	X	X	X	X	X	X	X	X	X	X	X
pCO2	X	X	X	X	X	X	X	X	X	X	X
pO2	X	X	X	X	X	X	X	X	X	X	X
ctHb	X	X	X	X	X	X	X	X	X	X	X
sO2	X	X	X	X	X	X	X	X	X	X	X
FO2HB	X	X	X	X	X	X	X	X	X	X	X
FCOHB	X	X	X	X	X	X	X	X	X	X	X
FMetHb	X	X	X	X	X	X	X	X	X	X	X
K+	X	X	X	X	X	X	X	X	X	X	X
Na+	X	X	X	X	X	X	X	X	X	X	X
Ca2+	X	X	X	X	X	X	X	X	X	X	X
Cl-	X	X	X	X	X	X	X	X	X	X	X
cGlucose	X	X	X	X	X	X	X	X	X	X	X
cLactate	X	X	X	X	X	X	X	X	X	X	X
Creat					X					X	X

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Specimen Stability

5/27/2022
Attachment H

	Blood Gas Syringe*			Heparinized Tube			Gold top SST (Not Uncapped)		
	RT	Wet Ice	-20° C pourover	RT	2° - 8° C	-20° C pourover	RT	2° - 8° C	-20° C pourover
Arterial Blood Gas		1 Hour							
Critical Care Panel		1 Hour							
Venous Blood Gas		1 Hour							
Mixed Venous Blood Gas		1 Hour							
Capillary Blood Gas		1 Hour							
Arterial Cord Blood Gas		1 Hour							
Venous Cord Blood Gas		1 Hour							
Oxyhemoglobin		1 Hour							

	Blood Gas Syringe*			Heparinized Tube			Gold top SST (Not Uncapped)		
	RT	Wet Ice	-20° C pourover	RT	Wet Ice	-20° C pourover	RT	2° - 8° C	-20° C pourover
Carboxyhemoglobin		1 Hour		4 Hours	7 Days				
Methemoglobin		1 Hour			72 Hours				
Ionized Calcium		1 Hour					4 Hours	48 Hours	
Venous pH		1 Hour			1 Hour				
Lactate, Whole Blood		1 Hour			1 Hour				
Chloride, Whole Blood		1 Hour		2 Hours					
Potassium, Whole Blood		1 Hour		2 Hours^					
Sodium, Whole Blood		1 Hour		2 Hours^					
Glucose, Whole Blood		1 Hour		2 Hours#			2 Hours		
Creatinine		1 Hour		2 Hours^					

**Blood gas syringe coated with dry electrolyte-balanced heparin* #Separator Tube *^Only lithium heparin tube is accepted*

Tests ordered with samples collected in respective conditions shaded in the table above are unacceptable