ARTERIALIZED VENOUS BLOOD GAS

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ARTERIALIZED VENOUS BLOOD GAS

1. Background and Rationale

Several smaller studies have demonstrated that acid-base status in postmenopausal women affects nitrogen balance and markers of bone turnover. The animal protein based diet common in industrialized societies, combined with the gradual reduction in renal function with aging, results in a chronic mild metabolic acidosis. With aging, body systems other than the kidney become increasingly important in buffering this acid. Muscle and bone can both be used as buffers. This examination is being performed to examine the contribution of acid-base status to losses in muscle and bone mass with aging.

While the gold standard measurement is an arterial blood gas, acid-base status can be accurately determined by obtaining an arterialized venous blood sample. Small shunts exist normally between arterioles and venules. In this procedure the participant's hand is warmed long enough for these small shunts to open. At that point there is enough mixing of arterial and venous blood locally that a venous sample very closely correlates with arterial values for pH, carbon dioxide (CO2), and bicarbonate (HCO3).

IMPORTANT:

Participants who do NOT need the cell collection (see Question #1 on the Phlebotomy form [Year 3 Clinic Visit Workbook, page 42]) will have their blood drawn exactly as described in this protocol. They will have a 10 mL red top and a 3 mL purple top vacutainer tube drawn before collection of the blood gas sample.

Participants who DO need the cell collection need to have four vacutainer tubes filled (two 10 mL red tops in addition to the 10 mL red top and the 3 mL purple top that will be collected on all participants). This number of tubes cannot be drawn from the same hand vein as the blood gas. Consequently, participants who DO need the cell collection will have two venipunctures: one for filling all four vacutainer tubes and one for the blood gas. Details for drawing the four vacutainer tubes for these participants are in the Blood Collection operations manual chapter (Chapter 2D). To obtain the blood gas for these participants, follow the protocol outlined below but do not collect the red top and purple top vacutainer prior to drawing the blood gas. This is further clarified in the protocol section describing these procedures.

2. Equipment and Supplies

- Gloves, disposable, non-sterile
- Tourniquets
- 21 gauge butterfly needle with 12-inch tubing; 19 gauge may be used in participants with appropriate veins-makes blood draw easier
- Heplock cap (optional)
- Alcohol wipes
- 2X2 gauze pads
- 3 mL preheparinized syringe
- Band-aids
- Tape
- 3 mL plain syringes (2 per participant)
- 5 mL plain syringes (2 per participant)
- 10 mL plain syringes (1 per participant)
- Sodium heparin 100 USP units / ml for heparin flush
- 21 gauge straight, hollow needles
- 10 mL plain red top vacutainer tube (1 per participant)
- 3 mL purple top vacutainer tube (1 per participant)
- Cup of regular ice, crushed
- Microtemp 2000 T-pump
- 16" X 21" reusable heating pad
- Radiometer ABL5 Blood Gas Machine and supplies (solutions, paper, cylinders)
- One red and one yellow QC control ampoule (1 of each color ampoule per participant)
- Thermometer for taking participant's temperature
- Digital wall thermometer for recording room temperature

3. Safety Issues and Exclusions

The risks of this examination are those associated with phlebotomy: discomfort at the site, bruising, and, rarely, infection. The heating pad is automatically set to 42ºC and cannot become any warmer. The only exclusions for not performing the arterialized blood gas are persons who cannot have phlebotomy due to dialysis grafts, mastectomies, or other medical conditions (please see section 3.2.1 of the operations manual for specifics), or allergy to heparin. Also, review Section 3 in the Blood Collection chapter (Chapter 2D) for precautions to be used when handling biologic

specimens as well as procedures to follow when a participant looks or feels faint during the blood draw.

4.0 Preparation

4.1 Equipment Preparation

4.11 Heating Pad Preparation

- The heating pad should be cleaned between uses with a surface cleaner and disinfectant such as Cavicide Hospital Disinfectant and Decontaminant.
- Thirty minutes before the first participant arrives, attach the reusable pad to the heating pump and plug it in. It has an internal thermostat set to 42ºC and will automatically warm to this temperature. The pad will take approximately 30 minutes to warm to this temperature.

4.12 Preparing the Radiometer ABL5 for sample measurement:

(This can be done in the morning before participants arrive)

- Remove from "STANDBY"- In order to save on supplies such as calibrating solutions and gases, you will place your ABL5 into the STANDBY mode at the end of each day it is used. The procedure for placing the ABL5 into standby is described below. When in the STANDBY mode only a Cal 2 is performed every 4th hour to keep the analyzer ready for use at a short notice. When you arrive in the morning, you must remove it from the STANDBY mode.
- You should see "STANDBY" in the upper left hand corner. To exit the STANDBY mode, press the softkey under the word "Exit" in the lower right hand corner. This causes the machine to perform a CAL 1 procedure ("CAL 1" will show in the upper right corner while it is calibrating). After 2 3/4 minutes you should see a reading of the Cal 1 pH, a "READY" message (upper left), and a green light to the left of the target sign. The ABL5 is now ready for action.

4.13 Daily maintenance

Below are the daily maintenance procedures to be done, recorded and initialed each day on the "Maintenance Schedule for ABL5" log that will come from the

manufacturer with your machine.

- Check solution levels- Because of the design of these bottles, almost all the solution will be used before it is necessary to install a new bottle. See page 7.2.5 of Operator's Manual or page 8 of Short Form Instructions for changing solution bottles.
- Check thermal paper supply: Replace when low. Instructions on page 7.2.1 of Operator's Manual or page 15 of Short Form Instructions.
- Check pressure in gas cylinders- It is not empty until the indicator is below the green (50 psi). (see pg 7.2.6 of Operator's Manual for instructions on changing the gas tanks). They should last about 6 months.
- Examine / clean inlet: Wipe off any blood. If very dirty, see page 7.2.6 of Operator's Manual.
- Check waste level in container—If full, replace. See Page 7.2.6 of Operator's Manual or page 14 of Short Form Instructions for replacement directions.
- Perform a Cleansing program- (page 6 - Short Form Instructions)
    1. You will need the Cleaning Solution (S5332). Fill a syringe with at least 15µl (microliters) of Cleaning Solution.
    2. Press Menu softkey
    3. Press 2 on the keyboard (Maintenance). A new menu will appear.
    4. Press 2 on the keyboard (Cleansing)
    5. When prompted by the display, open the inlet to the syringe / test tube position (#1)
    6. Once you have opened it, the display will tell you to aspirate the cleaning solution (#5332) from the syringe.
    7. Push the aspirate button momentarily, and let the machine aspirate the Cleaning Solution until it beeps.
    8. Remove the syringe, wipe the inlet, and close it.
    9. The analyzer will perform a cleansing, then a rinse cycle and return to the "READY" mode after a few minutes.

- Perform a 2-Point Calibration-
    1. Hit the "Menu" softkey. Choose "1" (Calibration), then "2" (Cal 2). The machine will begin a 2-point calibration. It will take about 5 1/2 minutes to perform a 2-point calibration.

2. When done, you can check the calibration status by hitting the "Menu" softkey, then "4" for System Status, then "2" for Cal status. The first page will show you the time of the last calibration. Hit the "Page" softkey for the pH electrode status. There are two pH readings because it is a 2-point calibration. Hit "Page" and you will see the pCO2 electrode status, then "Page" again to see the pO2 electrode status. Things to look for are the sensitivity readings for the electrodes and the "zero" reading for the pO2 electrode. The values should be in the range listed below:
    1) Sensitivity (pH) 92-102%
    2) Sensitivity (pCO2) 85-100%
    3) Sensitivity (pO2) 5-40 mmHg
    4) Zero: (pO2) < 6 mmHg
3. You can print this by hitting the "Menu" softkey. Choose "5" (Print/Send), then "2" (Print System Status).
4. If the values you obtained are not within the range above, the machine either needs to be cleaned or the electrodes for the value which is out of range needs to be remembraned. Follow the troubleshooting guidelines outlined in section 5.3 below.

4.14 Shut down of ABL5 at the end of the day

The ABL5 should be shut down at the end of the day after all samples have been analyzed and any weekly or monthly maintenance has been performed and the machine has returned to a "READY" mode.

- Hit the “Menu” softkey.
- Hit "3" on the keyboard (Utilities)
- Hit “1” on the keyboard (Standby)

4.2 Participant Preparation

- Although allergy to heparin is rare, ask if the participant is allergic to heparin. If they say “yes” do not do the arterialized venous blood gas protocol. Mark “No” to Question #13 (“Was arterialized venous blood sample obtained?”) on page 44 of the Year 3 Clinic Visit Workbook.
- Explain procedure to the participant. Suggested text: "As people get older, the amount of acid in their blood rises very slightly. This may contribute to muscle weakness and thinning of the bones. To look at the amount of acid in your blood, we need to draw the blood in a special way. We'll put a regular blood drawing

needle in a vein on the back of your hand and then warm your hand in a heating pad for 15 minutes before drawing the blood."

- Take participant's temperature. Record temperature on the Phlebotomy data collection form. **You will not need to enter this information into the blood gas machine.** Also record the room temperature where the control vials are stored on the Blood Gas Results data collection form (Year 3 Clinic Visit Workbook, page 45).
- Warming the participant's hands by wrapping them in the heating pad for a few minutes prior to venipuncture helps dilate the hand veins and make venipuncture easier. This should be done while the blood drawing equipment is being set up.
- Prepare the heparin flush syringes by drawing up 200 units (2 mL of 100 USP units/ml) sodium heparin into each of the plain 3 mL syringes to make two heparin flush syringes. Set the heparin flush syringes aside for use later.
- Participants should not eat for 2 hours before the arterialized blood draw. They have been asked in the clinic visit instructions not to eat for at least 1 hour prior to their appointment. Ask the participant when they last ate and record this time on the Phlebotomy form (page 43 of the Year 3 Clinic Visit Workbook). Ensure participant has been fasting 2 hours before performing blood draw.
- If the participant is on oxygen, enter the amount of oxygen they are using (e.g. 2 liters) on the Phlebotomy data collection form (Year 3 Clinic Visit Workbook, page 43). **You will not need to enter this information into the blood gas machine.** The oxygen level is pre-set on the machine – you do not need to change it even if the participant is on oxygen because the machine only uses the oxygen level to calculate certain results – none of which we are measuring. The values we are measuring are measured directly by the electrodes and are not affected by the amount of oxygen the participant is breathing. We do need to know the amount of oxygen they are on to interpret the blood gas results and will obtain this information from the data collection form.
- Record the time the blood draw started on the data collection form.

5. Detailed Measurement Procedures

5.1 Drawing Arterialized Venous Blood Gas Sample

- Wash hands thoroughly. Put on gloves.
- Venipuncture and arterialization of blood can be difficult in elderly people. It is

essential that the participant be as warm as possible to ensure ease of venipuncture and good peripheral circulation to improve blood gas results. Using blankets or small heaters to ensure the participant is warm will help. Warm the participant's hand with the heating pad while setting up for the blood draw to make veins more prominent. Use of the heating pad to warm the hand prior to venipuncture has resulted in an increased success rate in obtaining venous access in prior studies and does not interfere with the blood test results. Venipuncture can be challenging in older individuals and routine use of the heating pad to warm the participant's hand prior to venipuncture attempts is helpful. Once the butterfly has been inserted, only the hand with the butterfly should be placed in the heating pad and the pad wrapped around the hand as snugly as possible. To limit the discomfort of the participants, please limit venipuncture to two attempts per participant.

- Label the pre-heparinized 3 mL syringe (this is the pre-packaged syringe containing dry heparin, not to be confused with the heparin flush syringes containing liquid heparin that you prepared earlier) with the participant's Enrollment ID #.
- Select a rack of pre-labeled blood collection tubes. Affix the matching barcode labels to the Phlebotomy and Laboratory Processing forms.
- Unwrap and break the vacuum on one 10-mL syringe and one 5-mL syringe by withdrawing the plunger and then expelling all air.
- Place the tourniquet on participant's forearm and, after cleaning skin with alcohol wipe, insert butterfly catheter into a dorsal hand vein with heplock at end. Insertion site must be at or distal to the wrist.
- Secure the butterfly in place on the participant's hand with tape.

IMPORTANT:

Participants who do NOT need the cell collection (see Question #1 on the Phlebotomy form) will have a 10 mL red top and a 3 mL purple top vacutainer tube drawn before collection of the blood gas sample. Follow the directions in every bulleted item below.

Participants who DO need the cell collection need to have four vacutainer tubes filled (two 10 mL red tops in addition to the 10 mL red top and the 3 mL purple top that will be collected on all participants). This number of tubes cannot be drawn from the same hand vein as the blood gas. Consequently, participants who DO need the cell collection will have two venipunctures: one for filling all four vacutainer

tubes and one for the blood gas. Details for drawing the four vacutainer tubes for these participants are in the Blood Collection chapter. To obtain the blood gas for these participants, skip the next two bulleted items and resume following the protocol at the third bullet which begins "Remove the tourniquet now—before warming. . . "

- You will withdraw the regular lab samples for participants who DO NOT need the cell collection before flushing with heparin or warming the hand. This must be done gently as the hand and wrist veins are more delicate than the usual antecubital vein. For this reason, do not withdraw the sample directly into vacutainers. The vacuum in these tubes is strong enough to collapse and damage the vein and may prevent completion of the arterialized sample. Remove the heplock cap from the end of the butterfly and attach the 3 mL syringe. Gently and slowly withdraw 3 mL into the 5 mL plain syringe. After the 3 mL syringe is filled, detach it from the butterfly. Attach the 10 mL syringe to the end of the butterfly to prevent blood from seeping out the uncapped end while you place the blood from the filled 3 mL syringe into the purple top vacutainer tube. Attach a new 21-gauge needle to the filled 3 mL syringe and push the sharp end of the needle through the rubber stopper of the purple top vacutainer. Let the vacuum in the vacutainer pull the blood from the syringe into the vacutainer while you draw the next sample. Do not push down on the syringe to speed the process as this can result in a hemolyzed sample and is not necessary. It is simpler and safer to leave the syringe and needle inserted while you withdraw the second sample. Draw 10 mL's of blood into the 10 mL syringe, detach it from the butterfly, and replace the heparin cap on the end of the butterfly. Attach a new 21g straight needle to the syringe and push the sharp end of the needle through the rubber stopper of the red top vacutainer. To avoid the onset of clotting, do not wait until both syringes are filled before transferring to the vacutainers.
- Leaving butterfly in place, remove the tourniquet at or before 2 minutes. If blood flow ceases after the tourniquet is removed and the blood draw for the vacutainer tubes is not complete, the tourniquet may be reapplied for another 2 minutes. Note the total tourniquet time on the Phlebotomy form. The arterialized blood gas will be drawn later without a tourniquet.
- Remove the tourniquet now—before warming the participant's hand and drawing the arterialized sample. Be sure to note the total tourniquet time on the Phlebotomy form. Warming the participant's arm and drawing the arterialized sample should all be done without a tourniquet. Flush the butterfly tubing with 200 units (2 mL of 100 USP units / ml) of sodium heparin flush using one of the 3 mL heparin flush syringes prepared earlier, and replace the heplock on the end of

the butterfly.

- Wrap hand and forearm in heating pad that has been warmed to 42ºC as snugly as possible, leaving no air between hand and pad. The pad may be secured loosely with tape or string wrapped around the outside of the pad. Caution should be used to ensure that the tape or string is not snug enough to alter blood flow in the participant's arm. The end of the heplock should extend out the front of the pad past the edge of the pad which covers the fingers. It is very important that the entire hand and as much as possible of the arm be snugly wrapped in the heating pad. The end of the heating pad past the participant's fingers should be tucked under to prevent cool air from coming in contact with the participant's hand.
- Remove the syringes and needles from the vacutainers and dispose of them in the appropriate biohazard container.
- Wait at least fifteen minutes. Longer warming periods are permitted and will result in improved arterialization. A minimum of 15 minutes is required.
- Leave the hand wrapped in the heating pad. Using the second 3 mL heparin flush syringe prepared earlier, inject 100 units (1 mL of 100 USP units/ml) sodium heparin into the end of the IV.
- Withdraw 3 to 5 mL from the IV using the plain 5 mL syringe. Discard this syringe of blood/heparin mixture; this is to ensure that all the heparin has been withdrawn from the IV line.
- Attach the pre-heparinized (containing dry heparin) 3 mL syringe to the IV.
- Withdraw 3 mL of blood. Expel all air from the syringe. Air bubbles in the sample will make the readings inaccurate. Cap syringe immediately and place on ice. The minimum amount of blood needed for blood gas analysis is 1mL but 3 mL is best for optimal analysis.
- If necessary, you may partially unwrap the hand after the 15 minutes of warming to adjust the needle positioning as necessary to draw blood more readily. The hand and arm should be kept wrapped as much as possible at all times.
- If no blood can be withdrawn, inject the 100 units (1 mL of 100 USP units/ml) remaining in the 3 mL heparin flush syringe and then repeat the previous four steps.
- Unwrap hand and remove butterfly. Apply band-aid to venipuncture site.
- The heating pad should be cleaned between uses with a surface cleaner and disinfectant such as Cavicide Hospital Disinfectant and Decontaminant. It does not have to be unplugged or cooled before cleaning. After the last participant of

the day, heating pad should be unplugged, cleaned and stored for next use.

5.2 Analyzing Arterialized Blood Gas Sample

- Perform daily quality control. These values are to be plotted in the logbook. This can be done before the first participant arrives. Readings for the yellow control can be used for the first participant's Data Collection Form.
- We are going to use two levels of a quality control system, QUALICHECK, to evaluate the performance of the ABL5 by comparing measurements of test solutions to predetermined values. These quality control solutions are a valuable tool in detecting possible errors in blood measurement and in checking the precision and accuracy of the systems.
- Each center will be testing the same lot numbers of the Yellow QUALICHECK (S2040) and the Red QUALICHECK (S2030) every time a participant sample is analyzed. By looking at the recorded values of pH, pCO2 and pO2 values for the Yellow QC and Red QC, we will have a reference point for the participant values obtained. Only in this way will we be able to compare the values obtained at each center to those obtained at the other center.
- Store all ampoules of Qualichek at constant room temperature (preferably 25 degrees Centigrade as this is the temperature assumed by the blood gas machine).
- Check the Following Items:
  1. Is machine out of "Standby?"
  2. Have you performed the "Daily Maintenance?"
  3. Is the ABL5 in "READY" mode?
  4. Is the green light on?
  5. Do you have the following equipment ready:
     Yellow Ampoule (S2040) - unopened
     Daily QC log
     Gauze pads
     Blood Gas Results data collection form for the first participant of the day
- Remember to save all the tape readouts for the yellow QC, the participant values, and the red QC. These will be an additional backup for the data collection forms on which you will record the values. Tape readouts should be stored at each clinic.

5.21 Running the Yellow QC Ampoule

- Write the room temperature where the ampoules have been stored on the data collection form.
- One yellow ampoule will be analyzed in duplicate before each participant sample.
- Remember, you have 30 seconds after the inlet is opened to introduce the QC solution or the blood to the inlet needle and begin aspiration.
- Hold the ampoule between your thumb and index finger with thumb and index finger on the ends of ampoule and shake vigorously for at least 15 seconds. Do not hold the ampoule by the body of the ampoule as this will change the temperature of the control solution, and the results produced.
- Tap the top of the ampoule until all the solution collects at the bottom of the ampoule. Be sure no solution remains in the neck of the ampoule.
- The following steps will be done on each yellow ampoule and then repeated (except for opening the ampoule) on the same yellow ampoule before analyzing the participant's blood gas.
- Open the inlet one stop (for syringe).
- Hit the "QC" softkey. The display will say "aspirate sample QC."
- Open the ampoule by holding it in gauze and cracking open at the neck.
- Immerse the inlet into the control solution so that it nearly reaches the bottom of the ampoule.
- Supporting the ampoule in the gauze pad, press the Aspirate button (target) momentarily. Hold the ampoule in the inlet until a beep is heard and the yellow LED lights.
- Remove the ampoule, wipe the inlet with the gauze, and close the inlet.
- Let the ampoule sit open on the counter until the machine returns to "Ready" with the green LED light on after the first reading. It is stable this way for 2 to 3 minutes. If you hold it in your hand, it will warm up and the oxygen reading will rise, possibly out of the normal range. It is not necessary to try to block off the opening of the ampoule.
- Enter the information on the QC identification screen.
    1. The cursor is placed on the first data line. To move the cursor, use the ENTER key.
    2. Op ID: you can identify the operator- optional. Hit ENTER.
    3. Type: hit ENTER since you will be using QUALICHECK.
    4. Temp: hit ENTER leaving room temperature at 25ºC.

5. Level: since this is the Yellow level, hit the "Change" softkey until YELLOW-S2040 shows; then hit ENTER.

- The results are displayed on the screen and printed out on the tape. The reading is identified as a Yellow level reading.
- The first reading (pH, pCO2, and pO2) of the day on the Yellow control will also be your QC reading for that day to be plotted in your logbook.
- This first reading (pH, pCO2, and pO2) will also be recorded on the first participant's data collection form as Yellow Control #1.
- Repeat the above steps, from opening the inlet to printing out the results, on the same (already opened) Yellow ampoule. Record the results (pH, pCO2, and pO2) as Yellow Control #2.
- Check the readings you just obtained for the Yellow Quality Control against the manufacturer's given ranges for your particular lot number and machine (ABL5). The pH, pCO2 and pO2 readings should be within range.
- If the readings are not within range, or if you see a question mark in the upper right corner ("status corner"), see troubleshooting section below.

5.22 Running the Participant Sample

(Always wear gloves)

- Check the following items:
  1. Is machine out of "Standby?"
  2. Have you performed the "Daily Maintenance?"
  3. Is the ABL5 in "READY" mode?
  4. Is the green light on?
  5. Do you have the following equipment ready?
     Yellow Ampoule (S2040) (unopened)
     Red Ampoule (S030) (unopened)
     Participant's arterialized venous blood gas sample (in syringe from SE 1403 kit—on ice)
  6. Participant's Blood Gas Results data collection form
  7. Gauze pads
- Write the participant's ID number on the Blood Gas Results data collection form for that participant.
- Run the Yellow QC as described on page 11. You can use the yellow QC values obtained during the morning daily maintenance as the yellow QC values for the

first participant of the day.

- Write the yellow QC values obtained just prior to running the participant sample on the Blood Gas Results data collection form for that participant.
- The participant sample should be in a 3 mL pre-heparinized syringe, which has been kept in ice after the sample was drawn. The ice will slow down cell metabolism and keep the blood gas readings constant for about 10 to 15 minutes.
- You should already have expelled any air bubbles from the syringe holding the participant sample. Air in the capped syringe is a potential source of error.
- The following steps will be done in sequence and then repeated twice for a total of three times on each participant sample.
  - The sample in the syringe needs to be mixed well with the anticoagulant after being drawn from the participant.
  - Mix the sample well for at least 15 seconds by inverting the syringe repeatedly and rolling the syringe between your hands.
  - Remove the cap. Expel a few drops of blood into a piece of gauze, and withdraw the plunger slightly to remove blood from tip.
  - Open the inlet. "Blood" should already be selected.
  - Insert the inlet into the syringe well below the surface.
  - Press the Aspirate button momentarily. Wait for the yellow LED to light and the short beep to sound. This tells you that the sample has been received.
  - Remove the syringe, wipe the inlet with the gauze, and close the inlet.
  - Expel any air from the syringe, re-cap the syringe, and place back on ice.
  - Enter the participant information on the screen.
    1. The Cursor is positioned at the Op ID. Press ENTER to move it to the next line.
    2. Pt ID - input the participant's ID #, then press ENTER.
    3. Type - "Mixed Venous" is already there. Just push ENTER.
  - You can skip the rest of the ID keys. The temperature on the machine is set to 37ºC; leave it at this temperature. The oxygen level is pre-set on the machine- you do not need to change it even if the participant is on oxygen because the machine only uses the oxygen level to calculate certain results, none of which we are measuring. The values we are measuring are measured directly by the electrodes and are not affected by the amount of oxygen the participant is breathing. We do need to know the amount of oxygen they are on to interpret the blood gas results and will obtain this information from the data collection

form.

- The Patient Report will appear on the screen and will be automatically printed. You should record the pH, pCO2, pO2, and HCO3 on the Blood Gas Results data collection form as Participant Reading #1 (2a.).

- As soon as the "READY" sign comes back on and the green LED light is lit, repeat the above steps, from mixing the sample to printing out the report two more times. These will be Participant readings #2 and #3. Record them on the Blood Gas Results data collection form in the appropriate spaces (2b. and 2c.).
- After running the participant sample in triplicate, run a red control ampoule in duplicate as described below.

5.23 Running the Red QC Ampoule

One red ampoule will be analyzed in duplicate after each participant sample.

- Hold the ampoule between your thumb and index finger with thumb and index finger on the ends of ampoule and shake vigorously for at least 15 seconds. Do not hold the ampoule by the body of the ampoule as this will change the temperature of the control solution, and the results produced.
- Tap the top of the ampoule until all the solution collects at the bottom of the ampoule. Be sure no solution remains in the neck of the ampoule.
- The following steps will be done in sequence on each red ampoule and then repeated (except for opening the ampoule) on the same red ampoule after analyzing the participant's blood gas.
- Open the inlet one stop (for syringe).
- Hit the "QC" softkey. The display will say "aspirate sample QC."
- Open the ampoule by holding it in the gauze and cracking open at the neck.
- Immerse the inlet into the control solution so that it nearly reaches the bottom of the ampoule.
- Supporting the ampoule in the gauze pad, press the Aspirate button (target) momentarily. Hold the ampoule in the inlet until a beep is heard and the yellow LED lights.
- Remove the ampoule, wipe the inlet with the gauze, and close the inlet.
- Let the ampoule sit open on the counter until the machine returns to "Ready" with the green LED light on after the first reading. It is stable this way for 2 to 3

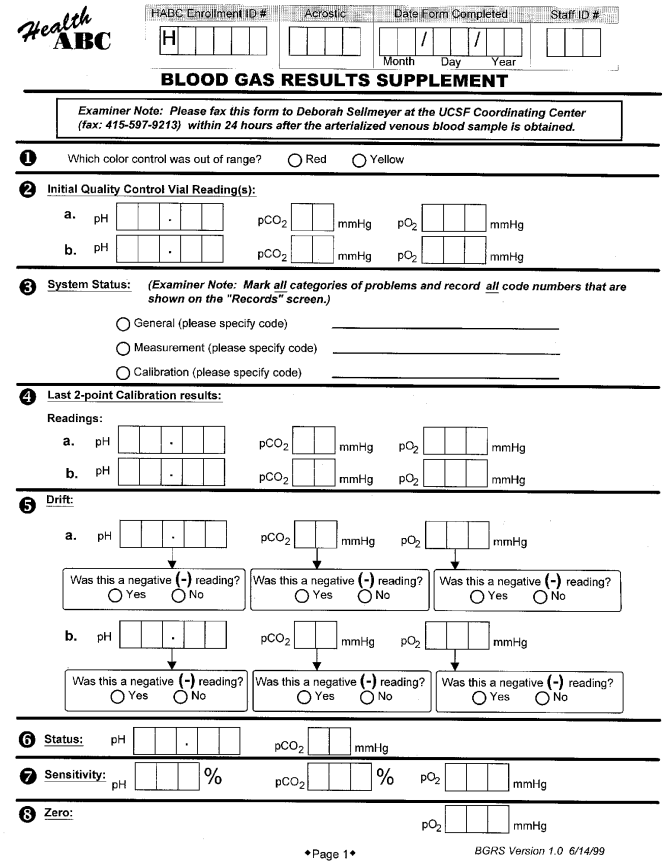
minutes. If you hold it in your hand, it will warm up and the oxygen reading will rise, possibly out of the normal range. It is not necessary to try to block off the opening of the ampoule.

- Enter the information on the QC identification screen.
    1. The cursor is placed on the first data line. To move the cursor, use the ENTER key.
    2. Op ID: you can identify the operator- optional. Hit ENTER.
    3. Type: hit ENTER since you will be using QUALICHECK.
    4. Temp: hit ENTER to leave room temperature at 25ºC.
    5. Level: hit ENTER since Red-S2030 is already showing.
- The results are displayed on the screen and printed out on the tape.
- This reading (pH, pCO2, and pO2) will be recorded on the participant's data collection form as Red Control #1.
- Repeat the above steps, from opening the inlet to printing out the results, on the same (already opened) Red ampoule. Record the results (pH, pCO2, and pO2) as Red Control #2.
- Keep reports which print out with the control and participant values in the participant's chart at each clinic site.
- Check the readings for the Red Quality Control against the manufacturer's given ranges for your particular lot number and machine (ABL5). pH, pCO2 and pO2 readings should be within range.
- If the readings are not within range, or if you see a question mark in the upper right corner ("status corner"), see section 5.3 below.

5.3 Troubleshooting

5.31 QC vial readings are not within manufacturer specified range

- All QC readings should fall within the ranges specified with the control material. You will receive a chart listing these ranges so that you can check to see that your QC data for both the Yellow and Red levels are within range. If your values are not within range, perform the steps outlined below. For participants whose control values fall out of the manufacturer's range, record the values obtained during this section on the Blood Gas Results Supplement data collection form (see below).



Health ABC

HABC Enrollment ID # H | Acrostic | Date Form Completed (Month / Day / Year) | Staff ID #

BLOOD GAS RESULTS SUPPLEMENT

Examiner Note: Please fax this form to Deborah Sellmeyer at the UCSF Coordinating Center (fax: 415-597-9213) within 24 hours after the arterialized venous blood sample is obtained.

❶ Which color control was out of range? ○ Red ○ Yellow

❷ **Initial Quality Control Vial Reading(s):**

a. pH . pCO_2 mmHg pO_2 mmHg

b. pH . pCO_2 mmHg pO_2 mmHg

❸ **System Status:** *(Examiner Note: Mark all categories of problems and record all code numbers that are shown on the "Records" screen.)*

○ General (please specify code) _____

○ Measurement (please specify code) _____

○ Calibration (please specify code) _____

❹ **Last 2-point Calibration results:**

Readings:

a. pH . pCO_2 mmHg pO_2 mmHg

b. pH . pCO_2 mmHg pO_2 mmHg

❺ **Drift:**

a. pH . pCO_2 mmHg pO_2 mmHg

Was this a negative (-) reading? ○ Yes ○ No | Was this a negative (-) reading? ○ Yes ○ No | Was this a negative (-) reading? ○ Yes ○ No

b. pH . pCO_2 mmHg pO_2 mmHg

Was this a negative (-) reading? ○ Yes ○ No | Was this a negative (-) reading? ○ Yes ○ No | Was this a negative (-) reading? ○ Yes ○ No

❻ **Status:** pH . pCO_2 mmHg

❼ **Sensitivity:** pH % pCO_2 % pO_2 mmHg

❽ **Zero:** pO_2 mmHg

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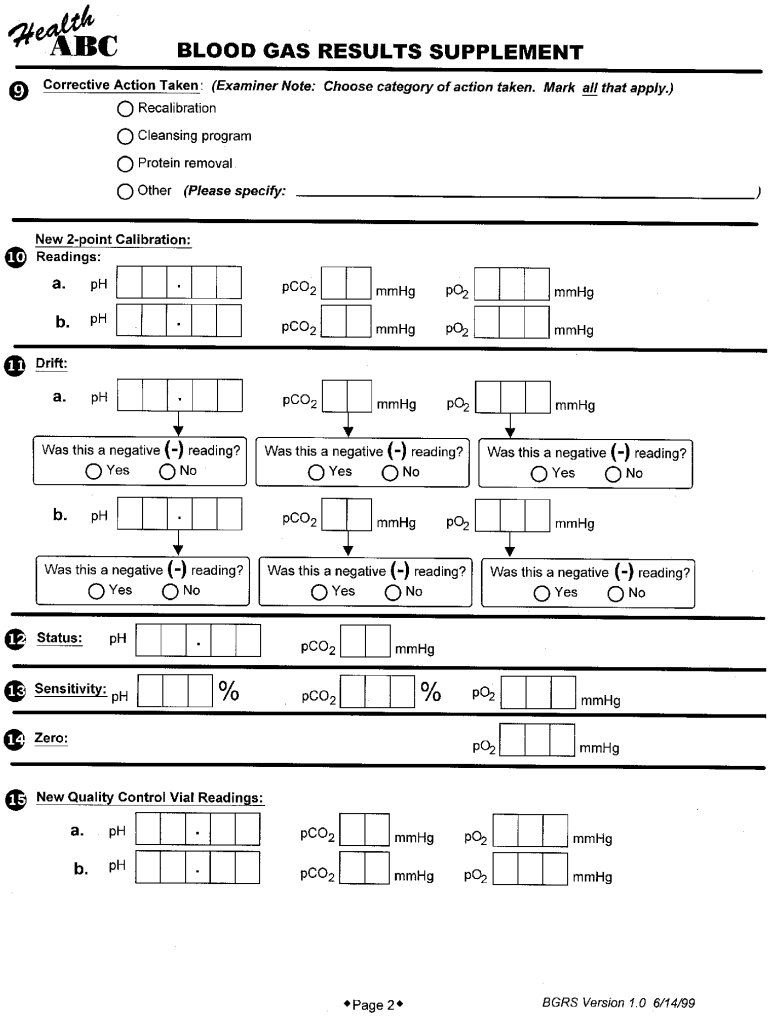

Health ABC

BLOOD GAS RESULTS SUPPLEMENT

9 Corrective Action Taken: *(Examiner Note: Choose category of action taken. Mark all that apply.)*

- ○ Recalibration
- ○ Cleansing program
- ○ Protein removal
- ○ Other *(Please specify:* _____ *)*

10 New 2-point Calibration:
Readings:

a. pH . pCO_2 mmHg pO_2 mmHg

b. pH . pCO_2 mmHg pO_2 mmHg

11 Drift:

a. pH . pCO_2 mmHg pO_2 mmHg

Was this a negative (-) reading? ○ Yes ○ No | Was this a negative (-) reading? ○ Yes ○ No | Was this a negative (-) reading? ○ Yes ○ No

b. pH . pCO_2 mmHg pO_2 mmHg

Was this a negative (-) reading? ○ Yes ○ No | Was this a negative (-) reading? ○ Yes ○ No | Was this a negative (-) reading? ○ Yes ○ No

12 Status: pH . pCO_2 mmHg

13 Sensitivity: pH % pCO_2 % pO_2 mmHg

14 Zero: pO_2 mmHg

15 New Quality Control Vial Readings:

a. pH . pCO_2 mmHg pO_2 mmHg

b. pH . pCO_2 mmHg pO_2 mmHg

◆Page 2◆ *BGRS Version 1.0 6/14/99*

- The blood gas machine assumes room temperature (and the temperature of the ampoule) to be 25ºC (77ºF). If the room temperature and thus, the temperature of the ampoule, is significantly (more than 10ºF) different from that, it will alter the readings. If your QC ampoule readings are not within the manufacturer's range and the room is warmer or colder than the temperature assumed by the machine, you may need to change the temperature on the machine. To do this, aspirate the QC sample normally. After you have wiped the inlet and closed it, the screen will list a menu. This is the menu where you can change the color of the QC control from red to yellow. The line above the color has the temperature listed. Go to this line and type in the correct room temperature. This new temperature will be used to compute the results on the sample you just aspirated. If the results are now in range, document that you had to change the temperature on the machine on the supplemental data collection form and continue processing the participant sample. If this appears to have been the problem, you will have to

change the temperature on the machine with each QC sample as long as the room is significantly above or below the pre-set temperature on the machine. Use the supplemental form for each participant who requires this change. Note that this only affects the QC ampoules; participant samples are assumed by the machine to be body temperature (37ºC or 98.6ºF) and are not affected by room temperature. All supplemental forms should be faxed the same day to:

Dr. Deborah Sellmeyer (415) 597-9213

5.32 Question mark appears in upper right hand corner or other problem

- Check the "System Status" by pushing the "Menu" softkey, then push "4" (System Status), then "1" (Records).
- The "Records" screen will give you an idea what the problem is ("General," "Measurement," or "Calibration") and give you a code number.
- Refer to the Key to Record Codes (page 8.3 in your Operator's Manual)., then refer to pages 8.4 to 8.9 for ways to remedy specific problems.
- General Approach to Troubleshooting:
    1. First perform a 2 point calibration. (Refer to section 4.12 for details on a 2-point calibration.) If that is OK, open a new ampoule of QC and repeat operation.
    2. Perform a Cleansing Operation, (refer to section 4.13 for details on the cleansing operation) then a 2 point calibration. If this does not clear up the problem,
    3. Perform a Protein Removal, then a 2 point calibration. If this does not clear up the problem,
    4. Perform troubleshooting steps relating to the specific problem (see pages 8.4 to 8.9 of Operator's Manual). Remember, if you remove, clean, or remembrane an electrode, the machine will go into a "re-startup procedure" which takes several minutes. During this time you cannot perform any action with the machine.
    5. If the problem lies with the O2 value, brush the O2 electrode and remembrane (see operator's manual for instructions). Perform a 2-point calibration (see section 4.13 above), then open a new yellow QC ampoule and repeat the protocol section on running the yellow ampoule (section 5.21 above). If OK, continue with analysis of participant sample. If still incorrect, record the readings obtained on the Blood Gas Results data collection form, run the participant sample and record these readings on the Blood Gas Results data collection form. Call the Radiometer Technical Service Advisor.

6. If the problem lies with the CO2 value, remembrane the electrode (see operator's manual for instructions). Perform a 2-point calibration (see section 4.13 above), then open a new yellow QC ampoule and repeat the protocol section on running the yellow ampoule (section 5.21 above). If OK, continue with analysis of participant sample. If still incorrect, record the readings obtained on the Blood Gas Results data collection form, run the participant sample and record these readings on the Blood Gas Results data collection form. Call the Radiometer Technical Service Advisor. Also be sure to fill out a Blood Gas Results Supplement form and fax it to the Coordinating Center at the number listed above (section 5.31).
7. If the problem lies with the pH, remembrane the reference electrode and clean the pH electrode with distilled water. Perform a 2-point calibration (see section 4.13 above), then open a new yellow QC ampoule and repeat the protocol section on running the yellow ampoule (section 5.21 above). If OK, continue with analysis of participant sample. If still incorrect, record the readings obtained on the Blood Gas Results data collection form, run the participant sample and record these readings on the Blood Gas Results data collection form. Also, be sure to fill out a Blood Gas Results Supplement form and fax it to the Coordinating Center at the number listed above (section 5.31). Call the Radiometer Technical Service Advisor.

6. Procedures for Performing the Measurement at Home

Not applicable.

7. Alert values/Follow-up/Reporting to Participants

If a participant's pH is less than 7.30, they should be advised that this lab result needs to be discussed with their physician. Suggested text: "Your blood test shows that you have more acid in your blood than most people. This could indicate a medical problem and we need to pass this on to your doctor. Most likely this is something that has been going on for a while and your doctor already knows about it but we want to make sure." This occurred in only 2 of the over 5,000 women on whom blood gasses were obtained in The Study of Osteoporotic Fractures. This could indicate an uncompensated or inadequately treated acidosis and the participant's physician should be notified. If the participant appears in medical distress or short of breath, the clinic supervisor should be notified immediately. If the participant has no complaints, obtain the name and contact information for the

participant's physician and notify the clinic physician who will contact the participant's physician.

8. Quality Assurance

8.1 Training Requirements

Proficiency with phlebotomy is mandatory. Training should also include:

- Reading and studying operations manual
- Attending Health ABC training session on techniques and use of the Radiometer blood gas machine
- Discussing problems and questions with QC officer

8.2 Certification Requirements

- Complete training requirements
- Practice performing blood gas analysis including controls twice on control vials and participant samples which have already been analyzed
- Perform daily maintenance on Radiometer ABL-5 blood gas machine while being observed by QC officer using QC checklist
- Conduct exam on two participants while being observed by QC officer using QC checklist

8.3 Quality Assurance Checklist

QC Checklist for Preparation

- ☐ Clean and warm heating pad
- ☐ Remove ABL 5 machine from Standby
- ☐ Perform daily maintenance and record on maintenance log
- ☐ Perform 2 point calibration
- ☐ Explain procedure to participant using suggested text
- ☐ Prepare heparin flush syringes

QC Checklist for drawing blood gas sample

- ☐ Record fasting status, oxygen use, time, and temp on data collection sheet

- ☐ Label syringe, verify participant number
- ☐ Wash hands, put on gloves
- ☐ Insert butterfly needle with heplock into dorsal hand vein
- ☐ Break suction on 3 cc syringe and 10 cc syringe
- ☐ Correctly draw standard blood samples
- ☐ Flush heplock with 200 units of heparin flush
- ☐ Wrap hand in warm heating pad
- ☐ Wait 15 minutes
- ☐ Flush with 100 units of heparin flush
- ☐ Draw off waste with waste syringe
- ☐ Draw blood gas in preheparinized syringe
- ☐ Invert syringe three to four times to mix heparin and blood
- ☐ Put cap on syringe
- ☐ Expel all air from syringe and place on ice
- ☐ Remove butterfly and apply band-aid
- ☐ Clean heating pad for next participant

QC Checklist for analyzing blood gas sample

- ☐ Ensure daily maintenance has been performed and machine is ready
- ☐ Write room temperature on the Blood Gas Results data collection form
- ☐ Analyze yellow QC ampoule in duplicate and record
  - ☐ Shake QC vial for 15 seconds
  - ☐ Select “QC” on machine
- ☐ Analyze participant sample in triplicate and record
  - ☐ Select “Blood” on machine
  - ☐ Aspirate sample
  - ☐ Enter Health ABC Enrollment ID number
- ☐ Analyze red QC ampoule in duplicate and record
  - ☐ Shake QC vial for 15 seconds
  - ☐ Select “QC” on machine
- ☐ Place blood gas machine back into Standby mode