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ABL90 FLEX PLUS Blood Gases and Electrolytes in Whole Blood

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform ABL90 FLEX PLUS (ABL90) testing and to provide quality control (QC) and troubleshooting instructions for non-laboratory personnel.

B. The ABL90 is a portable, automated analyzer that requires heparinized whole blood to measure pH, blood gases, oximetry parameters, electrolytes, glucose, and lactate. Heparinized capillary blood is required to measure neonatal bilirubin on configured analyzers. Analysis time is approximately 35 seconds.

C. 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. The ABL90 may be used for the purpose of monitoring, diagnosis, and treatment of patients in approved testing areas. The ABL90 aids in assessing the status of acid-base balance, oximetry, respiratory oxygenation, electrolytes, and metabolites.

1. pH: Key measure of acid-base status of a patient. It is an indicator of the balance between the blood, kidneys, and lungs.
2. pCO_2 (partial pressure of carbon dioxide): Used to assess how well the body eliminates carbon dioxide from the blood.
3. pO_2 (oxygen concentration): Used to assess how well the body is able to absorb oxygen in the lungs in arterial samples.

4. Glucose: Used in the diagnosis and management of disorders of carbohydrate metabolism; these include diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia.
5. Sodium (Na+): Used in the diagnosis and monitoring of disturbances of water balance, infusion therapies, vomiting, diarrhea, burns, heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances, and primary or secondary adrenal cortex insufficiency, or other diseases involving electrolyte imbalances.
6. Potassium (K+): Used to monitor electrolyte imbalance and aid in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, therapy with diuretics, kidney problems, diarrhea, hyper- and hypo- function of adrenal cortex, and other diseases involving electrolyte imbalance.
7. Chloride (Cl-): Used to monitor electrolyte and water balance.
8. Ionized Calcium (Ca++): Used to diagnose or monitor hypertension, malnutrition, parathyroidism, renal disease, kidney stones, multiple myeloma, and diabetes mellitus.
9. (Calculated) Total Hemoglobin (ctHb): Used to screen for disease associated with anemia, to follow the response to treatment for anemia, determine the severity of anemia, and to evaluate polycythemia.
10. Lactic Acid (Lactate): Values are elevated during septic shock, shock, or tissue hypo-perfusion.
11. Carboxyhemoglobin (FCOHb): Values are elevated in cases of carbon monoxide or methylene chloride poisoning.
12. Methemoglobin (FMetHb): Values are increased in cases of congenital or acquired methemoglobinemia.
13. Oxyhemoglobin (FO_2Hb): Values are indicative of how much oxygen is being carried in the blood and aids in determining cardiac output.
14. Bilirubin (ctBil): Aids in assessing the risk of kernicterus in neonates (under 28 days old).

B. The ABL90 uses thick film sensor technology contained in a multi-use disposable cassette. The cassette is composed of layers of ceramic slabs, microelectrodes, and membranes. Electrical signals are measured via sensors located on the cassette sensor boards. Four different measuring principles are employed:
    1. Potentiometry: A voltmeter records the potential of a sensor chain and relates to the concentration of the sample. This principle is applied to the pH, pCO_2, K+, Na+, Ca++, and Cl- sensors.
    2. Amperometry: Measures the magnitude of an electrical current and is proportional to the concentration of the substance being oxidized or reduced. This principle is applied to the glucose and lactate sensors.
    3. Optical pO_2: Phosphorescent dye is used to measure the ability of oxygen to reduce the phosphorescence intensity and is applied to the pO_2 sensor.

4. Spectrophotometry: At specific wavelengths, light absorption is measured and used to calculate oximetry parameters. This principle is used for measuring ctHb, ctBil, sO_2 (oxygen saturation), FO_2Hb, FCOHb, FHHb (fractional deoxyhemoglobin), FMetHb, and FHbF (fractionated hemoglobin F).

C. A solution pack is used for calibrations including quality control (QC) and rinse procedures as well as collection of waste fluids. The pack contains 8 foil pouches:
    1. 3 with calibration solutions
    2. 1 with a gas mixture
    3. 3 with QC solutions
    4. 1 for waste

D. The ABL90 is a closed system with sensors to compensate for barometric pressure. The ABL90 will will lock-out the operator from patient testing in the event of barometric pressure sensor failure.

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.

Note: The Wayne Special Pathogens Lab (SPL) may have additional requirements. See the current Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing document provided by the Centers for Disease Control and Prevention (CDC). Only employees with the appropriate personal protective equipment (PPE) donning and doffing training should participate in SPL testing.

A. Patient Preparation
    1. The collection site should be warmed prior to collection for capillary samples. See the capillary section below.
    2. Warming of the collection site is not required for arterial and venous samples.

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)) 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 the patient name and identification (ID) number (Joint Commission).

D. Specimen Types

1. Arterial, capillary, and venous heparinized whole blood 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. Sodium heparin should not be used when measuring sodium.
    d. Use only heparin salts as anticoagulants. Electrolyte-balanced heparin syringes are acceptable.

E. Specimen Collection, Handling, Transportation, and Processing

1. Verify that the specimen collection supplies are not expired.
2. Collect the sample according to the blood drawing policy.
    a. Arterial and venous specimens
        i. Arterial specimens are obtained from an arterial line or from a cardiopulmonary bypass pump.
            a. Arterial puncture complication verification checks should be documented in the patient's chart (i.e. presence of collateral blood flow, collection site, Modified Allen's test, etc.).
        ii. Flush indwelling arterial or venous lines according to clinical protocols to obtain an uncontaminated representative sample. This process minimizes the chance of specimen contamination with intravenous solutions.
        iii. Obtain 1 mL of blood in a *safe*PICO syringe.
            a. *safe*PICO syringes must be utilized with the ABL90s. Other syringes contain silicone, which can enter the analyzer and cause technical issues (e.g. consumable failures).
            b. Although the sample size required for ABL90 testing is approximately 65 µL, a minimum of 1.5 mL should be collected. Using a syringe with a volume less than 1.5 mL may inhibit adequate sample mixing.
        iv. Remove ambient air from the syringe immediately after collection and before mixing.
        v. The sample must be capped and mixed well.
            a. Use of the ABL90 on-board automatic PICO syringe mixer is recommended.
            b. Analysis must occur within 10 minutes of sample collection. If transportation from the bedside to a

testing area is required, there should be no delay in transit and the labeled specimen must still be tested promptly.

vi. Push out 2-3 drops of the sample onto a gauze pad, prior to analysis, to verify that there is no clotting in the syringe tip.

b. Capillary

i. Warm the puncture site for 5-10 minutes prior to sampling. Failure to do so will make the blood sample representative of the local tissue and not the general status of the patient. A heel warmer may be used.

ii. Clean the collection site.

iii. Only use single-use lancets for blood collection. Do not squeeze the area.

iv. Remove the first drop of blood since it may be diluted with tissue fluid.

v. Collect samples using Radiometer *safe*CLINITUBES.

a. Do not use glass capillary collection tubes.

vi. Avoid taking up ambient air into the capillary. To prevent air from entering the capillary tube, collect the sample from the center of the blood drop.

a. Squeezing or milking the puncture site should be avoided as this will result in an admixture of blood and tissue fluid. It may also cause hemolysis, resulting in a falsly-elevated potassium value.

vii. Cap the ends of the capillary straw in order to prevent ambient air contamination.

viii. Mix the sample with heparin immediately after collection to prevent clotting. Mix the sample, again, prior to analysis by rolling the capillary straw between the palms of the hands and invert the sample (end to end) multiple times.

a. A metal mixing bar (flea) may be used to to aid in the mixing process.

i. Make sure the flea moves from one end to the other 20 times to mix. If the wire does not move, gently use a magnet to move it end to end in the capillary tube.

b. Specimens must be tested within 10 minutes of collection. If transportation from the bedside to a testing area is required, there should be no delay in transit and the labeled specimen must still be tested

promptly. The specimen should be maintained in a horizontal position prior to testing.

F. Specimen Storage and Disposal

Sampling Device	Handling and Storage	Analyze within this Time Period
*safe*PICO Syringe	Keep at room temperature	<30 minutes
*safe*CLINITUBE Capillary Tube	Keep at room temperature	<10 minutes

1. Specimens should be discarded in a biohazard container after testing is complete.
2. Specimens should not be retained for later use.

G. Specimen Acceptability Criteria

1. Room temperature heparinized specimens collected in a *safe*PICO syringe or *safe*CLINITUBE capillary tube

H. Specimen Rejection Criteria

1. Specimens collected in a syringe smaller than 1.5 mL
2. Non-heparinized specimens
3. Specimens collected in glass capillary tubes
4. Clotted specimens
5. Specimens contaminated with air bubbles
6. Specimens collected more than 10 minutes prior to instrument analysis for capillary or 30 minutes for syringe
7. Unlabeled specimens not tested at the bedside
8. Specimens to be tested for glucose that are collected from lines coated in Total Parenteral Nutrition (TPN)

IV. REAGENTS:

A. Solution Pack

1. The solution pack is used for calibrations including QC and rinse procedures as well as the collection of waste fluids. The pack contains 8 foil pouches:
    a. 3 with calibration solutions
    b. 1 with a gas mixture
    c. 3 with QC solutions
    d. 1 pouch collects all liquid waste, both from the internal solutions and all external solutions including the biohazardous patient blood samples.
2. The solution pack may be exchanged with a solution pack from another instrument for troubleshooting and/or inventory control purposes.

a. Availability
    i. Dearborn: Ordered and stored in testing areas.
    ii. Farmington Hills: Ordered by POC and stored in Microbiology.
    iii. Royal Oak: Solution packs are obtained in the Ancillary Testing workroom on the labeled ABL90 shelf.
    iv. Trenton: Ordered by the OR and stored in the OR.
    v. Troy: Ordered by POC and stored in the Decentralized Testing office.
    vi. Wayne: Ordered and stored by SPL.

b. Ingredients
    i. Organic buffers, inorganic salts, surfactant, heparin, preservatives, enzyme, and colorant

c. Handling
    i. Store the solution packs at 2-25°C (36-77°F).
    ii. Store in a well-ventalated area.

d. Expiration
    i. Do not use beyond the manufacturer's expiration date printed on the packaging.
    ii. The solution pack may be used on the analyzer for up to 30 days, or until fully consumed.

e. Warnings/Precautions
    i. For *in vitro* diagnostic use only.
    ii. Keep the valves and fittings free from oil and grease.
    iii. Dispose in a biohazard container.

B. Sensor Cassette
1. The sensor cassette may be exchanged with a sensor cassette from another instrument for troubleshooting and/or inventory control purposes.
    a. Availability
        i. The sensor cassettes arrive dry-stored and must remain in the conditioning unit until ready for use.
            a. Dearborn: Ordered and stored in the testing areas.
            b. Farmington Hills: Ordered by POC and stored in Microbiology.
            c. Royal Oak: Sensor cassettes are obtained in the Ancillary Testing workroom refrigerator.
            d. Trenton: Ordered by the OR and stored in the OR.

e. Troy: Ordered by POC and stored in the Decentralized Testing refrigerator.

f. Wayne: Ordered and stored by SPL.

b. Composition

i. The sensor cassette includes sensors for pH, pCO_2, pO_2, Na+, K+, ionized calcium, glucose, lactate, hemoglobin and sO_2.

c. Handling

i. Refrigerate sensor cassettes at 2-8°C (36-46°F).

d. Expiration

i. Do not use beyond the manufacturer's expiration date printed on the packaging.

ii. The sensor cassette may be used on the analyzer for up to 30 days, or until fully consumed.

e. Warnings/Precautions

i. For *in vitro* diagnostic use only.

ii. Dispose in a biohazard container.

C. QUALICHECK5+ Aqueous External Controls

1. Availability: The 3 levels of quality control (QC) are packaged separately with 30 (2 mL) vials in each box.

a. Dearborn: Ordered and stored in the testing areas.

b. Farmington Hills: Ordered by POC and stored in Microbiology.

c. Royal Oak: Controls are distributed to testing areas by POC staff.

d. Trenton: Ordered by the OR and stored in the OR.

e. Troy: Ordered by POC and stored in the Decentralized Testing office.

f. Wayne: Ordered and stored by SPL.

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 ABL90 prompts to aspirate the sample. 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 biohazard sharps container.

D. ctHb Calibration Solution

1. Availability: Each box contains 4 (2 mL) vials.
    a. Dearborn: Ordered and stored in the testing areas.
    b. Farmington Hills: Ordered by POC and stored in Microbiology.
    c. Royal Oak: Ordered by POC and stored in Ancillary Testing.
    d. Trenton: Ordered by the OR and stored in the OR.
    e. Troy: Ordered by POC and stored in the Decentralized Testing office.
    f. Wayne: Ordered and stored by SPL.
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 biohazard sharps container.

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

1. Availability: Each box contains 4 (2 mL) vials of 3 levels of calibrators plus QUALICHEK5+ level 3 QC.
    a. Dearborn: Ordered and stored in the testing areas.
    b. Farmington Hills: Ordered by POC and stored in Microbiology.
    c. Royal Oak: Ordered by POC and stored in Ancillary Testing.
    d. Trenton: Ordered by the OR and stored in the OR.
    e. Troy: Ordered by POC and stored in the Decentralized Testing refrigerator.
    f. Wayne: Ordered and stored by SPL.
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. ABL90 Instrument
B. ABL90 Power Cord
C. Thermal Printer Paper
D. Personal Protective Equipment
E. Specimen Collection Supplies
F. Protective Sleeve or QUALICHECK Opener/Adapter (for breaking glass ampoules)
G. Gauze (for maintenance)
H. Water (for maintenance)
I. 70% Isopropyl Alcohol or 5% Bleach (for maintenance)
J. Hospital-Approved Wipes (for maintenance)
K. Biohazard Sharps Container
L. QC Vial Adapter

VI. HEMOGLOBIN CALIBRATION:

A. A ctHb calibration is performed every 90 days using the ctHb calibration solution to maintain the accuracy of the optical system (cuvette factor and wavelength).
    1. Verify the analyzer is in "Ready" mode.
    2. Mix the ampoule by gently inverting several times.
    3. Press "Menu" > "Start Programs" > "Calibration Programs" > "tHb" > "Calibration".
    4. Scan the Hb calibration barcode for the ABL90 analyzer, located on the S7770 package insert.
    5. Open one ampoule of ctHb calibration solution.
    6. Wait for the inlet to open.
    7. Place the sample in the vial adapter.
    8. Place the adapter against the gasket and press it upwards. The probe will extend into the syringe and automatically aspirate the solution.
    9. When prompted, remove the syringe. The inlet will close automatically.
    10. Once analysis is complete, the analyzer will display the results.
    11. Refer to the package insert/operator manual for the acceptable ranges.
        a. Sensitivity results between 80-120% without errors are acceptable.
        b. When reviewing the result, a result in red/bolded or associated with "?", ".....", or an error message (e.g. 582 or 584) indicates an unacceptable value. If the tHb results are not accepted, press "Messages" for the explanation.

c. Remedy the error and perform a new tHb calibration before performing patient testing.

d. If the calibration fails a second time, contact Radiometer Technical Support for assistance at 800-736-0601.

VII. CALIBRATION VERIFICATION/LINEARITY:

A. The ABL90 analyzer periodically performs calibration checks with 3 on-board calibration solutions and ambient air. The ABL90 solution pack is pre-loaded with calibration material that is in conformance with Radiometer's specifications and the certification of traceability can be found in the ABL90 Reference Manual. The ABL90 automatically performs calibration and QC checks at frequent intervals for the first 24 hours after the analyzer start-up and/or sensor cassette replacement. pO_2, pH, K+, Na+, and Ca++ are sensitivity-calibrated once a day and status-checked with every sample measurement. pCO_2, glucose, and lactic acid are sensitivity-calibrated every 4 hours and status-calibrated with every sample measurement. Hemoglobin and the oximetry parameters are status calibrated every 4 hours and if the temperature of the oximetry optical system changes to a temperature outside drift limits. The ABL90 will perform a rinse and a 1-point calibration before and after every patient test. All calibration results are recorded in the "Calibration Log" in the instrument.

B. 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 is performed twice per year (approximately every six months) using assayed 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. QUALICHEK+ materials are National Institute Standards and Technology (NIST) traceable with assayed ranges for Radiometer analyzers. Acceptable recovery is based upon measured values falling within the assayed parameters' high and low limits for each level.

1. Calibration Verification Procedure

a. Verify the analyzer is in "Ready" mode.

b. Run the material in the order of level 1, level 2, level 3 for optimal performance.

i. Note: The additional vials of QC5+ level 3 are only required if a glucose value is not achieved due to a low pO_2 value.

c. Hold the ampoule between the thumb and forefinger and shake vigorously for 15 seconds.

d. Tap the top of the ampoule until all the solution drops to the bottom of the ampoule.

e. Allow the bubbles to settle for 30 seconds before sampling.

f. Press the "Syringe" button.

g. Select "Other Modes" then "Cal. Verification".

h. The inlet will raise to the syringe position.

i. Break the ampoule at the neck.

j. Quickly insert the ampoule into the adapter.

k. With the ® logo visible on the adapter, place the adapter against the gasket and press it towards the analyzer. The probe will extend into the ampoule and automatically aspirate the solution.

l. When prompted, remove the adapter.

m. The inlet will close automatically.

n. Discard the ampoule in a sharps container. Retain the adapter.

o. Enter the calibration level on the "Patient ID" screen.

    i. Note: Do not enter a temperature as temperature correction will not be performed by the analyzer.

p. The analyzer will compute and display the results. Verify the results are within acceptable ranges on the package insert.

q. Analyze each level of VK-R5 a total of 3 times, using a new vial for each replicate.

r. Record the results on the electronic log provided by Radiometer. Record the room temperature on the log.

s. Submit the results to the Point of Care Manager, Lab Manager, Supervisor, or designee for review and approval.

2. Calibration Failure Procedure

a. Verify the VK-R5 vials are at the appropriate temperature and vial preparation was performed correctly.

b. Repeat the study.

c. If the error persists, use a new lot of VK-R5 for the study.

VIII. MAINTENANCE:

A. The ABL90 self-monitors internal circuity and reports problems on the display screen. Routine maintenance includes cleaning and changing the solution pack, sensor cassette, and printer paper. Annual maintenance involves replacing the connector gasket and inlet gasket.

B. Wear gloves during replacement and maintenance procedures.

C. Dispose and handle all used sampling devices, QC ampoules, solution packs, sensor cassettes, inlet probes, inlet gasket holders, inlet connector gaskets, and inlet modules as biohazardous waste.

1. Cleaning and Disinfection of the Instrument Casing

a. The surfaces of the instrument should be kept clean of blood and other liquids.

b. Clean the casing with 70% isopropyl alcohol or 5% bleach if it becomes contaminated with blood.

i. Do not use abrasive cleansers or pads, or ethanol-based substances for cleaning.

c. Wipe the exterior of the instrument and allow it to remain damp for 1 minute.

d. Allow the surface to air-dry before use.

2. Cleaning and Disinfection of the Touch Screen

a. Clean and disinfect the screen becomes contaminated with blood. Lightly dampen a lint-free cloth with 70% isopropyl or use a 70% isopropyl wipe.

i. Do not used bleach products on the touch screen.

ii. Do not use abrasive cleansers or pads, or ethanol-based substances for cleaning.

b. Press a finger on a part of the screen that is not active and hold it there.

c. Gently wipe the screen.

d. Allow the screen to remain damp for 1 minute.

e. Allow the screen to air-dry before use.

3. Cleaning the Inlet

a. Cleaning the inlet is performed as needed. Cleaning is needed when the inlet becomes blocked due to dried blood.

b. Press "Menu" > "Analyzer Status" > "Other Activities" > "Inlet Check".

c. Remove the inlet gasket with holder and the probe from the inlet.

d. Soak the inlet gasket with holder and the inlet probe in cleaning solution.

e. Rinse thoroughly with demineralized water to remove all cleaning solution.

f. Remount the inlet gasket with holder and the inlet probe. Verify that the inlet probe is in the correct position.

g. Remount the inlet and close it.

h. Press "Done".

4. Replacing the Solution Pack

a. In most cases, the instrument will prompt the user when a change is needed. Changing the solution pack may be used for some troubleshooting procedures. See the Troubleshooting section below for more information.

b. Press "Analyzer Status" > "Replace" > "Replace Solution Pack".

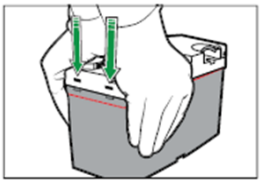
i. Note: The instrument will provide videos to demonstrate the procedure.

c. Wait for the inlet to automatically lift to the capillary position.

d. Wait for the solution pack to unlock. An audible click will be heard.

e. Remove the used solution pack and discard in biohazard waste.

f. To activate the new solution pack, remove the red safety pin, press the elevated side of the lid down until the side tabs click into place.



ABL90 FLEX PLUS Instructions for Use, Radiometer America Inc.

g. The inlet will close automatically.

h. The message "Replacing Solution Pack" will appear on the screen. If the instrument determines that the solution pack has been used prior to this installation, a question will appear on the screen. Select the appropriate response by pressing either "Cancel" or "Accept".

i. Press "OK" to complete the installation and initiate an automatic solution pack verification.

j. Assay the 3 levels of external QC.

5. Replacing the Sensor Cassette

a. In most cases, the instrument will prompt the user when a change is needed. Changing the sensor cassette may be used for some troubleshooting procedures. See the Troubleshooting section below for more information.

b. Press "Analyzer Status" > "Replace" > "Replace Sensor Cassette".

i. Note: The instrument will provide videos to demonstrate the procedure.

c. The sensor cassette compartment will open automatically.

d. Follow the instructions on the screen.

i. Remove the old sensor cassette by pulling it upwards and out of the compartment. Dispose of the used sensor cassette in biohazard waste.

ii. Remove the foil on top of the conditioning unit.

iii. Unscrew the lid of the unit by turning it counter-clockwise.

iv. Take out the new sensor cassette and insert it into the analyzer sensor cassette compartment by pressing firmly until resistance is met.

e. Press "Proceed". The compartment door will close and "Replacing Sensor Cassette" appears on the screen. If the instrument determines that the sensor cassette has been used prior to this installation, a question will appear on the screen. Select the appropriate response by pressing either "Cancel" or "Accept".

f. Press "OK" to complete the installation and initiate the sensor cassette initialization.
    i. Note: The sensor cassette must be conditioned in the analyzer by releasing a rinse solution to the sensors. It may take 1-2 hours before the analyzer will be ready for testing.
g. Assay the 3 levels of external QC.

6. Installing Printer Paper
    a. Press "Analyzer Status" > "Consumables" > "Replace Paper".
        i. It is also possible to navigate to the appropriate screen by following the following steps: "Analyzer Status" > "Replacement" > "Replace" > "Replace Paper".
    b. Press the release button to unlock the compartment cover.
    c. Remove any remaining paper.
    d. Place the new roll in the middle of the printer and verify that the paper unreels from underneath.
    e. Pull some paper out so it will extend out of the compartment when the cover is closed.
    f. Close the cover and press down until a click is heard.
    g. Press "Replaced".
    h. Press "OK" to exit the screen.
7. Replace Inlet Gasket with Holder
    a. This is performed annually by the vendor, or by POC staff if prompted by the instrument when troubleshooting.
        i. Press "Menu" > Analyzer Status" > "Other Activities" > "Inlet Check" > "Repl. Inlet Gasket Holder".
        ii. Press the "Start Video Guidance" button.
        iii. Pull off the inlet cover.
        iv. Press the "Action Completed" button. The analyzer will automatically open the inlet.
        v. Pull out the inlet gasket holder.
        vi. Press the "Action Completed" button.
        vii. Place the new inlet gasket holder over the slide and insert it. Make sure the inlet probe is in the center of the gasket.
            a. Note: Make sure the inlet gasket holder clicks in place.
        viii. Press the "Action Completed" button. The analyzer will automatically close the inlet.
        ix. Replace the inlet cover.

x. Press the "Action Completed" button.

8. Replace Connector Gasket
    a. This is performed annually by the vendor, or by POC staff if prompted by the instrument when troubleshooting.
        i. Press "Menu" > "Analyzer Status" > "Other Activities" > "Inlet Check" > "Repl. Inlet Connector Gasket".
        ii. Tap the "Press to Start Video Guidance" button.
        iii. Remove the inlet cover.
        iv. Press the "Action Completed" button. The analyzer will open the inlet.
        v. Hold the inlet module and pull to the right.
        vi. Make sure that the tabs on the inner side of the inlet module are in the correct position.
        vii. Press the "Action Completed" button.
        viii. Pull out the inlet connector gasket with a pair of tweezers.
        ix. Press the "Action Completed" button.
        x. Put tap water on the new inlet connector gasket.
        xi. Press the "Action Completed" button.
        xii. Push the new inlet connector gasket in place.
        xiii. Press the "Action Completed" button.
        xiv. When the instrument prompts, hold the inlet module as shown on the screen and push the end into the inlet connector until it clicks in place.
        xv. Press the "Action Completed" button.
        xvi. The analyzer will automatically close the inlet.
        xvii. Replace the inlet cover.
        xviii. Press the "Action Completed" button.

9. Flush
    a. Press "Analyzer Status" > "Consumables" > "Replace" > "Replace Solution Pack".
    b. Remove the solution pack when ejected.
    c. Fill the ABL90 flush syringe with 50% tap water and 50% air.
    d. Connect the syringe to the waste connector.
    e. Hold the syringe upright and inject a little water. It may be necessary to push and pull the plunger back and forth.
    f. Hold the syringe upside down and inject a little air.

g. Repeat several times, finishing with the water.

h. Expose the probe by pushing the inlet gasket holder back and examine the fluidic path of water. If an unbroken stream of water comes out, the fluidic path is cleaned.

i. Re-insert the solution pack and follow the instructions on the screen.

10. Temporary Shutdown

    a. In some situations, it is necessary to perform a temporary shutdown:

        i. When an analyzer with a low-charge battery level must be moved to a new location

        ii. When the analyzer instructs the operator to perform a shutdown

            a. Press "Menu" > "Utilities" > "Temporary Shutdown".

            b. Press the "Confirm Shutdown" button.

            c. When the Windows program has shut down, push the analyzer power switch to the off position (O).

11. Long-Term Shutdown

    a. A long-term shutdown prepares the analyzer by emptying the solutions and removing the components in the event it will not be used for a period of time or if the analyzer has to move to another location. This procedure takes approximately 15 minutes.

        i. It is recommended to clean the inlet gasket before beginning the long-term shutdown procedure.

        ii. Press "Menu" > "Utilities" > "Long Term Shutdown" > "Read Instructions".

        iii. Press "OK" to confirm. This procedure cannot be canceled once it progresses beyond this point.

        iv. Follow the on-screen instructions to decontaminate and flush the sensor cassette.

        v. Remove the sensor cassette and solution pack.

            a. The sensor cassette cannot be reused after this procedure, but the solution pack can be reinstalled if it is not expired.

        vi. Store the analyzer or transport it in the original shipping box.

12. Emergency Shutdown

    a. It may be necessary to perform an emergency shutdown if the analyzer becomes non-responsive.

        i. Press the round black stand-by button on the upper left rear of the analyzer to power down completely.

        ii. Unplug the power cord, if necessary.

13. Restarting the Analyzer
    a. Press the toggle switch on the lower back side of the analyzer to turn it on. The restart may take up to 3-5 minutes.
        i. After a temporary shutdown, the analyzer may be used as soon as it returns to "Ready" mode with a green traffic light.
        ii. After a long-term shutdown, follow the user-intervetion-required instructions that appear on the screen. Perform a solution pack and sensor cassette replacement. Then, press "Test Again".
14. SPL
    a. In the event that an Ebola patient is tested on the ABL90, contact Radiometer Technical Support at 800-736-0600 for decontamination and/or disposal guidance.

IX. NEW LOT VALIDATION:

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 ABL90 New Lot Number Validation form.

1. Open the Radiometer Aqure software.
2. Navigate to "Device Center" > "Hospital Choice" > "Department Choice".
3. Select an instrument and press "Show Data From" and search back to two months from the received date of the reagent.
4. Press "Device Messages" and de-select the red critical and the yellow attention boxes.
5. 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.
    a. Make note of the date.
6. Continue to the left and look for the previous lot of reagent.
    a. Make note of the date and lot number.
7. Open the Telcor QML software.
8. Navigate to "Results" > "Repository" > "Aqueous QC" > "Result Date" (date of reagent installation).
9. Select the "Disposable Code" (ABL90) > "OK".
10. Click on the "Device" to sort the results.
11. Find the liquid QC result.
    a. The date of QC analysis may be one day later than the installation date because the ABL90s need time to equilibrate.
12. Document the operator and results on the ABL90 New Lot Number Validation form.

13. Filter the results by the date of the previous reagent installation.
14. Press "OK" > click on the "Device" to sort the results.
15. Find the liquid QC and document the results on the form.
16. If a new lot of sensor cassettes or solution packs fail validation, follow-up investigations can include repeat QC analysis, review of external liquid QC results on other instruments, calibration verification, and instrument maintenance. If validation of a new lot fails, the lot should be rejected and removed from patient testing use.

X. QUALITY CONTROL (QC):

A. Quality management confirms the reliability, accuracy, and precision of patient results. The ABL90 analyzer monitors the entire system by continually and automatically performing calibrations and system checks consisting of: communication, software, mechanical, electronic, temperature, and consumable integrity, at least once a day. Additionally, the ABL90 performs analysis checks during patient sample analysis, calibrations, and QC measurements. Analysis checks performed with each sample measurement include: status of calibrations and sensors, sample integrity (volume, bubbles, and obstructions), temperatures, mechanical pressures and pumps, consumable lifetime checks, electronic functions, and measurement preparation after each test. If any of the analysis checks fail, they are automatically reinitialized by the analyzer. If they fail a second time, the analyzer enters a "User-Intervention-Required" screen which appears with instructions for the user on recommended actions to remedy the problem. See the Troubleshooting section below for more information.

    1. QC is not required on days when patient testing is not performed (i.e. the testing area is closed or the instrument is designated as a loaner and not in a testing area). QC must be run prior to resuming patient testing, when changes occur that may impact the patient results, including after a reagent change, major maintenance, change of a critical instrument component, or with software changes, if indicated.

B. Quality management is performed on 6 different solutions built into the solution pack. Each level of QC is run at least once every 24 hours (one level every 8 hours). If system checks fail, they are automatically repeated. If the issue is not resolved, the instrument will not be available for patient testing until the issue is remedied.

    1. Internal (Automatic) QC

        a. Internal QC consists of 3 levels (QC1, QC2, and QC3) and calibration and system checks are performed using 3 solutions (CAL1, CAL2, and CAL3). Each time a new solution pack is installed, acceptable ranges for each parameter are automatically entered into the analyzer database.

            i. The instruments are configured to perform 1 level of QC for pH, pCO_2, and pO_2 every 8 hours of instrument operation when patient testing is being performed and when changes occur that may impact patient results.

                a. To force an unscheduled QC measurement, press "Analyzer Status" > "Quality Control".

                b. Highlight the QC solution to run.

c. Press "Start QC".

d. The analyzer will compute and display the results. Parameters that fall within acceptable ranges will display without any flags next to the result.

e. The ABL90 will not allow patient testing unless the QC has passed successfully. The analyzer will take action to correct a problem that it finds. If the action fails, a message is displayed and the analyzer enters one of the following modes:

    i. Operator Action Needed

    ii. Troubleshooting Needed

    iii. Intervention Required

2. External (Liquid) QC

    a. External QC will be performed after preventative maintenance procedures, for troubleshooting, and when the test results do not match patient's clinical findings. Liquid QC must be performed after a solution pack and/or sensor cassette change or minimally once every 30 days during patient testing.

    b. QC ampoules must be stored at a constant temperature 18-32°C (64-89°F) for a minimum of 5 hours before sampling. QC solutions are sensitive to light. Keep the ampoule box closed between uses.

    c. Verify that the QC ranges have been scanned from the package insert before starting (see the Scanning in New Lots of External QC section below).

        i. Verify that the analyzer is in "Ready" mode.

        ii. Hold the ampoule between the thumb and forefinger and shake vigorously for 15 seconds.

        iii. Tap the top of the ampoule until all the solution drops to the bottom.

        iv. Press "Syringe" > "Other Modes" > "Ampoule-QC".

        v. Choose the QC solution as identified on the solution name and lot number.

        vi. Press the "Start Ampoule QC" button.

        vii. Using the ampoule opener, break the ampoule at the neck.

        viii. Quickly insert the ampoule into the adapter.

        ix. With the ® logo visible on the adapter, place the adapter against the gasket and press it upwards. The probe will automatically extend into the ampoule and aspirate the solution.

        x. When prompted, remove the adapter.

        xi. The inlet will close automatically.

xii. Discard the used ampoule in a sharps container. Retain the adapter.

xiii. The ambient temperature will need to be entered from the QC storage tray, depending on the instrument configuration. Press "Enter" to confirm the temperature.

xiv. The analyzer will compute and display the results. Parameters that fall within acceptable ranges will display without any flags next to the result.

xv. The ABL90 will not allow patient testing unless the QC has passed successfully.

3. Scanning in New Lots of External QC

    a. New lots of QC should be validated and ready for use prior to distribution to testing areas. The QC will be scanned into an ABL90 instrument and the values will be entered into the Telcor QML software. The current lot is removed from the ABL90 database, the new lot is added to the database, then, QC is performed. The current lot is then re-scanned and used until the current lot is depleted.

        i. Use an instrument that analyzes bilirubin, unless bilirubin is not tested at the performing location.

        ii. Press "Menu" > "Utilities" > "Set Up" > "QC Set Up".

        iii. Delete each level of QC.

        iv. Scan in the new lot number of each QC by following step "ii". Use the appropriate barcode from the QC package inserts (e.g. ABL90 FLEX SW ≥ V3.0).

        v. Perform QC and print results.

        vi. Delete new lot following steps "ii" and "iii".

        vii. Check the 2 boxes on the QC screen to request QC after the solution pack and sensor cassette are replaced.

        viii. Enter the fixed means and SDs in to Telcor QML. Use the package inserts to verify that Telcor QML ranges do not fall above or below the manufacturer ranges.

4. QC Failure Procedure

    a. Out-of-range QC values are highlighted in red on the display and must be repeated and/or corrective action must be performed before patient testing is allowed.

    b. One of the flags in the chart below may appear with the out-of-range result.

Result Flag	Definition
↑ or ↓	Result outside control range, but not outside statistics range.

↑ or ↓	Result is above or below statistics range and will not be included in the statistics.
↑↑ or ↓↓	Result is outside the analyzer's reportable range and will not be included in the statistics.
.....	A parameter cannot be calculated or exceeds the numerical limit of the analyzer.
*	Values with user-defined correction factors
?	Error in the last QC, calibration, sample problem, or analyzer malfunction
W	Violated Westgard rule
R	Violated RiLiBAK rule

c. In most cases, system check failures are automatically remedied. When system checks fail during repeat testing, the analyzer displays the "User-Intervention-Required" screen with instructions for troubleshooting the problem.

d. The operator should also try the troubleshooting steps below.

    i. Confirm that the lot number of QC matches the lot number stored in the ABL90.

    ii. Verify that all storage and handling criteria have been met for the QC solutions.

    iii. Perform calibration and repeat QC.

    iv. Out-of-range ampoule QC should be repeated with a new vial while confirming that the vial is handled properly.

    v. Out-of-range internal QC can be repeated after a calibration by selecting the QC level to run from the "Analyzer Status" > "Quality Control" screen then pressing "Start QC".

e. If the repeated QC does not fall within the expect range, follow the site-specific instructions below for assistance:

    i. Dearborn: Call POC at 313-436-2367, 313-593-7970, or 313-982-5661.

    ii. Farmington Hills: Call the POC/Quality Lead MT at 947-521-7167.

    iii. Royal Oak: Call Ancillary Testing at 248-898-8012.

    iv. Trenton: Call the Trenton Lab Manager at 734-671-3859.

    v. Troy: Call Decentralized Testing at 248-964-8009.

    vi. Wayne: Call the Wayne Lab Manager at 734-467-4233.

XI. INSTRUMENT COMPARISONS:

A. Instrument comparisons are performed twice per year (approximately every 6 months) to verify that results on the ABL90 correlate with results from the main laboratory performing the same tests. Each measured parameter on the ABL90 is compared to a main laboratory reference analyzer by using previously-tested heparinized blood gas samples and running them simultaneously in the same manner as patient testing. See the Point of Care Testing Policy.

B. On a rotational basis, one ABL90 will be compared to a variety of ranges throughout the analyzer's measurement range for each measured analyte, if possible. QC material may be utilized for some of the harder to find ranges. Furthermore, neonatal bilirubin results will be assessed by patient correlation testing with one or two samples annually in the clinical target range of 5-25 mg/dL on instruments configured to analyze bilirubin.

C. Instrument comparisons will also be performed on new analyzers and when an analyzer has undergone major service or repair.

    1. Obtain a previously-analyzed whole blood gas sample from the lab that has sufficient volume.
        a. Do not use cord blood.
    2. Mix the sample well.
    3. Run the sample on the reference instrument in the lab.
    4. Immediately test the same sample on the ABL90.
    5. Bilirubin:
        a. Transfer the remaining sample to a labeled, clear plastic tube.
        b. Cap the tube and spin it down to obtain plasma.
        c. Run the plasma sample for total bilirubin on the reference laboratory instrument.
    6. Record the results on the ABL90 Instrument Comparison Log.
    7. Calculate the difference between each measured parameter on the ABL90 and laboratory reference analyzer. Refer to the log for the allowable differences.
        a. Repeat one time with a fresh sample if the allowable difference is exceeded.
    8. The POC Manager/Lab Manager/Supervisor/designee will review the data.
        a. Note: The neonatal bilirubin assay on the ABL90 is a spectrophotometric-based method on the co-oximetry module, while the Abbott Architect measures plasma total bilirubin using the diazo method. The bilirubin assay on the ABL90 is strictly for neonatal whole blood specimens and it is sensitive to mean corpuscular hemoglobin concentration and pH. The difference in measuring principles, specimen types, and limitations should be taken into consideration when assessing the accuracy. The ABL90 bilirubin assay may be deemed acceptable if it demonstrates a reasonable

correlation with the reference method and appropriateness for clinical utility.

XII. PROCEDURE:

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

A. The analyzer should remain plugged into an electrical outlet and left in the "on" position whenever possible.
    1. For a limited period of time, the battery pack allows the performance of sample measurements and the storage of data without the analyzer being connected to an electrical outlet or during a power failure. The battery level indicator on the screen is only visible if the battery is installed. The battery charge level is indicated by a percentage and warns, with a red icon, when the battery is less than 13% charged.

B. Analyzer Status
    1. Check the top section of the main screen and resolve any issues before proceeding to testing.
        a. Status Bar: Describes current task in progress or status (ready or locked).
        b. Count: Displays the number of remaining tests/activities.
        c. Parameter Bar: Lists measurement parameters that are activated.
        d. 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 reminders.
	Red Light: Critical messages. Analyzer is unavailable due to a serious error or the parameter(s) are suppressed.

    2. For more details, touch the "Analyzer Status" button and the following status element buttons will be displayed along with individual traffic light icons:
        a. Calibrations
        b. QC
        c. Consumables
        d. Other Activities
        e. System Messages

C. Log into the instrument by scanning the barcode on the employee badge or manually enter the employee ID on the touch screen and press "Enter".

D. Mix the sample well prior to analyzing.

1. Capillary: Cap the ends of the capillary tube. Roll the tube between the palms of the hands to mix. Invert (end to end) several times.
2. Syringe: Cap the syringe. Roll the syringe between the palms of the hands an invert multiple times or place the *safe*PICO syringe in the built-in PICO syringe mixer. The mixer will start and stop automatically.
    a. Non-PICO syringes must be mixed manually and an inlet clip must be attached to the sampler.

E. Remove air gap, if present.

F. Press the button on the screen to select the sample type and the inlet will open automatically.

G. Select the panel/sample type from the menu and follow the on-screen instructions.
1. Capillary: Place the tube in the center of the inlet gasket and gently push. Then, hold as the specimen is aspirated.
    a. An ABL90 clot catcher may be used.
2. Syringe: Gently press the *safe*TIP cap of the *safe*PICO syringe up towards the inlet gasket. The inlet probe extends into the syringe and aspirates the sample.
    a. Verify that the inlet probe does not touch the plunger or the fiber disk in the syringe as this may cause the sample to be aspirated incorrectly.
    b. If the sample is in a *safe*PICO syringe with a *safe*TIPCAP, do not remove the *safe*TIPCAP cap during sample analysis.

H. When prompted, remove the sample.

I. The inlet will close automatically.

J. Enter the required information on the "Patient Identification" screen.
1. Scan the patient CSN or use the keypad to enter the patient's ID. Press "Enter".
2. Enter the FiO_2 for arterial and capillary specimens. Press "Enter".

K. When measurements are complete, the results are displayed on the "Patient Result" screen.

L. Press the keyboard icon to manually type in a note, if needed.

M. Press "Confirm" if the patient demographics displayed are correct. If the patient information is incorrect, press "Reject" and reenter the CSN.

N. TROY ONLY (Required Documentation Entry)
1. Modified Allen's Test: Select one of the following options:
    a. A-line
    b. Non-radial site
    c. Performed positive
    d. Performed negative
2. Site: Choose one of the following options:
    a. Brachial left

b. Brachial right
c. Femoral left
d. Femoral right
e. Not specified
f. Radial left
g. Radial right

3. Mode: Select an option below:
    a. AC/PRVC
    b. APRV/Bi-level
    c. Aerosol
    d. BiPAP/NIV
    e. CPAP
    f. High Flow NC
    g. Nasal cannula
    h. Non-rebreather
    i. PC
    j. PC-Inverse IE
    k. Partial-rebreather
    l. Room air
    m. SIMV c PSV
    n. SIMV/PCV
    o. Simple
    p. T-piece
    q. Trach
    r. Venti

4. Non-Operating Room locations must enter a FiO_2

O. TROY ONLY (Optional Documentation Entry)
1. FiO2 lpm (L/min)
2. RR (b/min)
3. Volume (mL)
4. PEEPCPAP (cmH_2O)
5. PSV (cmH_2O)
6. PCV (cmH_2O)
7. P-hi (cmH_2O)

8. Plo (cmH_2O)
9. T-hi (cmH_2O)
10. Tlo (cmH_2O)
11. SETPIP (cmH_2O)
12. Inspiratory Time (sec)
13. IPAP (cmH_2O)
14. EPAP (cmH_2O)

XIII. INTERPRETATION OF RESULTS:

A. Interpretation of Flagged Results

Flag	Definition
↑ or ↓	Result outside reference range
↟ or ↡	Result is above or below critical limits
⇞ or ⇟	Result is outside the analyzer's reportable range
.....	A parameter cannot be calculated or exceeds the numerical limit of the analyzer
*	Values with user-defined correction factors
?	Error in the last QC, calibration or sample problem. Do not report value.

B. Unexpected Values

1. Any result with a "?" next to the value must not be reported.
2. As with all diagnostic tests, results should be interpreted in the context of a patient's specific condition.
3. Clots, air bubbles, improper mixing, and delay in testing are factors that will cause erroneous results and require repeat testing with a properly collected and well-mixed specimen.
4. Results that are questionable or not consistent with the patient's clinical status should be repeated, or a specimen should be sent to the main laboratory for testing.
    a. Note: Wayne SPL samples may not be sent to the main laboratory.

XIV. RESULT REPORTING:

A. The ABL90 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 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. Correcting an Incorrect CSN

1. Press "Menu" > "Data Logs" > "Patient Results Log" > Select the ID that needs to be corrected > "Result" > "ID" > Input the correct ID > "Back" > "Send".

XV. EXPECTED VALUES:

Measured Values

Analyte	Specimen Type	Age	Normal Range
pH	Arterial/Capillary	0-4 Days ≥5 Days	7.27-7.47 7.35-7.45
	Venous	All	7.32-7.42
pCO_2 (mmHg)	Arterial	0-5 Days 6 Days-23 Months ≥24 Months	27-40 27-41 32-45
	Capillary	0-5 Days 6 Days-23 Months ≥24 Months	27-40 27-41 35-45
	Venous	All	41-51
pO_2 (mmHg)	Arterial/Capillary	0-1 Day ≥2 Days	54-95 80-100
tHb (g/dL)	All	0-1 Day 2-14 Days 15 Days-3 Months 4-6 Months 7-12 Months 13-24 Months 25 Months-5 Years 6-9 Years 10-12 Years 13-17 Years ≥18 Years (Male) ≥18 Years (Female)	14.6-22.7 13.2-21.3 9.8-12.9 10.4-14.7 10.2-14.7 11.1-13.7 11.1-14.1 11.4-14.7 11.0-15.1 11.7-15.6 13.5-17.0 12.1-15.0
O_2Hb (%)	Arterial/Capillary	All	95-98
	Venous	All	55-85
COHb (%)	All	All	<1.5 Non-Smoker <9 Heavy Smoker >20 Toxic
MetHb (%)	All	All	0-2

K+ (mmol/L)	All	0-1 Day 2 Days-3 Months ≥4 Months	5.0-7.5 4.0-6.0 3.5-5.2
Na+ (mmol/L)	All	0-1 Day 2-29 Days 30 Days-1 Year 2-12 Years ≥13 Years	126-166 134-144 139-146 138-145 135-145
Ca++ (mg/dL)	All	0-1 Day 2-3 Days 4-5 Days ≥6 Days	4.20-5.48 4.40-5.68 4.80-5.92 4.48-5.28
Cl- (mmol/L)	All	All	98-111
Glucose (mg/dL)	Fasting Random	All All	71-99 71-139
Lactic Acid (mmol/L)	Arterial Venous	All All	0-1.3 0.5-2.0
Total Bilirubin (mg/dL) Neonates Only	Capillary	0-23 Hours 24-35 Hours 36-47 Hours 48-59 Hours 60-71 Hours 72-83 Hours 84-144 Hours 145 Hours-13 Days 14-20 Days 21-27 Days	0.3-7.9 0.3-10.0 0.3-12.0 0.3-12.0 0.3-15.0 0.3-15.0 0.3-15.0 0.3-15.0 0.3-8.0 0.3-6.0

Calculated Values

Analyte	Specimen Type	Age	Normal Range
HCO_3 (mmol/L)	Arterial/Capillary Venous	0-4 Days 5 Days-12 Years ≥13 Years All	16-23 19-27 19-27 19-27
Base Excess (mmol/L)	Arterial	All	-3 - 3

	Capillary Venous	All All	-2-2 -5 - 5
O_2 Content (Vol)	Arterial/Capillary	All	18-21
Hct (%)	All	0-1 Day 2-14 Days 15 Days-3 Months 4-6 Months 7-12 Months 13-24 Months 25 Months-5 Years 6-9 Years 10-12 Years 13-17 Years ≥18 Years (Male) ≥18 Years (Female)	41.0-67.0 38.0-61.0 29.0-38.2 31.3-43.3 30.8-43.7 33.1-41.0 32.9-42.0 33.6-43.4 32.2-44.4 34.6-45.5 40.1-50.1 35.4-44.2

XVI. REPORTABLE RANGE:

Note: Results outside the ranges below will download to the EHR as < or > the indicated value.

Analyte	Arterial/Venous	Units
pH	6.8-7.8	N/A
pCO_2	15-98	mmHg
pO_2	30-488	mmHg
tHb	0.1-23.0	g/dL
O_2Hb	3-98	%
COHb	1-70	%
MetHb	1-70	%
K+	2.1-10.5	mmol/L
Na+	116-180	mmol/L
Ca++	2.0-8.8	mg/dL
Cl-	86-150	mmol/L
Glucose	9-738	mg/dL
Lactic Acid	0.4-24	mmol/L
Bilirubin	1.6-30.0	mg/dL

Blood gas and co-oximetery linearity materials for AMR verification are used according to instructions for the manufacturer. For some analytes, these materials do not cover the entire range of values reported. For example, the highest level of COHb reaches approximately 70% of the upper limit of the

reportable range. Medical and Technical Directors have approved the indicated reportable ranges to provide clinical benefit in cases of extreme carboxyhemoglobinemia and methemoglobinemia. 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).

XVII. CRITICAL VALUES:

Follow the institutional policy for critical result reporting and documentation.

Analyte	Specimen Type	Age	Values
pH	All	All	<7.20 and >7.60
pCO_2 (mmHg)	Arterial/Capillary	All	>70
pO_2 (mmHg)	Arterial	All	<50
Hb (g/dL)	All	0-14 Days 15-28 Days 29 Days-2 Years ≥3 Years	<10.0 and >25.0 <9.0 and >20.0 <8.0 and >20.0 <7.0 and >20.0
O_2Hb (%)	Arterial	All	<85
COHb (%)	All	All	>20
MetHb (%)	All	All	>9.9
Hct (%)	All	0-14 Days ≥15 Days	<15.0 and >70.0 <15.0 and >60.0
K+ (mmol/L)	All	0-1 Day 2 Days-Adult	<2.7 and >7.5 <2.5 and >6.0
Na+ (mmol/L)	All	0-1 Day 2 Days-17 Years ≥18 Years	<120 and >166 <125 and >155 <120 and >160
Ca++ (mg/dL)	All	All	<3.00 and >6.50
Glucose (mg/dL)	All	0-23 Months 24 Months-16 Years ≥17 Years	<45 and >180 <50 and >300 <50 and >500
Lactate (mmol/L)	Arterial/Venous	All	>3.9
Cl- (mmol/L)	All	All	<75 and >130
Bilirubin (mg/dL)	All	0-23 Hours 24-35 Hours	>7.9 >10.9

		36-47 Hours	>13.9
		48-59 Hours	>14.9
		60-71 Hours	>15.9
		72-83 Hours	>16.9
		84-144 Hours	>17.9
		145 Hours-13 Days	>15.0
		14-20 Days	>15.0

XVIII. RESULT REVIEW:

A. To retrieve patient results press "Menu" > "My Results".

B. Results may also be retrieved by pressing "Menu" > "Data Logs" > "Patient Results Log" > highlight the desired result > "Result".

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.

XX. LIMITATIONS:

A. Glucose results are blanked when the pO_2 is <10 mmHg.

B. When the measured glucose result is >270 mg/dL and the pO_2 level in the sample is between 10-25 mmHg, the glucose will be reported as >270 mg/dL along with an instrument message: "No. 1402, pO_2 too low. cGlucose linearity out of range".

C. When a sample has low pO_2 levels and the glucose result is required, repeat the measurement with an arterial sample in order to obtain a glucose result.

D. Glucose levels that are measured ≤ 270 mg/dL are not affected at a pO_2 level of 10-25 mmHg in the sample. Send a specimen to the main laboratory if results are questionable.

    1. Note: Wayne SPL samples may not be sent to the main laboratory.

E. Lack of mixing or delay in testing will affect the results.

F. Dispose and handle all used sampling devices, QC ampoules, solution packs, sensor cassettes, inlet probes, inlet gasket holders, inlet connector gaskets, and inlet modules as biohazardous waste.

XXI. INTERFERING SUBSTANCES:

A. Most Radiometer sampling devices contain dry, electrolyte-balanced heparin. In general, this type of heparin gives good results because it minimizes the bias on sodium, potassium, and

calcium results. Heparin in liquid form causes biased results on all parameters and should not be used. Different types of anticoagulant may change the concentration of some parameters and give false results.

1. Anticoagulants containing sodium salts give incorrectly high Na+ results.
2. Sodium fluoride with or without EDTA and oxalate interferes with glucose and lactate measurements.
3. Sodium fluoride gives incorrectly high Na+ and low Ca++, glucose, and lactate results.
4. Trisodium citrate affects Na+, K+, Ca++, pH, glucose, and lactate results.

B. Hemolysis will cause high K+ results. If doubt exists regarding the validity of the K+ results, a sample should be sent to the lab for K+ measurement via serum or plasma to rule out hemolysis.

C. Nitrous oxide used as anesthetics, may give unreliable pO_2 results due to the influence of these gases on the pO_2 sensor.

D. High turbidity from food and lipid therapy may affect oximetry measurements (e.g., total hemoglobin, oxyhemoglobin).

E. Anions such as Br-, I-, S^{2-}, ClO_4- which may be used as chemotherapies, will cause erroneously high Cl- results.

F. Thiocyanic acid will produce erroneously high glucose results.

XXII. TROUBLESHOOTING:

A. In most cases, system check failures are automatically remedied by the analyzer. When system checks fail repeat testing, the analyzer displays the "User-Intervention-Required" screen with instructions for troubleshooting the problem.

B. If the instrument presents with a frozen screen and will not boot upon restarting the system, use the arrow key to adjust the time to "hh:mm:ss" then press the "Restart" button on the bottom of the screen.

C. See the QC section to force an unscheduled internal QC analysis and/or internal calibration.

D. Verify that the instrument is within the designated operating temperature (15-32°C) and that relative humidity is 20-80%.

E. See the chart below for the most common error codes. A full list may be found in the ABL90 FLEX PLUS Instructions for Use literature.

Number	Message	Interpretation	Action
212	System message(s) present	One or more system errors are present.	Check the System Messages Status for errors. Take corrective action required.
331	No sample detected during sample aspiration	No sample detected in the sensor. Measurement is aborted.	Verify that adequate sample volume is in collection device. Check the sample for clots.

			Do not push the probe against the syringe plunger.
521	Inhomogeneous sample	Air bubbles were detected in the sample. Results may have "?".	Verify that there are no air bubbles in the sample and repeat the measurement.
522	Calibration error	One or more calibration values are erroneous.	Check for and remedy any system messages. Repeat calibration. Check sensor cassette and solution pack status and replace, if necessary.
593	Insufficient sample	Sample volume is too small for the selected measurement mode. affected parameters will be marked with "?".	Repeat the measurement, confirming sufficient sample volume. If error persists, contact the site-specific POC department as Radiometer may need to be consulted.
773	Remote operator logged on	POC staff has logged into the analyzer from a remote location.	No action is required unless the analyzer is needed immediately for patient testing. If immediate testing is required, contact the site-specific POC department and request remote log-off.
970	Replace solution pack	The message is shown when the solution pack needs to be replaced. The analyzer will enter the "Operator-intervention required" state.	Replace solution pack.
971	Replace sensor cassette	The message is shown when the sensor cassette needs to be replaced. The analyzer will enter the "Operator-intervention required" state.	Replace sensor cassette.
979 983 984	Inhomogeneous solution	Shown in Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1061	Pressure error	Flow has been hindered or a	The analyzer will

1062 1063		leak has been detected.	automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1216 1217 1218	Lifetime in analyzer exceeded No more tests left Expiration date reached	Shown in Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen. In most situations the sensor cassette and/or solution pack needs to be changed.
1384	Replace inlet gasket holder	The inlet gasket holder needs to be replaced.	Contact the site-specific POC department to replace the part.

F. If the above items do not resolve the issue, contact the site-specific POC department for assistance or to see if a loaner instrument is available. Alternately, send a specimen to the main laboratory for analysis.
    1. Note: Wayne SPL samples may not be sent to the main laboratory.

G. Follow the site-specific instructions below for further assistance:
    1. Dearborn: Call POC at 313-436-2367, 313-593-7970, or 313-982-5661.
    2. Farmington Hills: Call the POC/Quality Lead MT at 947-521-7167.
    3. Royal Oak: Call Ancillary Testing at 248-898-8012.
    4. Trenton: Call the Trenton Lab Manager at 734-671-3859.
    5. Troy: Call Decentralized Testing at 248-964-8009.
    6. 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. ABL90 FLEX PLUS Instructions for Use, Radiometer America Inc., 250 S. Kraemer Blvd., Brea, CA 92821, revision 202009J 2020, www.radiometeramerica.com

D. ABL90 FLEX Instructions for Use, Radiometer America Inc., 250 S. Kraemer Blvd., Brea, CA 92821, revision 201602A 2016, www.radiometeramerica.com

E. Skin Puncture Techniques

F. Chemistry and Toxicology Checklist, CAP, Northfield, IL, 2021 version

Attachments

ABL90 Chart Result Troubleshooting Reference Guide.pdf

ABL90 Instrument Comparison.pdf

ABL90 New Lot External QC Validation.pdf

ABL90 New Lot Validation.pdf

ABL90 Reagent Loading Reference Guide.pdf

ABL90 Training and Competency Assessment.pdf

ABL90 Training Guide.pdf

b64_57f030b1-0329-4248-8d8c-1f0f730e56ed

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b64_d184a0a3-5a93-48de-a752-b481c783ee34

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	11/2/2023
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	11/1/2023
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
	Caitlin Schein: Staff Physician	10/18/2023
Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	10/3/2023

POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	10/3/2023
	Jessica Czinder: Mgr, Division Laboratory	10/3/2023

Applicability

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