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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. Samples collected in a Capillary tube containing dry heparin are accepted for Capillary Blood Gases, and P50.
5. Follow all usual precautions for collecting blood by venipuncture to avoid specimen hemolysis. See Respiratory procedure.
6. Verify the correct specimen type is used. The Radiometer system does not verify specimen type.
7. 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 ensure 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. Capillary tubes containing dry heparin: Inspect tubes to ensure that there are no air bubbles present in the sample, collection time is within 1 hour of receipt and the sample is received in the lab on crushed ice.
3. 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.
4. 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.
5. Sodium Heparin: Acceptable tests include pH, Venous; Methemoglobin, Arterial; Carboxyhemoglobin, Arterial; Carboxyhemoglobin, Whole Blood; Lactate, Whole Blood.
6. Methemoglobin, Carboxyhemoglobin, Whole Blood Lactate, and pH must be received on ice.

7. 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 Module, 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 daily 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

I. 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 patient 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 two 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 values 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

Attachment B - Radiometer ABL 800 FLEX Reagent Guide

Attachment C - Radiometer ABL 800 FLEX Solutions and Calibrators

Attachment D - Radiometer ABL FLEX Reference Ranges

Attachment E - Radiometer ABL 800 FLEX Reportable Range

Attachment F - Radiometer ABL 800 FLEX Potential Causes of Error

Attachment G - Radiometer ABL 800 FLEX Tests by Campus

Attachment H - Radiometer ABL 800 FLEX Sample Storage Stability

Approval Signatures

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