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ABL80 Flex Co-Ox OSM Total Hemoglobin and Oxyhemoglobin in Whole Blood

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform ABL80 Flex Co-Ox OSM (ABL80) instrument testing and to provide troubleshooting instructions for non-laboratory personnel.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PRINCIPLE AND CLINICAL SIGNIFICANCE:

A. Hemoglobin and oxyhemoglobin are indicative of how much oxygen is being delivered to body tissues and aid in determining cardiac output. When samples are obtained from adjacent anatomical sites, results may be used to aid in diagnosing great vessel shunts. Samples obtained during a right heart catheterization allow for monitoring an increase in oxyhemoglobin when progressing through the heart chambers (e.g., right atrium, right ventricle, and pulmonary artery). This definitive result could be an indication of shunting of the blood from the left side to the right side of the heart, possibly aiding in the diagnosis of an arterial or ventricular septal defect.

B. The ABL80 measures the total hemoglobin concentration and percent oxyhemoglobin of a whole blood sample by spectrophotometry. Blood is transported to a cuvette and warmed to

37°C. Here, it is ultrasonically hemolyzed. After a light-emitting diode (LED) light passes through the sample, the light is guided to a spectrophotometer via an optical fiber. The spectrophotometer separates the light into 138 wavelengths and converts the light signals to currents, creating an absorption spectrum. This spectrum is sent to the analyzer's computer where calculations are made to determine oximetry parameter values.

C. There are 4 different measuring principles employed in the sensors of the ABL80 analyzer.
    1. Potentiometry: The potential of a sensor chain is recorded using a voltmeter and related to the concentration of the sample using the Nernst equation.
    2. Amperometry: The magnitude of an electrical current flowing through a sensor chain is proportional to the concentration of the substance being oxidized or reduced at an electrode in the chain.
    3. Conductometry: Specific impedance of a sample as measured by 2 conducting electrodes held at a constant voltage as directly proportional to the conductive properties of that sample.
    4. Spectrophotometry: Light passes through a cuvette containing a hemolyzed blood sample. The specific wavelengths are absorbed and their intensity generates an absorption spectrum used to calculate oximetry parameters. The optical system is based on a 138-wavelength spectrophotometer with a measuring range of 467-672 nm.

III. SPECIMEN COLLECTION AND HANDLING:

Always follow established procedures for Standard Precautions/Hand Hygiene when drawing and handling a blood specimen. Hands must be washed or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control Policy before and after gloves are used. Gloves must be worn when performing patient testing and changed between patients.

A. Patient Preparation
    1. The respiratory condition of the patient should be stable. The patient should preferably be in a steady state of ventilation before and during the collection of the blood sample to avoid changes to the oxyhemoglobin result.

B. Patient Identification
    1. Patients must be identified at the bedside using two identifiers (Joint Commission). Where applicable, scan the barcode on the patient's wristband to obtain the contact serial number (CSN).
    2. Areas where patients do not have wristbands or where the wristband is not readily accessible (e.g. operating room (OR), cardiac cath lab, etc.) the patient CSN will be entered manually using the touchscreen. Verify that the CSN appears correctly on the display before proceeding with testing.

C. Specimen Labeling
    1. Testing should be performed at the patient's bedside, when possible. If the specimen is taken to another location for patient testing, the specimen must be labeled with patient name and identification (ID) number (Joint Commission).

D. Specimen Types

1. Free flowing arterial, venous, or mixed venous heparinized whole blood drawn in a plastic syringe or *safe*PICO syringe are the only acceptable specimens.
    a. Dry lithium heparin is the recommended anticoagulant.
    b. Do not use liquid heparin as it may cause dilution errors.
    c. EDTA, citrate, oxalate, and sodium fluoride collection devices are not acceptable for use.

E. Specimen Collection, Handling, Transportation, and Processing

1. Verify that the specimen collection supplies are not expired.
2. Flush arterial or indwelling venous lines by drawing at least 5-10 mL of blood and discard into a biohazard container.
    a. The amount of blood wasted varies based on the diameter and length of the line.
    b. Arterial puncture complication verification checks should be documented in the patient's chart (i.e. presense of collateral blood flow, collection site, modified Allen's test, etc.)
3. Draw at least 1.5 mL in the second syringe and cap the syringe immediately.
    a. Although the sample size required for ABL80 testing is approximately 65 µL, a minimum of 1.5 mL should be collected. Collecting less than 1.5 mL in the syringe may prevent adequate sample mixing.
4. Remove ambient air from the syringe immediately after collection and before mixing the sample.
5. The sample must be capped and mixed well.
6. Perform testing immediately after the specimen is collected.
    a. If testing is not performed at the bedside, verify that the sample is labelled with the patient's name and ID prior to transporting to the testing area.
7. Push out a couple drops of the sample onto a gauze pad prior to analysis to verify that there is no clotting in the syringe tip.

F. Specimen Storage and Disposal

1. Heparinized samples should be maintained at room temperature and assayed within 30 minutes of collection.
2. Specimens should be discarded in a biohazard container after testing is complete.
3. Specimens should not be retained for later use.

G. Specimen Acceptability Criteria

1. Room temperature (dry) heparinized specimens collected in a plastic syringe or *safe*PICO syringe.

H. Specimen Rejection Criteria

1. Non-heparinized specimens
2. Specimens with liquid heparin as the anticoagulant
3. Clotted specimens
4. Specimens contaminated with air bubbles
5. Specimens collected more than 30 minutes prior to instrument analysis
6. Unlabeled specimens not tested at the bedside

IV. REAGENTS:

A. Solution Pack - SP80 CO-OX with QC[3]

1. The solution pack contains five foil pouches. Four pouches are filled with National Institute of Standards and Technology (NIST) traceable calibration solutions. The fifth pouch collects all liquid waste, both from the internal solutions and all external solutions including the biohazardous patient blood samples.
    a. The waste pouch contains an additive which combines with the liquid waste to form a gel. This gel prevents spillage and provides an added level of safety.
    b. After use, the solution pack will contain biohazardous material. Avoid contact with the waste inlet port. Clean any spillage and dispose of the cleaning materials and solution pack in a biohazard container.
2. There are three solutions contained in the pouches of the solution pack. One is for flushing and zeroing the CO-OX. The other two contain dyes and are used as quality control (QC) solutions during the system cycle.
3. Each solution pack contains a smart chip that provides information to the system regarding the status of the solution pack. The analyzer automatically reads this information when the solution pack is installed onto the analyzer and writes additional information to the smart chip during use. This information includes the following:
    a. Serial number of the solution pack
    b. Lot number for each of the four solution pouches
    c. Install by date (the last day this solution pack can be installed onto an analyzer)
    d. Installation date (the date the solution pack was installed onto an analyzer)
    e. Analyzer serial number (the analyzer onto which this solution pack was installed)
    f. Number of allowable days in use
    g. True (calibration) values for each parameter
    h. QC assigned values and acceptable ranges for each parameter
    i. Number of cycles for each pouch

4. A solution pack cannot be exchanged with a solution pack from another instrument. Each solution pack is single-use in one instrument.
    a. Availability: Each box contains one solution pack capable of performing 600 patient tests/system operations.
        i. Dearborn: Ordered and stored by testing areas.
        ii. Farmington Hills: The Cath Lab orders and stores their own reagents.
        iii. Grosse Pointe: Point of Care (POC) orders and stores in the Microbiology Lab.
        iv. Royal Oak: Ancillary Testing orders and stores in the Ancillary Testing workroom.
        v. Trenton: The Cath Lab orders and stores their own reagents.
        vi. Troy: POC orders and stores in the Decentralized Testing office.
        vii. Wayne: The Cath Lab orders and stores their own reagents.
    b. Ingredients: Organic buffers, inorganic salts, surfactant, heparin, preservatives, and colorant
    c. Handling: The solution packs are stored at 2-25°C (36-77°F).
    d. Expiration: The solution pack may be used on the analyzer for up to 60 days (or until fully consumed) but not beyond the manufacturer's expiration date printed on the packaging and stored in the analyzer.
    e. Warnings/Precautions: For *in vitro* diagnostic use only. Dispose in a biohazard container. Avoid contact with the waste inlet port.

B. Sensor Cassette - SC80 CO-OX
    1. The sensor cassettes contain smart chips that provides information to the analyzer regarding the type and status of each sensor cassette. The analyzer automatically reads this information upon sensor cassette installation.
    2. While in use, the analyzer also records additional information on the smart chip. Information recorded in the smart chip includes:
        a. Serial number of the sensor cassette
        b. Lot number of the sensor cassette
        c. Number of tests allowed
        d. Number of tests remaining
        e. Installation date (the date the sensor cassette was first installed onto an analyzer)
        f. Analyzer serial number (the analyzer onto which the sensor cassette is currently installed)
        g. Expiration date
    3. The inlet probe introduces samples into the measuring chamber.

4. The inlet handle will raise the inlet probe to a 45° angle for syringe and ampoule samples. It also controls the automatic wiping mechanism that cleans the outer surface of the inlet probe.
5. The guide allows for guiding the placement of inlet probe into the sample.
6. The release latch allows for disengaging and removing the cassette.
7. A sensor cassette may be exchanged with a sensor cassette from another instrument for troubleshooting and/or inventory control purposes.
    a. Availability: Each box contains one solution pack capable of performing 600 patient tests/system operations.
        i. Dearborn: Ordered and stored by testing areas.
        ii. Farmington Hills: The Cath Lab orders and stores their own reagents.
        iii. Grosse Pointe: POC orders and stores in the Microbiology Lab.
        iv. Royal Oak: Ancillary Testing orders and stores in the Ancillary Testing workroom.
        v. Trenton: The Cath Lab orders and stores their own reagents.
        vi. Troy: POC orders and stores in the Decentralized Testing office.
        vii. Wayne: The Cath Lab orders and stores their own reagents.
    b. Handling: The sensor cassettes are stored at 2-25°C (36-77°F).
    c. Expiration: The sensor cassette may be used on the analyzer for up to 60 days (or until fully consumed) but not beyond the manufacturer's expiration date printed on the packaging and stored in the analyzer.
    d. Warnings/Precautions: For *in vitro* diagnostic use only. Dispose in a biohazard container. Avoid contact with the inlet probe.

C. QUALICHECK5+ Aqueous External Controls

1. Availability: The three levels of QC are packaged separately with 30 (2 mL) vials in each box.
    a. Dearborn: Testing areas order and store their own QC.
    b. Farmington Hills: The Cath Lab orders and stores their own QC.
    c. Grosse Pointe: POC orders and stores in the Microbiology Lab.
    d. Royal Oak: QC is distributed to testing areas by Ancillary Testing.
    e. Trenton: The Cath Lab orders and stores their own QC.
    f. Troy: POC orders and stores in the Decentralized Testing office.
    g. Wayne: The Cath Lab orders and stores their own QC.
2. Ingredients: Aqueous solutions containing biological buffer, salts, preservative, and dye
3. Handling: The unopened QC is stored at 2-25°C (36-77°F). Keep the vials in the

closed container (sensitive to light). QC ampoules must be conditioned for at least 5 hours at a constant temperature between 18-32°C (64-89°F) before use.

4. Expiration: The vials are stable until the manufacturer's expiration date.
5. Warnings/Precautions: For *in vitro* diagnostic use only. Avoid warming the ampoule in hands before use. Do not open the ampoules until the ABL80 displays the QC aspiration screen. QC must be analyzed immediately after opening. The QC solutions are light and heat sensitive. Avoid storage in direct sunlight. Dispose of the glass vial in a sharps container.

D. ctHb Calibration Solution

1. Availability: Each box contains four (2 mL) vials.
    a. Dearborn: Testing areas order and store the ctHb calibrator.
    b. Farmington Hills: POC orders and stores the ctHb calibrator.
    c. Grosse Pointe: POC orders and stores in the Microbiology Lab.
    d. Royal Oak: Ancillary Testing orders and stores the ctHb calibrator.
    e. Trenton: The Cath Lab orders and stores their own reagents.
    f. Troy: POC orders and stores in the Decentralized Testing office.
    g. Wayne: The Cath Lab orders and stores their own reagents.
2. Ingredients: Salts, buffer, preservatives, and a coloring agent
3. Handling: The unopened calibrator is stored at 2-25°C (36-77°F). Keep the vials in the closed container (sensitive to light). Ampoules must be conditioned for at least 5 hours at a constant temperature between 18-32°C (64-89°F) before use.
4. Expiration: The vials are stable until the manufacturer's expiration date.
5. Warnings/Precautions: For *in vitro* diagnostic use only. There are no mixing requirements. The calibrator is not affected by ambient air. Dispose of the glass vial in a sharps container.

E. VK-R5 Blood Gas Verification Kit (Linearity Kit)

1. Availability: Each box contains four (2 mL) vials of three levels of calibrators plus QUALICHECK5+ level 3 QC.
    a. Dearborn: Testing areas order and store the linearity kit.
    b. Farmington Hills: POC orders and stores the linearity kit.
    c. Grosse Pointe: POC orders and stores in the Microbiology Lab.
    d. Royal Oak: Ancillary Testing orders and stores the linearity kit.
    e. Trenton: The Cath Lab orders and stores their own reagents.
    f. Troy: POC orders and stores in the Decentralized Testing office.
    g. Wayne: The Cath Lab orders and stores their own reagents.
2. Ingredients: Aqueous solutions containing a biological buffer, salts, and preservative. They are equilibrated with carbon dioxide and oxygen.

3. Handling: The unopened vials are refrigerated at 2-8°C (36-46°F). The vials must be allowed to warm to room temperature and remain at a constant temperature between 18-32°C (64-89°F) overnight before use.
4. Expiration: The vials are stable until the manufacturer's expiration date when stored properly.
5. Warnings/Precautions: For *in vitro* diagnostic use only. Avoid warming the ampoule in hands before use. Hold the vials in hand by the ends. Mix samples by shaking vigorously for 15 seconds. Dispose of the glass vial in a sharps container.

V. EQUIPMENT AND SUPPLIES:

A. ABL80 Instrument
B. ABL80 Power Cord
C. Thermal Printer Paper
D. Gloves
E. Specimen Collection Supplies
F. Protective Sleeve or Gauze (for breaking glass ampoules)
G. Gauze (for maintenance)
H. Biohazard Receptacle
I. Sharps Container
J. Water (for maintenance)
K. Hospital-Approved Wipes

VI. HEMOGLOBIN CALIBRATION:

A. A ctHb (hemoglobin) calibration is performed every 90 days using the ctHb calibration solution to maintain the accuracy of the optical system (cuvette factor and wavelength).
    1. Navigate to "Menu" > "Utilities" > "Hb Calibration".
    2. Press the "Scan" button and scan the Hb calibration barcode for the ABL80 analyzer, located on the S7770 package insert.
    3. The system will perform a blank calibration then prompt the user to aspirate the calibration solution.
    4. Mix the ampoule by gently inverting several times.
    5. Open one ampoule of ctHb Calibration Solution.
    6. Raise the sample inlet probe and guide the probe fully into the ampoule solution, confirming that the tip is fully immersed in the solution.
    7. Press "Aspirate"  .
    8. When aspiration is complete, two short beeps will be heard.
    9. Remove the ampoule and lower the inlet probe.

10. Once analysis is complete, the analyzer will display results.
11. The screen displays a value for the cuvette factor (Fcuv). The cuvette factor expresses the ratio of the effective light path of the analyzer cuvette to that of a reference cuvette determined by Radiometer.
    a. The Fcuv acceptable range is 0.80-1.20.
12. Following a successful Hb calibration, the system will automatically initiate a system cycle.
13. If the calibration fails, repeat the steps above.
14. If the calibration fails a second time, remove the instrument from use and contact Radiometer Technical Support for assistance at 800-736-0601.

VII. CALIBRATION VERIFICATION/LINEARITY:

A. Calibration verification is the process of assaying calibration/linearity materials to confirm that the calibration of the analyzer has remained stable throughout the reportable range for all measured parameters (analytical measurement range (AMR)). This will be performed twice per year (approximately every six months) using vendor-supplied linearity samples. Calibration verification is also performed for the initial analyzer set up, as needed for troubleshooting, when QC begins to reflect an unusual trend or is consistently out-of-range, and after major analyzer repair or major analyzer maintenance. QUALICHEK 5+ materials are NIST traceable with assayed ranges for Radiometer analyzers. Acceptable linearity recovery is based upon measured values falling within the assayed parameters' high and low limits.

1. Navigate to the manual QC ranges setup screen to modify the settings in preparation for testing. Select "Menu" > "Settings" > "Manual QC" > "Ranges".
2. Remove (and leave blank) the current lot numbers entered in the QC ranges setup screen. Verify that the standard solution ID's (S7730, S7740, S7750) remain in place. Performing this step confirms that these Range+ QUALICHEK results are not included in the daily QC statistics.
3. Set the default temperature to 25°C.
4. Press "OK" to save changes.
5. Run the material in the order of level 1, level 2, level 3 for optimal performance.
    a. Note: The additional vials of QC5+ level 3 included in this kit are not required for the ABL80.
6. Run each level of VK-R5 a minimum of three times (using a new ampoule for each measurement). This will allow for the coefficient of variation (CV) and repeatability calculations to be performed.
7. Upon completion of testing the VK-R5 samples, scan the QC insert sheet and review the individual QC ranges.
    a. If results fall outside of manufacturer assayed ranges, remove the instrument from use and contact Radiometer Technical Support for assistance at 800-736-0601.

8. Submit the results to the Technical Director, Medical Director, or designee for review.

VIII. MAINTENANCE:

A. The ABL80 is self-monitoring. It automatically monitors internal circuitry and reports problems on the display screen. Routine maintenance involves cleaning and changing the solution pack, sensor cassette, printer paper, and database management.

B. The instrument will provide videos to demonstrate most procedures below.

1. Cleaning and Disinfection
    a. The ABL80 should be kept clean of blood and other liquids.
    b. Clean the casing with a hospital-approved disinfectant wipe if it becomes contaminated with blood.
    c. Clean the screen with an alcohol-based cleaner (e.g. 70% isopropyl alcohol) followed by a water dampened cloth.
        i. Do not apply liquids directly to the screen. Do not use bleach. Never allow moisture to settle at the bottom of the screen.

2. Replacing Solution Pack
    a. The solution pack must be changed every 60 days or when the reagents are exhausted.
    b. If both the solution pack and sensor cassette need to be changed at the same time, change the solution pack first, then change the sensor cassette. The instrument will perform a rinse after the installation of the sensor cassette.
    c. Select the solution pack icon from the main screen.

    d. Follow the instructions on the screen to remove the existing solution pack.
        i. Never open the solution pack door unless instructed to do so by the system. Opening the door at an inappropriate time may corrupt the information stored on the smart chip of the solution pack, rendering the solution pack unusable.
    e. Press down on the door latch. The screen will advance when the door is lowered.
    f. Lower the door completely to release the pack.
    g. Remove and discard the solution pack into a biohazard waste container.
    h. Clean and dry the manifold and lures with a damp, lint-free cloth.
    i. Press "Continue".
    j. Remove the new solution pack from the packaging. Remove the foil tape from the back of the new solution pack.
    k. Slide the solution pack fully into the solution pack cavity of the instrument.

l. Raise the door and press near the top of the latch until a snap is heard. Wait for the hourglass to stop spinning on the analyzer screen.

m. Press "OK" to complete the installation and initiate an automatic solution pack verification. This check verifies the integrity of the new solution pack.

n. Assay the three levels of external QC.

3. Replacing Sensor Cassette

    a. The sensor cassette must be changed every 60 days or when the tests are exhausted.

    b. Select the sensor cassette icon from the main screen.

    

    c. When prompted, remove the existing sensor cassette by pushing up on the black latch at the bottom of the cassette. Grasp the cassette body and firmly pull the cassette straight out from the instrument.

    d. Clean the sensor cassette nest and waste port with a clean, lint-free cloth moistened with water.

        i. Never wipe the sensor cassette pins or analyzer pin with a damp cloth.

    e. Tear open the foil pouch on the new sensor cassette and remove the cassette.

    f. Press "Continue".

    g. Align the cassette to the front of the analyzer and push the cassette straight on the analyzer.

    h. If the sensor cassette is not installed promptly within two minutes, the screen reverts back to the home screen.

    i. Press firmly on the indented circle on the sensor cassette body until a snap is heard.

    j. Confirm that the inlet probe is completely lowered.

    k. Press "OK" to start the sensor cassette initialization phase.

    l. Assay the three levels of external QC.

4. Installing Printer Paper

    a. Press the release latch to disengage the printer cover.

    b. Slide the clamshell cover back to expose the paper roll compartment.

    c. Remove any existing roll of paper.

    d. Place the new roll of paper inside the compartment with the free end of the paper coming forward off the roll from the bottom. Make sure the free end of the paper extends beyond the lip of the printer cover.

    e. Slide the clamshell cover forward and press down on the cover over the

raised lines. Installation is complete when the cover snaps into place, securing the paper.

5. Data Maintenance
    a. The event log stores the chronological record of all events including installations, system cycles, system checks, manual QC results, parameter inactivation/reactivation, and out-of-range patient sample results. It also records the user and status of each record. Logs are downloaded monthly or when a message appears on the ABL80 that a log is full.
    b. Insert a removable storage device in the port on the back of the instrument.
    c. Press "Menu" > "Data" > "Download".
    d. Select the file to download.
    e. Check the box to delete the records after the download is complete.
    f. Press "Close" when the download is complete.
    g. Remove the storage device.
    h. Download the data to a computer.
        i. The files may be deleted off the computer if Aqure software is utilized, as Aqure stores this data.

IX. NEW LOT VALIDATION (POC USE ONLY):

A. New lots of sensor cassettes and solution packs must be validated on at least one instrument.
B. Result differences between lot numbers must be within the limits posted on the ABL80 New Lot Number Validation form.
C. Open the Radiometer Aqure software.
D. Navigate to "Device Center" > "Hospital Choice" > "Department Choice".
E. Select an instrument and press "Show Data From" and search back to two months from the received date of the reagent.
F. Press "Device Messages" and de-select the red critical and the yellow attention boxes.
G. Hover the cursor over the blue diamond on the right of the page. Look for either the sensor cassette or solution pack and the lot number desired.
    1. Make note of the date.
H. Continue to the left and look for the previous lot of reagent.
    1. Make note of the date and lot number.
I. Open the Telcor QML software.
J. Navigate to "Results" > "Repository" > "Aqueous QC" > "Result Date" (date of reagent installation).
K. Select the "Disposable Code" (ABL80) > "OK".

L. Click on the "Device" to sort the results.

M. Find the liquid QC result.

N. Document the operator and results on the ABL80 New Lot Number Validation form.

O. Filter the results by the date of the previous reagent installation.

P. Press "OK" > click on the "Device" to sort the results.

Q. Find the liquid QC and document the results on the form.

X. QUALITY CONTROL (QC):

A. Quality management confirms the reliability, accuracy, and precision of patient results. This is accomplished on the ABL80 via system checks, internal QC, and external QC.

1. Internal (Automatic) QC

    a. Every 30 minutes the ABL80 performs a system check to verify that the fluidic pathway is free of blockages. The heat circuitry and air detection system is activated. It also verifies proper electronic communications between internal analyzer boards. Also, a drift evaluation is performed automatically.

        i. If the system check fails, the analyzer will automatically initiate a sensor cassette flush and repeat the measurements. If repeat measurements fail, the analyzer will initiate a system cycle to fully evaluate the measurement system.

    b. The ABL80 performs a blank calibration every 12 hours. This calibration uses the clear solution from the solution pack to zero the oximeter.

    c. The ABL80 performs two levels of automatic QC measurements with each system cycle every 24 hours. The results are automatically assessed for each analyte and any out-of-range results are flagged. Results for out-of-range analytes will not be reported until the QC is within the acceptable range. This is accomplished by the automatic instrument lock-out system.

    d. With every patient sample analysis, a system check with a one-point calibration is performed. This process is termed an analysis check. During analysis, the blood sample is aspirated into the analyzer and sensor measurements are recorded. The sample is then flushed with solution one (from the solution pack) and measurements of this solution are recorded. The measurement results from both the sample and the flush (the one-point calibration) are used to determine the final blood sample results. This verifies compensation for any sensor drift with each sample analysis.

2. External (Liquid) QC

    a. The QUALICHECK 5+ levels 1, 2, and 3 are run at the following intervals by an instrument operator:

        i. Once every 30 days

        ii. When a new solution pack is installed

iii. When a new sensor cassette is installed
iv. After a software upgrade is installed
v. After troubleshooting or preventative maintenance that may alter instrument performance
vi. Whenever the performance of the instrument is in question

b. Entering New QC Lot Ranges
i. Press "Menu" > "Settings" > "Manual QC" > "Ranges".
ii. Either scan the appropriate barcode from the package insert or manually type in the lot, expiration, and ranges from the package insert.
iii. Verify the ranges and expiration date match the data in the package insert.
iv. Press "OK" to store the data.
v. When all entries are complete, press "OK".
vi. Repeat for the remaining levels of QC.

c. Store the QC ampoules for at least 5 hours at a constant temperature between 18-32°C prior to use.
d. Do not open the QC ampoules until prompted by the analyzer.
e. Press "Menu" > "Manual QC" > select the level of QC to be performed.
i. Do not select level 4. Doing so will render the instrument inoperable. Contact the site-specific POC department from the Troubleshooting section below if level 4 QC is selected.

f. Hold the ampoule between the thumb and index finger and shake vigorously for at least 15 seconds.
g. Tap the top of the ampoule until all the solution collects at the bottom.
h. When prompted, raise the inlet probe to the first position (45° angle).
i. Use gauze to protect hands and break off the ampoule neck. Use the QC ampoule immediately after opening.
j. Guide the inlet probe into the ampoule.
k. Verify that the tip of the inlet probe is fully immersed in the QC solution.
l. Press "Aspirate" .
m. Remove the QC ampoule when sample aspiration is complete, as indicated on the screen, and discard in a sharps container.
i. Use each ampoule for one measurement only.

n. Lower the inlet probe.
o. The results will appear on the screen after about 90 seconds. Review each parameter to confirm the results fall within the expected range. An out-of-

range QC result is indicated by marking the result with ↑ or ↓ to the left of the value. The instrument will lock-out patient testing until all QC is within acceptable ranges. See the QC Failure Procedure section below for more information.

p. If the instrument is interfaced, the results will automatically transmit to the POC software. For instruments without an interface, the operator must record the QC results on the ABL80 External QC Log.

3. Calibration
    a. The ABL80 automatically performs a two-point calibration during each system cycle. A system cycle is performed automatically every 24 hours. If the calibration fails, the system will not allow the user to perform sample analysis.
    b. A one-point calibration is automatically performed by the analyzer with each patient test.
    c. A blank calibration is performed every 12 hours using the clear solution from the solution pack. This zeros the oximeter.
4. QC Failure Procedure
    a. If the internal QC or calibration is out-of-range, repeat the process by manually selecting the appropriate function.
    b. If the external QC is out-of-range, perform the following steps.
        i. Confirm that the lot number of QC used matches the lot number stored in the ABL80.
        ii. Verify that all storage and handling criteria have been met for the QC solutions.
        iii. Initiate a manual system cycle from the main menu.
        iv. Repeat the failed level(s) of QC material using a fresh ampoule.
    c. If the repeat does not fall within the expected range, remove the instrument from use and, follow the site-specific instructions below for assistance.
        i. Dearborn: Dearborn: Call POC at 313-436-2367, 313-593-7970, or 313-982-5839.
        ii. Farmington Hills: Call the POC/Quality Lead MT at 947-521-7167.
        iii. Grosse Pointe: Call POC at 313-473-1831.
        iv. Royal Oak: Call Ancillary Testing at 248-898-8012.
        v. Trenton: Call the Trenton Lab Manager at 734-671-3859.
        vi. Troy: Call Decentralized Testing at 248-964-8009.
        vii. Wayne: Call the Wayne Lab Manager at 734-467-4233.

XI. INSTRUMENT COMPARISONS:

A. Instrument comparisons are performed twice per year (approximately every six months) to verify that the hemoglobin and oxyhemoglobin results correlate with the main laboratory instrumentation. Heparinized blood gas samples or stabilized comparison samples (e.g., College of American Pathologists (CAP) Quality Cross Check) are tested on both the ABL80 and the blood gas analyzer/co-oximeter in the main laboratory. See the Point of Care Testing Policy for more information.

B. Instrument comparisons are also performed for the initial analyzer set up, as needed for troubleshooting, and after major analyzer repair.

1. Mix the sample by rolling between the palms of the hands several times.
2. Analyze the specimen on the reference analyzer following the same procedure used for patient testing.
3. Assay the sample on the ABL80 in the same manner that is used for patient testing immediately after analyzing on the reference analyzer.
4. Record the results on the ABL80 Instrument Comparison Log (attachment).
5. Calculate the difference between the reference analyzer and each ABL80 instrument for each sample, using the equation on the instrument comparison form.
6. The POC Manager, Supervisor, or designee will review the comparison data. Differences should not exceed +/- 4% or +/-0.5 g/dL for hemoglobin and +/- 3% for oxyhemoglobin. If results fall outside of these acceptability criteria, remove the instrument from use, and submit the results to the Technical Director or Medical Director for review.

XII. PROCEDURE:

Note: Some of the instrument prompts may not appear based on the site-specific instrument configuration.

A. Analyzer Status

1. Check the top section of the main screen and resolve any issues before proceeding to testing.
    a. Status Bar: Describes the current task in progress or status (ready or locked).
    b. Count: Displays the number of remaining tests.
    c. Traffic Light Icon: Displays analyzer status. Errors must be resolved prior to progressing to patient testing.

	Green Light: The analyzer is ready for sample analysis.
	Yellow Light: Error(s) occurred during the last calibration or QC and/or scheduled reminder(s).

	Red Light: Critical Message(s). Analyzer is unavailable due to an error or the parameter(s) are suppressed.

2. Log into the instrument by pressing the "Menu" button then the key login icon.
    a. Note: Prior to running proficiency testing samples, contact the site-specific POC department to assist with changing the instrument settings.
3. Press the "Scan" button and hold employee ID badge barcode under the scanner window (do not press "OK"). The operator may also log in by manually typing the employee ID then pressing "OK".
4. Run the patient specimen immediately after collection. Place a cap on the syringe and thoroughly mix the sample by gently inverting the syringe several times, then, roll it between the palms of the hands repeatedly for 15 seconds prior to sample analysis. This step is critical for accurate hemoglobin values.
5. Select the "Analysis" blood drop icon from the main screen. 

6. Select the parameter panel then select the sample type from the drop-down menu.
7. Trenton and Wayne: Select the gender to allow the analyzer to print-out gender-related flags.
8. When prompted, gently slide the handle of the inlet probe to the first position.
9. Guide the inlet probe into the sample. Verify the tip of the inlet probe is fully immersed in the sample. Do not press the tip of the probe against the plunger. This may produce an airtight seal and prevent sample aspiration.
10. Touch "Aspirate" within 20 seconds of raising the inlet probe.
11. The analyzer will make an audible beep when aspiration is complete.
12. Follow the instructions on the screen to remove the sample and lower the inlet probe.
13. Touch "Patient ID" to enter the CSN.
14. Touch "VIEW LIST".
15. Touch "QUERY". This will allow the analyzer to query the laboratory information system (LIS) to obtain positive patient identification (PPID). The first and last name will populate on the analyzer.
16. Cath Lab, Taylor, Wayne: Choose a sample site from the drop-down menu.

Panel Name	Cardiac Panel	Arterial Panel	Venous Panel	Mixed Venous Panel
Sample Type	Other Fluids	Arterial	Venous	Mixed Venous
Sample Site	Inferior Vena Cava (IVC) Superior Vena Cava	Not Indicated	Not Indicated	Not Indicated

	(SVC) Right Atrium (RA) Left Atrium (LA) Right Ventricle (RV) Left Ventricle (LV) Pulmonary Artery (PA) Pulmonary Vein (PV) Arterial PA Wedge			

17. Press "Next" then "OK".
18. A progress bar will be displayed until the analysis is completed (approximately 30 seconds). The results will display when analysis is complete.

XIII. INTERPRETATION OF RESULTS:

A. Interpretation of Flagged Results

Flag	Definition
 or	The result is outside the reference range but not beyond the critical limits. The result is highlighted in yellow on the screen.
 or	The result is beyond the critical limits. The result is highlighted in red on the screen.
DO NOT REPORT RESULTS WITH ANY OF THE FOLLOWING FLAGS	
 or	The result is outside the test range of the analyzer. The result is highlighted in red on the screen.
R/R or *	The result is outside the reportable range.
***	The result is outside the measuring range of the analyzer.
###	The result is beyond the electrical range of the analyzer.
!!	Air was identified in either the sample or the flush during analysis.
?	One or more errors have been identified related to the oximetry results.
¿	The last external QC sampled run on this parameter was outside the acceptable range.

B. Unexpected Values

1. As with all diagnostic tests, results should be scrutinized in light of a patient's specific condition. Possible causes for pre-analytic errors include clots, air bubbles, improper or lack of mixing, heparin interference, heparin dilution, hemolysis, and delay in testing are factors that will cause erroneous results. Results that are

questionable or not consistent with the patient's clinical status should be repeated or supplemented with additional test data or a specimen should be sent to the main laboratory for analysis.

XIV. RESULT REPORTING:

A. The ABL80 is capable of printing results. If the device is not configured to automatically print results, a print-out may be obtained by pressing the printer icon on the lower left of the result screen.

B. Interfaced instruments will automatically send results to the patient's electronic health record (EHR).

    1. Contact the site-specific POC department to have a result removed from the patient's EHR.

C. Instruments that are not connected to an interface will have the results documented, by the operator, on the Point of Care Result Form for Non-Interfaced Instruments. The results will be entered into the LIS by POC staff or a designee or the results will be entered into the Epic chart notes.

XV. EXPECTED VALUES:

A. Total Hemoglobin (ctHb):

    1. Male: 13.5-17.0 g/dL
    2. Female: 12.1-15.0 g/dL

B. Oxyhemoglobin (FO_2Hb):

    1. Arterial: 95-98%
    2. Venous: 55-85%
    3. Mixed Venous: 60-80%

C. The expected values listed above are for an adult patient population. The ABL80s are only located in areas serving adult patients.

XVI. REPORTABLE RANGE:

A. Total Hemoglobin (ctHb): 4.0-25.0 g/dL

B. Oxyhemoglobin (FO_2Hb): 0-100%

XVII. CRITICAL VALUES:

A. Total Hemoglobin (ctHb): <7.0 g/dL and >20.0 g/dL

B. Oxyhemoglobin (FO_2Hb) (Arterial Samples): <85%

C. The critical values listed above are for an adult patient population. The ABL80s are only located in areas serving adult patients.

D. Follow the institutional policy for critical result reporting and documentation.

XVIII. RESULT REVIEW:

A. Select "Data Logs" from the top of the main screen.

B. Select "Patient Log".

C. Highlight the desired record the press the "Patient" button on the bottom of the screen to view the detailed information for that record.

XIX. SYSTEM DOWNTIME:

A. If results are not downloading to the EHR because one of the interfaces is down, continue testing and entering the required information (operator ID, patient ID, sample type, etc.) into the analyzer.

B. Results may be obtained from the printout or by following the steps in the Result Review section above.

C. Results will automatically transmit to the EHR when the system becomes available.

D. Contact the site-specific POC department if further assistance is needed.

XX. LIMITATIONS

A. The validity of test results from this instrument must be carefully examined by a clinician and related to the patient's clinical condition before any clinical decision is taken on the basis of the test results.

B. Analyzer operating environment: 12-28°C (54-82°F), sea level to 2290 meters (7513 feet), 100% non-condensing

C. Analyzer record retention: Up to 500 patient tests, 500 system cycle results, 500 2-point calibration results, 500 manual QC results, 1500 events, and 1500 security recores

XXI. INTERFERING SUBSTANCES:

A. The presence of fetal hemoglobin (Hemoglobin F) in a sample will interfere with the result of total hemoglobin and oxygen saturation in adults with thalessemia.

B. Blood pH levels of 6.85 will decrease oxygen saturation by approximately 1.1%.

C. Fluorescein dye at a concentration of 250 mg/L will decrease oxygen saturation by approximately 3.2% and will increase hemoglobin by approximately 1.3 g/dL.

D. Methylene Blue dye at a concentration of 30 mg/L will increase oxygen saturation by approximately 2.7% and decrease hemoglobin by approximately 1.6 g/dL.

E. Methylene Blue due at a concentration of 60 mg/L will increase oxygen saturation by approximately 4.2% and decrease hemoglobin by approximately 3.0 g/dL.

F. Cyanmethemoglobin (HiCN) at a concentration of 30% will decrease oxygen saturation by approximately 13.9% and increase hemoglobin by approximately 1.7 g/dL.

G. Hemoglobin S at a concentration of 20% will decrease hemoglobin by approximately 2.1 g/dL.

H. Hemoglobin S at a concentration of 50% will decrease hemoglobin by approximately 4.5 g/dL.

I. High turbidity from food and lipid therapy may affect oximetry results.

J.

Substance	Level	Hemoglobin	Oxyhemoglobin
Limit for Clinical Relevance		**>0.5**	**>1.0**
pH	6.85 7.15 8.00	<0.5 <0.5 <0.5	**-2.5** -1.0 **-1.1**
Fluorescein	250 mg/L	**1.3**	**-9.5**
Beta-carotene	3.7 µmol/L	<0.5	<1.0
Patent Blue V	10 mg/L	<0.5	**1.5**
Methylene Blue	10 mg/L 30 mg/L 60 mg/L	<0.5 **-1.6** **-3.0**	**3.7** **13.7** **27.8**
Cardio Green	7 mg/L 30 mg/L	<0.5 <0.5	<1.0 **1.6**
Evans Blue	5 mg/L	<0.5	<1.0
Intralipid	2% 5%	<0.5 <0.5	<1.0 **-1.4**
HiCN	30%	**1.74**	**6.6**
SHb	20% 50%	**-2.1** **-4.5**	<1.0 <1.0
Bilirubin (unconjugated)	342 µmol/L	<0.5	<1.0
Bilirubin (conjugated)	342 µmol/L	<0.5	<1.0

XXII. TROUBLESHOOTING:

A. Battery Maintenance

1. The ABL80 can remain in an idle state for about one hour with a fully charged battery. The battery charge level is indicated by a percentage and warns, with a red icon, when the battery charge is less than 13%.
2. A depleted battery will require about 80 minutes to fully recharge.
3. Review the battery status on the bottom bar of the main screen. This will also inform the operator if the device is plugged in or if it is utilizing battery power.

B. Interface Connectivity

1. Review the connectivity status on the bottom bar of the main screen.
2. Two blue icons should be present. If only one icon is visible, contact the site-specific

POC department.

C. System Cycle

1. The ABL80 may prompt the operator to perform a System Cycle. This is also useful for troubleshooting out-of-range QC values.
2. Perform a System Cycle by pressing "Menu" > "Manual System Cycle".

D. Rinse

1. A rinse flushes additional solution through the sensor cassette.
2. Press the "Rinse" button to initiate a single flush of solution 1.
3. Repeat as necessary.

E. Powering Down ABL80/Emergency Shut-down

1. Press "Menu" then select "Shutdown".
2. A pop up box will appear and ask the operator to confirm the intent to power down the ABL80.
3. Press "Yes".
    a. The analyzer must always be powered down through the software application. Pressing the on/off switch on the back of the analyzer while the software is running may result in file corruption.

F. Powering Up ABL80

1. Verify that the power cord is plugged into the power cord socket at the rear of the analyzer.
2. Verify that the three-pronged plug is connected to a wall outlet.
3. Press and hold the upper half of the power switch at the rear of the analyzer for at least 3 seconds.
    a. An audible click along with a flickering green light below the power switch signifies that the power has been restored.
4. Release the power switch and allow the analyzer operating system and application software to load. This process will take about 3 minutes.

G. Level 4 QC Remedy (POC Staff Only)

1. If level 4 QC is selected during QC performance, the FO_2Hb icon will appear yellow and render the ABL80 inoperable until a successful level 4 QC is performed. Since there is no level 4 QC, the ABL80 QC must be manipulated in its settings in order to allow an operator to proceed with QC and patient testing.
    a. Press "Menu" > "Settings" > "Manual QC" > "Ranges".
    b. Under level 4 solution ID select "SS7760" > "OK".
    c. Rerun any QC level.
    d. A pop-up box will appear that says the manual QC auto detection failed. Select "Level 4" > "OK" > "Close".

e. The traffic light and FO_2Hb icons will now be green.

f. Press "Menu" > "Settings" > "Manual QC" > "OK".

g. Under the level 4 solution ID select "Other" > "OK".

h. Verify all levels of external liquid QC are performed and within the expected ranges.

H. Printing Failure Report

1. A failure report allows the user to locate failed event records (calibration and QC) for consumables (sensor cassettes and solution packs) replaced in the past 3 months. This report is required when requesting a reimbursement from Radiometer for consumables.

    a. Select "Menu" > "Data" > "Failure Report" > select the appropriate event > "Print".

    b. Attach the print-out to the customer credit form provided by Radiometer and follow the submission instructions on the form.

I.

Error	Message	Interpretation	Corrective Action
1100	Solution pack is not installed	The solution pack present in the analyzer has never been successfully installed.	Install the solution pack. See the Maintence section above.
1102	The solution pack was installed on another analyzer. It cannot be used on this analyzer.	A solution pack cannot be installed into more than one analyzer.	Install a new solution pack.
1200	Sensor cassette is not connected	The sensor cassette smart chip was not dientified by the analyzer, indicating the sensor cassette is not connected to the analyzer.	Verify the cassette is fully seated onto the analyzer. Press in the center of the cassette until a snap is heard. if the problem persists, replace the sensor cassette. If the problem persists after replacing the sensor cassette, contact the site-specific POC department.
1202	Sample inlet flap is open	The sample inlet flap is not completely lowered.	Lower the inlet completely. If the problem persists, replace the sensor cassette. If the problem persists after replacing the sensor cassette, contact the site-specific POC department.

1204	Sensor cassette is not intitialized	The attached sensor cassette has not successfully competed an installation procedure.	Install the sensor cassette. See the Maintenance section above.
1214	Aspiration timed out because it did not complete within required time period.	During the aspiration of a sample the inlet probe was never lowered to allow sample analysis to proceed.	Lower the inlet. Re-analyze the sample, confirming the inlet is lowered at the appropriate time.
2106	Possible fluid pathway blockage	A possible blockage has been identified in the fluidic system during a system cycle or installation procedure.	Contact the site-specific POC department to notify Radiometer.

J. Contacting POC

1. If basic troubleshooting steps do not resolve the problem, follow the site-specific instructions below for further assistance. A loaner instrument may be available.
    a. Dearborn: Dearborn: Call POC at 313-436-2367, 313-593-7970, or 313-982-5839.
    b. Farmington Hills: Call the POC/Quality Lead MT at 947-521-7167.
    c. Grosse Pointe: Call POC at 313-473-1831.
    d. Royal Oak: Call Ancillary Testing at 248-898-8012.
    e. Trenton: Call the Trenton Lab Manager at 734-671-3859.
    f. Troy: Call Decentralized Testing at 248-964-8009.
    g. Wayne: Call the Wayne Lab Manager at 734-467-4233.

XXIII. REFERENCES:

A. Point of Care Testing Approval Process

B. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.

C. ABL80 FLEX Reference Manual, Radiometer America Inc., 250 S. Kraemer Blvd., Brea, CA 92821, revision 201601 2016 https://www.radiometeramerica.com/

D. ABL80 FLEX Operator's Manual, Radiometer America Inc., 250 S. Kraemer Blvd., Brea, CA 92821, revision 201601 2016 https://www.radiometeramerica.com/

Attachments

ABL80 External QC Log.pdf

ABL80 Instrument Comparison.pdf

ABL80 New Lot Number Validation.pdf

ABL80 Reagent Loading Reference Guide.pdf

ABL80 Specimen Collection Guide.pdf

ABL80 Training and Competency Assessment.pdf

ABL80 Training Guide.pdf

ABL80 Troubleshooting Blockage Guide.pdf

b64_81bbb1e2-07ef-4e76-a0c1-b9886f62d6f4

Green.png

POC Result Form for Non-Interfaced Instruments.pdf

Red.png

Yellow.png

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	11/2/2023
CLIA Medical Directors	Muhammad Arshad: Chief, Pathology	10/31/2023
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	10/27/2023
CLIA Medical Directors	John Pui: Chief, Pathology	10/27/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	10/27/2023
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	10/26/2023
POC System Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	9/25/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	9/20/2023
	Jessica Czinder: Mgr, Division Laboratory	9/20/2023

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Trenton, Troy, Wayne