A1C Point-of-Care Procedure	**Attachments** ☐ Yes ☒ No
Key words A1C; Glycosylated Hemoglobin, DCA meter, Siemens Vantage	**Number** **GHI-PC-CLINIC LAB-PROCEDURES-A1C POCT v. 04-2019**
Category Clinic Point of Care Laboratory Procedure	**Effective Date** **See Electronic File**
Manual Laboratory Point of Care Procedure Manual	**Last Review Date** **See Electronic File**
Issued By Laboratory	**Next Review Date** **See Electronic File**
Applicable Primary Care Nursing Staff	**Origination Date** **June 2007**
	Retired Date
Level of Complexity Waived	
Review Responsibility Regional Clinic Lab Supervisors	**Contact** Regional Clinic Lab Supervisors
APPROVAL(S) Laboratory Medical Director	**Approved Date**

A1C Point of Care Testing Procedure

I. PURPOSE/PRINCIPLE

The Hemoglobin A1C is used in monitoring the long-term care of persons with diabetes.

II. POLICY

Clinic nursing staff performing this testing will follow the approved techniques outlined in this procedure.

HealthPartners family of care uses single-use needle and devices for all phlebotomy and blood collection procedures. Should it be necessary to re-stick a patient, a new, single-use needle or device will be used.

III. PROCEDURE

Specimen:

The 1 microliter sample of whole blood will be collected by fingerstick technique.
*Venous blood collected in EDTA, heparin, fluoride/oxalate or citrate tube may also be acceptable.

Reagent/Materials:

Upon receipt of the kit containing reagent cartridges and calibration card, check the temperature indicator in the cover of the box. If the indicator has turned red, the reagent cartridges should not be used.

1. DCA Analyzer
2. DCA HbA1C Control Kit
3. DCA HbA1C Reagent Cartridges
4. Capillary Holders

5. Calibration Card
6. Lint-free tissues
7. Fingerstick Supplies

Storage:

Reagent cartridges can be kept for up to three months at room temperature anytime before the expiration date. If kept refrigerated, cartridges may be used up to the last day of the expiration month. The capillary holders may be refrigerated or stored at room temperature.

Note: If cartridges are to be kept at room temperature, document on the box the new expiration date of 3 months after placing at room temperature.

Running Controls:

1. Two levels of external controls are run monthly or with a new lot or shipment of cartridges.
2. Both the normal and abnormal controls are lyophilized and must be reconstituted prior to use. Prepare according to the following:
   a. Remove control vial from refrigerator just prior to reconstitution. Write the Opened expiration date (90 days after reconstitution) on the control vial.
   b. Gently tap the bottom of the vial on the counter to collect as much material as possible on the bottom of the vial.
   c. Remove cap from the control vial.
   d. Holding the Reconstitution Fluid dropper bottle vertically, add 6 drops of fluid to the vial.
      - Note: Discard the first drop to ensure constant volume of the drops thereafter. The number of drops used for reconstitution can vary $\pm$ 2 drops.
   e. Replace the cap and swirl the vial several times. Let stand at room temperature for 15 minutes.
   f. After 15 minutes, invert and rotate the vial being sure to coat all surfaces of the vial and cap. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.
   g. Replace cap with dropper bulb top.
   h. Control material may remain at room temperature for a period of 30 minutes when testing, but should be stored refrigerated at all other times. The control material should be used at room temperature.
   i. Store un-reconstituted controls according to package insert. Un-reconstituted vials may be used until the last day of the expiration month shown on the vial. Do not use if moisture is present in the vial, prior to reconstitution. This is an indication of deterioration of the control material.
3. After preparing control material remove a glass capillary holder from the plastic wrap.
4. Aspirate a small portion of the control material using the dropper bulb top. Avoid introducing any air bubbles into the solution. Hold the glass capillary tube to the Control Solution collected in the eyedropper and completely fill the 1microliter tube. Touch ONLY the tip of the tube to the Control Solution.
   a. Important: Do not allow the Control Solution to come in contact with the wider plastic part of the Capillary Holder. Any Control Solution adhering to the Capillary Holder may be transferred into the reaction buffer, along with the 1microliter Control Solution in the glass capillary tube. This may cause an invalid HbA1C control result or possibly an error message.

   NOTE: If Control Solution comes in contact with the plastic of the Capillary Holder, discard the Capillary Holder in a sharps container.
5. After filling the glass capillary, insert into a reagent cartridge and run sample as directed in the Analyzing Patient Sample section below.
6. Tape the printout on the control worksheet and verify the results are within the acceptable range indicated in the package insert located in each control kit. All control results must be within the acceptable range before any patient sample is tested and resulted.
7. If a control fails to perform as expected
   I. Verify use of correct control and kit, correct lot number, expiration dates acceptable
   II. Remix and repeat
      a. If acceptable – document corrective action, record results and proceed with patient testing

b. If repeat failure – document corrective action and proceed to step III.

III. Open a new control, mix and test
   a. If acceptable – document corrective action, record results and proceed with patient testing
   b. If repeat failure – document corrective action and proceed to step IV.

IV. Open a new box of cartridges
   a. If acceptable – document corrective action, record results and proceed with patient testing
   b. If repeat failure – document corrective action and proceed to step V.

V. Contact your clinic laboratory

Calibration:

Calibrate the System for each new lot number of reagents cartridges.

1. Locate the calibration card in the box of reagents.
2. Locate the dot (on the instrument) next to the bar code track.
3. Locate the bar code on the calibration card.
4. Hold the card so that the bar code faces right.
5. Insert the card into the bar code track (above dot). Hold card gently against the right side of track.
6. Quickly (within 1 sec.) and smoothly, slide the card down past the dot. A beep sounds to signal a successful scan.
   *If no beep sounds, repeat procedure. If a beep repeatedly fails to sound refer to troubleshooting.

Preparing Patient Samples:

1. Remove one foil package (containing a reagent cartridge) from storage.
   - Allow warming to room temperature for 10 minutes if refrigerated.
   - Do not use scissors to cut open the foil pouch. Scissors can damage the reagent cartridge, the flexible pull-tab on the cartridge, or the sack containing desiccant.
   - To open foil pouch, tear down from corner notch (until entire long side of pouch is open).
   - Discard the reagent cartridge if the cartridge is damaged, the flexible plastic pull tab is missing, the desiccant is missing, or if loose desiccant particles are found inside the foil pouch.
   - **Once the foil pouch has been opened it must be used within one hour.**
2. Obtain one capillary holder.
3. Following approved fingerstick technique; obtain a small drop of blood on the finger.
4. Hold the capillary holder at an angle.
5. Touch ONLY the tip of the glass capillary to the drop of blood on the finger until the capillary is filled. If blood touches the capillary holder, discard the holder.
   - If EDTA, heparin, fluoride/oxalate or citrate tubes were used for collection, remove the cap, carefully hold the tube at an angle and touch the tip of the capillary to the blood. A disposable pipette may also be used to obtain blood from the tube, and then touch the tip of the capillary to the blood at the end of the pipette.
6. Using a lint-free tissue, carefully wipe the outside of the glass capillary without allowing the tissue to touch the open end of the glass capillary. If sample loss is obvious, discard capillary holder in a sharps container. Inspect the glass capillary for the presence of bubble(s). If bubble(s) are present, discard capillary holder in a sharps container.
7. Carefully insert the capillary holder into the reagent cartridge until the holder gently snaps into place. **When handling the reagent cartridge, do not touch (or otherwise contaminate) the optical window or erroneous test results may occur.**
8. **Once the glass capillary is filled with sample, analysis MUST begin within 5 minutes.**

Analyzing the Patient Sample:

1. Locate the dot (on the instrument) next to the bar code track.
2. Locate the bar code on the reagent cartridge.

3. Hold the reagent cartridge so that the bar code faces right and insert the reagent cartridge above the dot into bar code track.
4. Quickly (within 1 sec.) and smoothly, slide the reagent cartridge down past the dot and listen for a beep sound to indicate a successful scan. If no beep sounds repeat the procedure.
5. Open the cartridge compartment door after seeing the display "load cartridge, pull tab, close door".
6. Insert the reagent cartridge with the bar code facing right into the cartridge compartment until a subtle snap is heard/felt.
7. Using a smooth, slow, continuous motion, pull flexible plastic pull-tab completely out of reagent cartridge and close the door.
   - If you should accidentally close the door before you pull the flexible plastic tab, you have 5 seconds to re-open the door; the display returns to "load cartridge." You may now pull the tab or correct existing problem.

8. Entering Patient Data Using the Touchscreen
   - The Sample Data screen displays when the system detects that the system door is closed. The appearance of this screen after the 5 second delay indicates that the test is in progress.
   - Select **Patient ID**
     Use the alphanumeric keypad to key in the MRN (medical record number) of the patient sample followed by Enter
   - Use the page down arrow key to advance to the next page
   - Select the **Operator ID** to key in your user ID/Initials
   - Touch the **NEXT** key to continue to the next page. The system screen displays the current test in progress with a count-down timer to indicate when the test will be completed. .
9. The patient result will display on the screen and a paper copy of the result will automatically print.
10. To remove the cartridge
    a. Open the cartridge compartment door.
    b. Locate the button on the right side of the cartridge compartment. Push and hold it down with your right hand.
    c. With your left hand, gently push the plastic tab on the cartridge to the right; this action releases (unlocks) cartridge.
    d. Pull the reagent cartridge out of the compartment.
    e. Dispose of the cartridge in the regular trash.

Reporting Results

Nursing staff:

- Tape the instrument printout to the A1Cpatientworksheet
- A1C results are linear from 2.5% - 14.0%.
- A1C results over 14.0% will be reported as >14.0% in the BEAKER lab computer system
- Send the A1C patient worksheet to the Clinic lab for entry into BEAKER, the laboratory information system.

Lab staff: Enter the number directly, ONE decimal place. If results >14.0, it will default to >14

All results above the reference range (>5.6%) will be appended with a comment to assist with interpretation. The comment will read:

For patients not previously diagnosed with diabetes:

5.7-6.4%: Increased risk for diabetes (pre-diabetic)

6.5% and greater: Diagnostic for diabetes

For diabetic patients:

<8.0%: Goal of therapy for ages 18-75. Providers may recommend a higher or lower goal for specific individuals.

Refer to EPIC Beaker for result entry procedure

Reference Range:

4.3-5.6%

Test Limitations:

- A1C results are accurate in patients with a hemoglobin of 7 to 24 g/dL. Most patients will fall within hemoglobin range.
- Patient with severe anemia or polycythemia may have hemoglobin values outside of the range of 7 to 24 g/dL. A1C results should be interpreted with caution in these patients or a different A1C methodology should be used.
- Patients with a hemolytic disease or a RBC turnover rate higher than normal may have a falsely low A1C value.

Notes:

1. Patients with hemoglobin values of less than 7.0 g/dL or greater than 24.0g/dL should be tested by an alternate method.
2. Patients with high amounts of Hemoglobin F (>10%) may yield lower than expected A1C results with this test.

Meter Maintenance

Weekly: Using a lint-free cloth dampened with water or ethanol, clean the onboard barcode reader window and the exterior of the meter.

Materials Required:

- Kim Wipe
- Distilled water

1. Turn the power off and disconnect the power cord before cleaning the barcode window.
2. Clean the barcode window with a lint-free cloth dampened with water
3. Clean the exterior of the instrument with a separate lint-free cloth dampened with water
4. Connect the power cord after the exterior is clean and dry

1 Onboard Barcode Reader

Quarterly Maintenance

a. **Perform Optical Test**

The DCA Vantage system is designed to run a comprehensive series of self checks of the optical measurement system. These self checks are run automatically during every patient and Quality Control sample measurement. If any of the measurement criteria are out of specification, the system displays an error code and no result is given for that measurement. In addition to the automatic self checks performed during every sample and Quality Control measurement, an optical test cartridge is available for you to run additional system performance checks before calling your local service provider for assistance. The main purpose of this test cartridge is to help you eliminate system hardware issues if errors are reported during sample and Quality Control measurements.

Use the optical test cartridge:

- When following troubleshooting steps in the Operator's Guide
- If Quality Control samples do not give the expected values
- During the installation procedure

- If you relocate the instrument
- As part of the quarterly maintenance schedule

NOTE: The optical test cartridge is reusable. Do not discard.

Optical Test Values

- Precision and drift—it measures the drift of the optics over 20 transmittance readings taken during that period. The measured values are Drift T, the average drift in transmittance, and Drift Max, the difference between the minimum and maximum transmittance of the 20 transmittance readings. When the optical test completes, the DCA Vantage system displays the **Mean T**, **SD T**, **Drift Max**, and Drift T readings.
  The following table displays the acceptable value ranges for the Optical Tests.

Values	Range
Mean Transmittance (Mean T)	0.95-1.05
Standard Deviation (SD T)	<0.0015
Drift Max	<0.0280
Drift T	No applicable limits

Materials Required:

- Optical Test Cartridge

Performing an Optical Test

1. Locate the barcode on the optical test cartridge.
2. Hold the cartridge so that the barcode faces right.
3. Insert the cartridge into the barcode track.
4. Smoothly slide the cartridge down the barcode track. A beep sounds to signal a successful scan.
5. Open the cartridge compartment door.
6. Hold the optical test cartridge so that the barcode faces to the right.
7. Insert the cartridge into the compartment until you hear a snap.

NOTE: The cartridge is designed to fit one way into the system

8. Close the door

a. The test runs for 6 minutes after which the test results will print

9. Tape the instrument printout to the back of the maintenance log
10. To remove the cartridge, open the cartridge compartment door and locate the button on the right side of the cartridge compartment.
11. Push and hold down the button with your right hand.
12. Gently push the plastic tab on the cartridge to the right with your left hand. This releases the cartridge.
13. Pull the cartridge out of the compartment and retain for future use.

b. **Changing the Air Filter**

Materials Required:

- Air Filter

Remove the filter holder from the back of the system

1. Pull the holder off from the top.
2. Dispose of the old air filter
3. Place the new air filter into the filter holder.
4. Place the filter holder back on the system

1 Filter Cover

1 Air Filter
2 Air Filter Holder

Removing and Cleaning the Cartridge Spring and Cartridge Area
CAUTION
Do not allow liquid to drip into system. If liquid drips into the system, you can damage the optics.
Materials Required:

- lint-free cloth
- water
- paper clip
- sponge swab

1. Turn the power off and disconnect the power cord before cleaning the cartridge compartment.
2. Open the cartridge compartment door as far as possible
3. Wipe the inside surface of the compartment door and surfaces on both sides of the compartment using a lint-free cloth dampened with water
4. Dry the surface using a clean, dry, lint-free cloth
5. Locate the cartridge return spring inside the cartridge holder

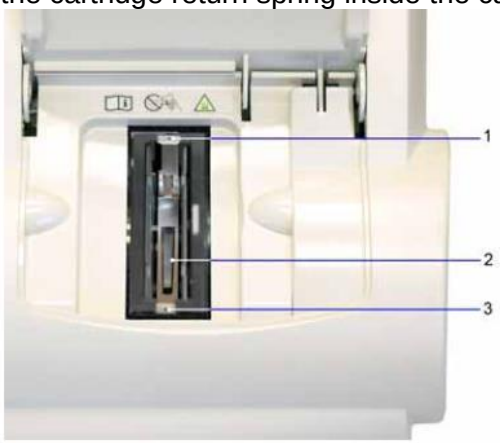


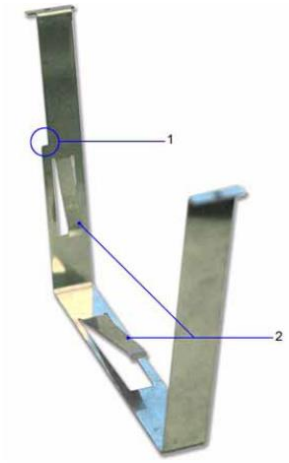
Figure 32 Return Spring in Cartridge Compartment

1 Top Hole
2 Leaf Spring
3 Bottom Hole

6. Insert the tip of a straightened paper clip into the top hole on the spring
7. Gently pull the metal end towards the center of the cartridge compartment to release one side of the spring from the cartridge holder
8. Insert the tip of a straightened paper clip into the bottom hole on the spring to release the other side of the spring from the cartridge holder
9. Pull the cartridge return spring completely out of the system
10. Clean the cartridge return spring using a lint-free cloth dampened in water

11. Dry the cartridge return spring with a clean, lint-free cloth

NOTE: Ensure the leaf springs are not bent or damaged while cleaning. Damaged leaf springs do not function properly.



1 Spring Cut-out
2 Leaf Springs

Cartridge Return Spring

1. Using a clean, dry, sponge swab, remove any spilled liquid from the cartridge holder.
2. Rotate the cartridge holder with the compartment door partially closed to locate and remove any additional liquid.
3. Dampen a sponge swab with water and clean the cartridge holder, rotating the cartridge holder as necessary
4. Locate the vertical grooves inside the cartridge compartment
5. Locate the front and back slots near the top of the compartment
6. Locate the leaf spring on one side of the cartridge return spring

CAUTION

- Do not use a cotton swab. Cotton fibers that are left on the surface can interfere with the system's optical systems.
- Do not allow liquid to drip off of the sponge swab into the system. If liquid drips into the system, you can damage the optics.

Rotating the Cartridge Compartment

With the leaf spring oriented toward the back of the system, complete the following steps to lower the leaf spring into the system:

1. Hold on to both sides of the cartridge return spring
2. Pinch the sides together and lower the spring into the system by sliding the sides of the spring between the vertical grooves in the compartment
3. Release the spring
4. Gently and carefully push down on the edge of the cartridge return spring and insert the edge into the slot

5. Release the spring again to attach the opposite side of the cartridge return spring to the cartridge compartment

As Needed Maintenance

The following are instructions for more commonly performed maintenance tasks that are performed on an as-needed basis. For instructions for other as-needed maintenance tasks, refer to the DCA Vantage Operator's Guide.

a. **Loading Paper on the Onboard Printer**

1. Ensure the system is at the Home screen
2. Turn the system so that you are looking at the back
3. Use the tab to lift the cover off
4. Lift the paper feeder up
5. Push the plastic paper cover down
6. Remove the paper roll
    a. Lift up the roll
    b. Tear the paper between the roll and the printer
    c. Remove the core and remaining paper on the roll
7. Remove any paper remaining in the printer
    a. Locate the printer paper release lever (this lever is colored dark gray and is located on the right of the printer when looking at the front of the system)
    b. Pinch and lift the front of the lever to raise the paper guide
    c. Carefully pull paper through the printer in its normal direction of travel

1 Printer Cover
2 Paper Feeder

8. Hold the roll just above the printer, with the paper unrolling from underneath
9. Push the paper gently under the roller at the back of the printer

10. Load the paper into the paper feeder
11. Push the plastic tab to cover the paper
12. Pull the paper feeder down
13. Pinch and push down on the gray paper release lever to hold the paper in place
14. Load the paper into the paper slot on the cover and close the cover

1 Printer Cover
2 Paper Feeder

Troubleshooting:

1. If there is a problem with the DCA Analyzer refer to the troubleshooting section of the Operating Manual.
2. Siemens Healthcare Diagnostic may be contacted for help with troubleshooting at 1-877-229-3711 option 14. To find the serial number for the meter, remove the panel to the air filters and it is located inside.
3. The laboratory may be contacted for assistance with troubleshooting or other problems or concerns.

Resources:

Reference:

DCA Operating Manual
DCA HemoglobinA1C Reagent Kit package insert

Author/Reviewer(s):

Sherry Cooper
Denise Bergo
AKHoward
Dylan Eaton
MLLaFromboise
CARussell
KKLindberg
AMWherry