HealthPartners/GHI

A1C Point-of-Care Procedure (Specific to Riverside Clinic, Health Specialty, Bloomington, Midway, and St. Paul clinics)	**Attachments** ☐ Yes ☒ No
Key words A1C; Glycosylated Hemoglobin, DCA meter, Siemens Vantage	**Number** **GHI-PC-CLINIC LAB-PROCEDURES-A1C POCT v. 04-2013**
Category Clinic Point of Care Laboratory Procedure	**Effective Date** **June 2007**
Manual Laboratory Point of Care Procedure Manual- Specific to Riverside Clinic	**Last Review Date** **April 2013**
Issued By Laboratory	**Next Review Date** **April 2014**
Applicable Riverside Primary Care Nursing Staff	**Origination Date** **June 2007**
	Retired Date
Level of Complexity Waived	
Review Responsibility Laboratory Technical Consultants	**Contact** Lab Technical Consultants
APPROVAL(S) Laboratory Medical Director	**Approved Date**

A1C Point of Care Testing Procedure
Test Procedure (Pages 1-8)
Quality Control (Page 5)
Maintenance (Pages 6-7)
Computer Entry (Pages 9-10)

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.

HealthPartners family of care will clean the outside of a POCT meter with an approved disinfectant wipe (i.e., Sanicloth AF) after each patient test for meters that come into direct contact with patients in accordance to HPMG policy and CDC requirements.

III. PROCEDURE

Specimen:

The 1 microliter sample of whole blood will be collected by fingerstick technique.

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. Calibration Log
7. Control Log
8. Lint-free tissues.
9. Fingerstick Supplies
10. Worksheets for logging results

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.

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.
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 listed 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. After the testing is completed record the displayed result before removing the cartridge.
9. 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.

   Note: If, for whatever reason, the meter is brought to the patient’s side for testing, the outside of the meter must be cleaned with an approved disinfectant wipe (i.e. Sanicloth AF) before testing the next patient. Allow the meter to dry before testing. Do not allow moisture into the reagent cartridge slot.

   e. Dispose of the cartridge.

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 then normal may have a falsely low A1C value.

Reporting Results

- Record the test results on the worksheet
- A1C results are linear from 2.5% - 14.0%.
- A1C results over 14.0% will be reported as >14.0% in SunQuest.
- Send the A1C worksheet to the Clinic lab for entry into SunQuest, the laboratory information system.
- Provider records results in EPIC. Results >14.0 should be recorded as >14.0%.

Running Controls:

1. Two levels of external controls should be run monthly or with a new lot or shipment.
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 ± 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 unreconstituted controls according to package insert. Unreconstituted 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. **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 above. Discard the glass capillary in a sharps container after analysis is complete.
6. Record controls values on Control Log and verify that they are within acceptable range indicated in the package insert located in each control kit before running patient samples.

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 TC may be contacted for assistance with troubleshooting or other problems or concerns.

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

- Clean the exterior meter after each patient.
- Quarterly, perform the following:
  - Change filter
  - Clean scanning screen
  - Run Optical cartridge
  - Clean cartridge area

Reference:

DCA Operating Manual
DCA HemoglobinA1C Reagent Kit package insert

Author/Reviewer(s):

Sherry Cooper
Denise Bergo
AKHoward

A1C , Whole Blood, Fingerstick

Order Code: PA1C
For Riverside, Health Specialty, Bloomington, Midway and St. Paul clinics

Nurses at Riverside, Health Specialty, Bloomington, Midway and St. Paul Clinics will order and perform the A1C fingerstick testing. The results will be recorded on a worksheet with the nurse code who performed the test.

Clinic Lab staff release PA1C order from Epic into Misys (Sunquest) and enter the PA1C results from the worksheet using their tech code PLUS the nurse's code.

ORDERING:

After the computer has assigned an accession number in RE, you will be prompted for the following:

RESULTING: PA1C

Function MEM
Enter your tech code plus the nurse's code
Example: 20-2381

WORKSHEET:
Worksheet _ _A1C

RESPONSE:

CODE	NAME	RESPONSE
PA1C	Point of Care A1C	Enter the number directly, ONE decimal place If results >14.0, the PA1C will result as >14.0%.

ADDITIONAL INFORMATION:
The computer will append the code –xxx PA1C results.

Authors
AKHoward