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Point of Care Testing	Procedure	8/11/15	POC-56 Revision 5

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Chelsie Ross	Karen Scott	Testing personnel documents acknowledge of reading procedures during training and annual competency

Approval*:
Point of Care Division Director University Hospitals Laboratory Medical Director

Approval and Acknowledgements
Refer to QPulse system and Document Details report for laboratory directors(s)' electronic signature approval, employee acknowledgment and effective date.

1. PRINCIPLE

1.1. Hemoglobin A1c is formed by the non-enzymatic glycation of the N-terminus of the ß-chain of hemoglobin Ao. The level of Hemoglobin A1c is proportional to the level of glucose in the blood over a period of approximately two months. Thus, Hemoglobin A1c is accepted as an indicator of the mean daily blood glucose concentration over the preceding two months. Studies have shown that the clinical values obtained through regular measurement of hemoglobin A1c leads to changes in diabetic treatment and improvement of metabolic control as indicated by a lowering of Hemoglobin A1c values. The American Diabetes Association (ADA) recommends measurement of hemoglobin A1c levels two to four times per year, less frequently in patients with stable control.

1.2. The DCA Vantage is a semi-automated, benchtop system. It is designed to quantitatively measure the percent of Hemoglobin A1c in blood. Tests performed using the DCA Vantage A1C systems are intended for *in vitro* diagnostic use. The A1C is used in correlation with the patient's glucose monitoring log to adjust clinical treatment.

1.3. This assay is based on a latex immunoagglutination inhibition methodology. Both the concentration of Hemoglobin A1c (HbA1c) specifically and the concentration of total hemoglobin are measured, and the ratio reported as a percent Hemoglobin A1c. All of the reagents for performing both reactions are contained in the DCA Systems Hemoglobin A1C Reagent Cartridge (Figure 1).

1.4. Chemical Principles:

1.4.1. For the measurement of total hemoglobin, potassium ferricyanide is used to oxidize hemoglobin in the sample to methemoglobin. The methemoglobin formed then complexes with thiocyanate to form thiocyanmethemoglobin, the colored species which is measured. The extent of color development at 531nm is proportional to the concentration of total hemoglobin in the sample.

1.4.2. For measurement of specific hemoglobin A1c, an inhibition of latex agglutination assay is used. An agglutinator (synthetic polymer containing multiple copies of the immunoreactive portion of HbA1c) causes agglutination of latex coated with HbA1c specific mouse monoclonal antibody. This agglutination reaction causes increased scattering of light which is measured as an increase in absorbance at 531nm. HbA1c in whole blood specimens competes for the limited number of antibody-latex binding sites causing an inhibition of agglutination and a decreased scattering of light. The decreased scattering is measured as a decrease in absorbance at 531 nm.

1.4.3. The HbA1c concentration is then quantified using a calibration curve of absorbance versus HbA1c concentration.

1.4.4. The percent HbA1c in the sample is calculated as follows:

$$\% \text{ HbA1c} = \frac{[\text{HbA1c}]}{[\text{Total Hemoglobin}]} \text{ X100}$$

1.4.5. All measurements and calculations are performed automatically by the DCA VANTAGE®+ Analyzer, and the screen displays percent HbA1c at the end of the assay.

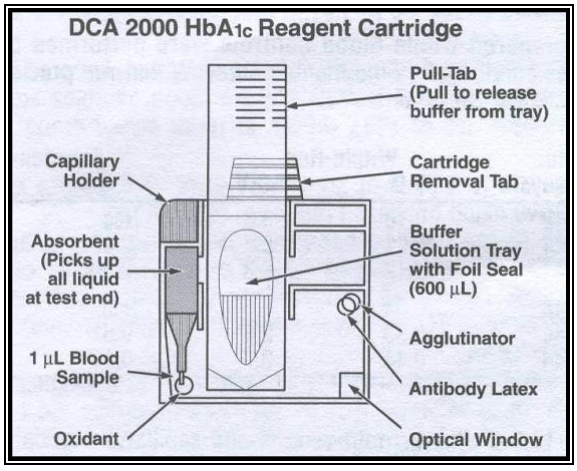


Figure 1

2. SCOPE OF DOCUMENT:

2.1. This document applies to OSU Doan/Rhodes /James/BS hospital Point of Care DCA Vantage Hemoglobin A1c testing locations

3. RESPONSIBILITY:

3.1. The coordinators and manager are responsible for maintaining this document and ensuring biennial review. The laboratory medical director is responsible for establishing and approving all changes before activating document.

4. SPECIMEN COLLECTION:

4.1. The provided glass capillary (within plastic capillary holder) holds 1 µL of whole blood. The blood sample may be obtained by finger stick or venipuncture.
4.2. Acceptable tube type for venous specimens is EDTA
4.3. Finger-stick(capillary) Procedure https://clinicallabs.osumc.edu/Pages/Laboratory-Policies-and-Procedures.aspx
4.3.1. Identify the patient with two identifiers
4.3.2. Using Universal / Standard Precautions set up the obtain all needed reagents and supplies:
a. DCA Systems HbA1c cartridge
b. Capillary holder
c. Lint free tissue
d. Alcohol wipes
e. Single use lancet
f. Gloves
g. Cotton ball
4.3.3. Check the patient's hand and fingers for any sign of edema. Make sure the puncture site is warm. Do not use the fifth finger, or any hand which has an IV. The puncture site should be on the palmer surface of the distal phalanx and not at the tip of the finger.
a. If evaluation of the fingers reveal edema or blood flow issues, collect a venipuncture sample. Follow laboratory specimen collection policy on venipuncture collection.
4.3.4. Finger stick: Select the puncture site and clean well with alcohol. Allow site to dry completely.
4.3.5. Using the lancet device, make a quick insertion of the lancet into the finger.
4.3.6. Wipe away the first drop of blood with a cotton ball; do not use alcohol, alcohol hemolyzes blood and may cause inaccurate results. Obtain a small drop of blood resting on the finger.
4.3.7. Dispose of all biohazard materials according to Hospital policy. Dispose of the single use lancets in a sharps container.
4.3.8. After the sample has been collected, apply pressure to the finger-stick site with a cotton ball.

5. REAGENTS/SUPPLIES:

5.1. Equipment: DCA Vantage® analyzer
5.2. DCA Systems® Reagent Kit
5.2.1. Each carton contains 10 reagent cartridges, 11 capillary holders, a calibration card, and 2 package inserts.
5.2.2. Reagents:
a. Antibody Latex: HbA1c-specific mouse monoclonal antibody adsorbed onto latex particles. 2.5% w/v antibody-latex in 10 mM glycine buffer; 16% w/v nonreactive ingredients (10µL dried in each reagent cartridge).
b. Agglutinator: 0.005% w/v poly (aspartic acid) polymer covalently attached to the HbA1c hapten in 20 mM sodium citrate buffer containing 0.1% w/v bovine serum albumin and 1% w/v nonreactive ingredients (10µL dried in each reagent cartridge).
c. Buffer Solution: 8.1% w/v lithium thiocyanate, 0.01% digitonin in 200 mM glycine buffer (0.6 mL in each cartridge).
d. Oxidant: 1.5% potassium ferricyanide in water, with 21% w/v nonreactive ingredients (10µL dried in each reagent cartridge).
5.2.3. Storage and Handling:

a. Temperature indicator: Upon receipt of the kit, check the temperature indicator located on the side of the carton. If the indicator has turned red, the reagent cartridges should not be used. Note time and date received, and for assistance in obtaining a replacement kit, refer to the instructions given on the carton.
b. Cartridge Storage: Recommended storage is refrigerated at 2-8ºC for maximum reagent life. Alternately, the cartridges can remain at room temperature (15–32ºC) provided the expiration date on the carton is changed to three months from the date the carton is removed from the refrigerator or the date the carton was received. Do not use the cartridges past their expiration date. The capillary holders may be stored refrigerated or at room temperature.

5.3. DCA ® Hemoglobin A1c Normal and Abnormal Control Kit

5.3.1. Each kit contains 2 DCA® Hemoglobin A1c Normal control vials, 2 DCA® Hemoglobin A1c Abnormal control vials, 1 bottle of reconstitution fluid, 4 eyedropper cap assemblies, 2 package inserts, and 1 DCA® Normal and Abnormal Control card.

WARNING: POTENTIALLY BIOHAZARDOUS MATERIAL. For in vitro diagnostic use. This product contains a substance known to cause cancer. Human sourced materials were used in the manufacturing of this product. Each donor unit was tested for Hepatitis B surface antigen, antibodies to Hepatitis C, and antibodies to HIV1 and HIV-2 and was found to be negative. Universal precautions must be observed when using this product.

5.3.2. The DCA® Hemoglobin A1c Normal and Abnormal controls included in the controls kit contain a stable lyophilized hemolysate of human blood. Each bottle, when reconstituted, contains enough control solution to run approximately 90 DCA® Hemoglobin A1c control tests. The reconstitution fluid (deionized water) contains 0.09% w/v sodium azide as a preservative.

5.3.3. Storage and Handling:

a. Unreconstituted: DCA® Hemoglobin A1c Normal and Abnormal controls are stored at 2 – 8ºC and can be used until the last day of the expiration month printed on the bottle. Any appearance of moisture in the bottle, prior to reconstitution, is an indication of deterioration of the material and renders it unusable and must be disposed of accordingly.
b. Reconstitute:
   5.3.3.b.1. Remove vials from the refrigerator
   5.3.3.b.2. Gently tap the bottom of the control bottle, to tap down the dry reagent.
   5.3.3.b.3. Discard any reconstituted control solution appearing turbid (cloudy) or contaminated
   5.3.3.b.4. Discard the first drop of the reconstitution fluid from the dropper bottle, then drop 6 drops on to the control vial.
   5.3.3.b.5. The reconstituted controls are stable for 3 months when stored at 2–8C. The expiration date on the bottle must be changed once reconstituted.
   5.3.3.b.6. Let the control set for 15 minutes before use. Mix well before use
c. Reconstituted: DCA® Hemoglobin A1c Normal and Abnormal control solutions, once reconstituted with six drops of the reconstitution fluid, must not be frozen or allowed to stand uncapped. The controls can remain at room temperature for 30 minutes during testing, but must be stored at 2 – 8ºC in an upright position and tightly capped at all other times.

6. SPECIAL SAFETY PRECAUTIONS:

WARNING: BODY FLUID PRECAUTION
Blood is a body fluid capable of transmitting infectious diseases. Universal precautions for the prevention of the transmission of blood borne pathogens must be in effect at all times.

6.1. PPE such as gloves, are required. Gloves should be replaced as soon as feasible if they become torn or punctured, or lose their ability to function as a barrier.
6.2. Use universal precautions when handling specimens.

7. CALIBRATION/PROGRAMMING/MAINTENANCE:

7.1. **Instrument calibration**: The DCA VANTAGE® Analyzer is calibrated by the manufacturer. Thereafter, the instrument automatically self-adjusts during first-time power-up and during each assay. In the event the system is unable to make appropriate internal adjustments, an error message is displayed.

7.2. **Reagent calibration**: Before reagent cartridges are released by the manufacturer, each lot of reagent cartridges undergoes a thorough analysis and characterization. Values of calibration parameters based on a DCCT reference method are determined which provide for optimal reagent performance. The DCA VANTAGE® HbA1c test method is NGSP Certified. The DCA VANTAGE® HbA1c test method is traceable to IFCC reference materials and test methods. The values for the calibration parameters are encoded onto the calibration card provided with each lot of reagent cartridges. Prior to use of each new lot of reagent cartridges, the calibration bar code is read by the instrument to store the calibration curve and lot number information in the instrument. The instrument can store up to sixteen calibrations for the DCA VANTAGE® HbA1c Assay. Each of the calibrations is for a different lot number. If no calibration curve is in the instrument for a particular lot number of cartridges, the instrument will prompt the user to scan the calibration card before the cartridge can be used.

7.2.1. Perform the calibration procedure for each new lot number of reagent cartridges.

a. Locate the dot (on the instrument) next to the bar code track.
b. Locate the bar code on the calibration card.
c. Hold the calibration card so that the bar code faces right.
d. Insert the calibration card (above dot) into bar code track. Hold card gently against the right side of track.

e. Quickly (within 1 second) and smoothly, slide the calibration 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, page 107 in the DCA VANTAGE® Operating Manual.

7.3. Viewing Calibration Data

7.3.1. At the Recall menu, select Calibration Data. The Calibration Data screen displays.

7.3.2. Select one of the following options:

a. HbA1c The HbA1c calibration data displays.

7.3.3. Highlight the calibration data that you want to display, and select View. The Calibration Data screen displays.

7.3.4. To return to the Recall menu, select Recall.

7.4. Maintenance procedure

7.4.1. Handle the instrument with extreme care. Severe mechanical shocks can damage and/or dislodge internal parts and connections.

⚠ **IMPORTANT**: Do not use sprays. Sprays will permanently damage the optical system.

7.4.2. Record all maintenance on the applicable maintenance form.

7.4.3. Weekly

a. Clean the exterior and the bar code window with a lint-free cloth dampened with water.

7.4.4. Quarterly

a. Change the air filter
b. Run the Optical Test Cartridge and record the results on the maintenance form.
c. Remove and clean the cartridge spring and cartridge area

7.4.4.c.1. Materials Required:
- 7.4.4.c.1.1. Lint free cloth
- 7.4.4.c.1.2. Water or ethanol
- 7.4.4.c.1.3. Paper clip or similar device
- 7.4.4.c.1.4. Mild detergent
- 7.4.4.c.1.5. Sponge swab

7.4.4.c.2. Ensure the power is off

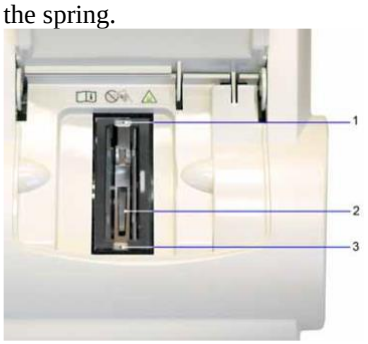
7.4.4.c.3. Open the cartridge compartment door as far as possible.

7.4.4.c.4. Wipe the inside surface of the compartment door and surfaces on both sides of the compartment using a lint-free cloth dampened with water or ethanol

7.4.4.c.5. Dry the surface using a clean, dry, lint-free cloth.

7.4.4.c.6. Locate the cartridge return spring inside the cartridge holder.

7.4.4.c.7. Insert the tip of a straightened paper clip (or other like device) into the top hole on the spring.



1. Top Hole
2. Leaf Spring
3. Bottom Hole

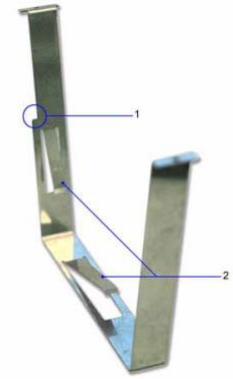
7.4.4.c.8. Gently pull the metal end towards the center of the cartridge compartment to release one side of the spring from the cartridge holder.

7.4.4.c.9. Repeat step 7.4.4.a.7 to release the other side of the spring from the cartridge holder

7.4.4.c.10. Pull the cartridge return spring completely out of the system.

7.4.4.c.11. Clean the cartridge return spring using any of the following items:
- 7.4.4.c.11.1. Lint-free cloth dampened in water or ethanol

Note: Ensure the leaf springs are not bent or damaged while cleaning.



1. Spring Cut-Out
2. Leaf Springs

7.4.4.c.12. Dry the cartridge return spring with a clean, lint-free cloth.

7.4.4.c.13. Using a clean, dry, sponge swab (provided in the Cleaning Kit), remove any spilled liquid from the cartridge holder. Do not use a cotton swab. Cotton fibers that are left on the surface can interfere with system's optical systems.

7.4.4.c.14. Rotate the cartridge holder with the compartment door partially closed to locate and remove any additional liquid.

Rotating the Cartridge Compartment

7.4.4.c.15. Dampen a sponge swab with water or ethanol

7.4.4.c.16. Clean the cartridge holder, rotating the cartridge holder as necessary

Caution: 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.

7.4.4.c.17. Locate the vertical grooves inside the cartridge compartment

7.4.4.c.18. Locate the front and back slots near the top of the compartment

7.4.4.c.19. Locate the leaf spring on one side of the cartridge return spring

7.4.4.c.20. With the leaf spring oriented toward the back of the system, complete the following steps to lower the leaf spring into the system:

7.4.4.c.20.1. Hold on to both sides of the cartridge return spring.

7.4.4.c.20.2. 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.

7.4.4.c.20.3. Release the spring.

7.4.4.c.20.4. Gently and carefully push down on the edge of the cartridge return spring and insert the edge into the slot.

7.4.4.c.20.5. Repeat to attach the opposite side of the cartridge return spring to the cartridge compartment.

7.4.4.c.21. ***Cleaning the Cartridge Compartment Optical Window***

7.4.4.c.21.1. Remove the air filter from the back of the instrument.

7.4.4.c.21.2. Rotate the cartridge holder with the compartment door partially closed to locate the optical window. See Figure 5, Rotating the Cartridge Compartment

7.4.4.c.21.3. With the cartridge holder fully rotated, locate the two round holes on either side of the cartridge compartment. The optical window is the lower of the 2 openings, nearest the cover.

1. Optical window

7.4.4.c.21.4. Fully open the cartridge compartment cover.

7.4.4.c.21.5. Using a canister of pressurized, compressed air, carefully direct the spray of air through the optical window holes on both sides of the cartridge holder, aiming the nozzle toward the side or back of the instrument.

Caution: When using compressed air, hold the canister as vertically as possible, tilting the instrument if necessary. If you hold the canister at a sharp angle to the vertical, liquid propellant can escape from the canister and damage the optics. You must hold the canister in a nearly vertical position to get only a spray of air with no liquid.

7.4.4.c.21.6. Return the cartridge holder to its original position and close the compartment door.
7.4.4.c.21.7. Replace the air filter

7.4.5. As needed
a. Perform any of the above weekly or quarterly procedures as needed as a result of spillage, troubleshooting or contamination.

8. QUALITY CONTROL:

8.1. Run the DCA VANTAGE® HbA1c Normal and Abnormal controls with each new shipment, with each new lot number of kit used, each time a calibration card is scanned, at least every 30 days and/or when results do not match the patient's clinical condition or symptoms. Controls must be completed and have results within established limits *before* patient samples are run.

8.2. Take corrective action if controls are not within expected limits *before* patient samples are run.

8.3. QC Test Procedure

8.3.1. Locate the dot (on the instrument) next to the bar code track.

8.3.2. Locate the bar code on the control card. Hold the control card so that the appropriate bar code faces right. Note: make sure you are using the correct side of the control card for the particular DCA VANTAGE® HbA1c Normal or Abnormal Control level in use. C1 = Normal, C2 = Abnormal.

8.3.3. Insert the control card (above dot) into bar code track. Hold the card gently against the right side of track.

8.3.4. Quickly (within 1 second) 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 in DCA VANTAGE Operating Manual (Located on OneSource)

8.3.5. Prepare the reagent cartridge following the instructions in the Test Procedure section.

8.3.6. Locate the bar code on the reagent cartridge.

8.3.7. Hold the reagent cartridge so that the bar code faces right.

8.3.8. Insert the reagent cartridge (above dot) into bar code track

8.3.9. Quickly (within 1 second) and smoothly, slide the reagent cartridge 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 in DCA VANTAGE Operating Manual (Located on OneSource)

8.3.10. Open the cartridge compartment door.

8.3.11. Hold the reagent cartridge so the bar code faces right. Insert the reagent cartridge into the cartridge compartment until a subtle snap is heard/ felt. Hint: the cartridge is designed to fit only one way into the instrument. Do not force cartridge into instrument.

8.3.12. Using a smooth, slow, continuous motion, pull flexible plastic pull-tab completely out of reagent cartridge.

8.3.13. Close door. Dispose of flexible plastic pull-tab. Five seconds after the door is closed, a beep sounds and the assay begins. Note: If you 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(s).

8.3.14. Enter Operator ID by scanning or manual entry of badge ID

8.3.15. Note: if "CONTROL OUT OF RANGE" is displayed, press ESCAPE to display values of out-of-range control.

8.3.16. Remove the reagent cartridge
a. Open cartridge compartment door
b. Locate button on right side of cartridge compartment, push and hold button down
c. While holding button down, push plastic tab (on cartridge) to the right; this action releases (unlocks) cartridge
d. Pull the reagent cartridge out of the compartment and dispose in biohazard trash.

8.4. Internal Quality Control

8.4.1. To assure quality of both testing procedures and patient results for hemoglobin A1C, the DCA System performs 48 optical, electronic mechanical and reagent systems checks during the course of each specimen assay. These checks include calibration verification during every test. If an assay or

system error occurs during any individual measurement, the system automatically reports an error message, preventing the reporting of erroneous patient results.

8.4.2. Refer to the Operators Manual (located on OneSource), for error code explanation and troubleshooting suggestions.

9. TEST PROCEDURE:

9.1. If the reagent cartridge was stored in the refrigerator, allow the reagent cartridge to warm to room temperature for 10 minutes if left in the foil pouch or 5 minutes if removed from the foil pouch.

9.2. Open foil package containing the reagent cartridge (do not use scissors to cut open the package because this may possibly cause damage to the reagent cartridge). After opening the foil pouch, the reagent cartridge must be used within one (1) hour.

9.3. Open capillary holder package.

9.4. If filling the capillary with whole blood from a finger stick:

9.4.1. Hold the capillary holder at an angle.

9.4.2. Touch only the tip of the capillary to a small drop of blood on the finger until the capillary is filled.

9.5. If filling the glass capillary with blood obtained by venipuncture:

9.5.1. Mix sample well.

9.5.2. Tilt the sample so that the whole blood is to the edge of the tube.

9.5.3. Hold the capillary holder at an angle.

9.5.4. Touch only the tip of the capillary to the sample in the tube.

9.6. Using a lint-free tissue, wipe the outside of the capillary holder.

9.7. Inspect the capillary holder for presence of bubbles. If present, discard the capillary holder and fill a new capillary holder and continue.

9.8. Carefully insert capillary holder into the reagent cartridge until the holder gently snaps into place.

9.9. Locate the dot (on the instrument) next to the bar code track.

9.10. Locate the bar code on the reagent cartridge.

9.11. Hold the reagent cartridge so that the bar code faces right.

9.12. Insert the reagent cartridge (above dot) into bar code track.

9.13. Quickly (within 1 second) and smoothly, slide the reagent cartridge 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 the Troubleshooting section in the DCA VANTAGE® Operating Manual.

9.14. Open the cartridge compartment door.
9.15. Hold the reagent cartridge so the bar code faces right. Insert the reagent cartridge into the cartridge compartment until a subtle snap is heard/felt. Hint: the cartridge is designed to fit only one way into the instrument. Do not force cartridge into instrument.
9.16. Using a smooth, slow, continuous motion, pull the flexible plastic pull-tab completely out of reagent cartridge.
9.17. Close the door. Dispose of flexible plastic pull-tab. Five seconds after the door is closed, a beep sounds and the assay begins. Note: If you accidentally close the door before you pull the flexible plastic pull-tab, you have 5 seconds to re-open the door; the display returns to "LOAD CARTRIDGE". You may now remove the pull-tab and close the door again.
9.18. Entering Sample Data
  9.18.1. The Sample Data menu screen displays when the system detects the system door closes, and indicates a test is in progress after the 5-second delay, You must enter the following sample demographic information:
    a. Patient ID
    b. Operator ID
  9.18.2. Select Patient ID. The Patient ID screen displays.
    a. Manually enter or scan the Patient CSN.
    b. Select Enter.
    c. The patient ID displays next to the Patient ID button.
  9.18.3. Select User ID.
    a. Manually enter or scan the User ID (Badge ID)
9.19. After 6 minutes, the DCA VANTAGE® will display the result.
  9.19.1. The system displays the following information for each patient HbA1c test.
  9.19.2. Result Description
    - System Serial Number
    - Test Name
    - Sample Sequence Number
    - Sample ID
    - Cartridge Lot Number
    - Test Cartridge Scan Date and Time
    - Operator ID (Badge ID)
    - Comments (Any comments you entered regarding the patient).
    - HbA1c% (The percentage of HbA1c in the sample).

9.20. Remove the reagent cartridge
  9.20.1. Open cartridge compartment door
  9.20.2. Locate button on right side of cartridge compartment, push and hold button down.
  9.20.3. While holding button down, push plastic tab (on cartridge) to the right; this action releases (unlocks) cartridge
  9.20.4. Pull the reagent cartridge out of the compartment.

10. CALCULATIONS:

10.1. The result displayed needs no further calculations. The DCA VANTAGE® makes all necessary calculations.

11. INTERPRETATION OF RESULTS:

11.1. A (+) sign after the patient result indicates the result is above the reference range (high)
11.2. A (-) sign after the patient result indicates the result is below the reference range (low)
11.3. Result preceded by a less than sign (<): indicates a concentration below the lower limit of the test (under range). Report the result as <2.5% HbA1c. This method does not provide for re-assay using a larger sample aliquot. Results less than 2.5% are rare and may indicate that the sample contains substantial amounts of fetal hemoglobin (HbF) (does not react in the immunoassay); or that the patient may be

suffering from hemolytic anemia or polycythemia (conditions which often result in a significant decrease in the life span of red blood cells).

11.4. Result preceded by a greater than sign (≥): indicates a concentration above the upper limit of the test (over range). Report the result as >14.0% HbA1c. This method does not provide for re-assay using a diluted sample. To obtain a more quantitative test value at levels greater than 14%, another test method is required.

11.5. All laboratory tests are subject to random error. If the test result is questionable, or if clinical signs and symptoms appear inconsistent with test results, confirm the result, send a specimen to the laboratory.

12. REPORTING RESULTS:

12.1. Patient results are automatically transmitted to the patient's EMR by the LIS.
12.2. Refer to master listing chart for reference intervals
12.3. Refer to master listing chart for Analytical measurement range (technical range)
12.4. Refer to master listing chart reportable range (reportable range) CRR
12.5. Refer to Critical Result / Critical Value policy for critical values
12.6. In case of a system downtime the results will be stored in the DCA Vantage and can be transmitted to the medical record once the system is up and running and the instrument is downloaded. Alternately, the testing personnel can document the A1C results in the patient's IHIS flowsheet.

13. LIMITATION OF PROCEDURE:

13.1. The DCA VANTAGE® HbA1c assay gives accurate and precise results over a range of total hemoglobin of 7 to 24 g/dL. Most patients will have hemoglobin concentrations within these values. However, patients with severe anemias may have hemoglobin concentrations lower than 7 g/dL, and patients with polycythemia may have hemoglobin concentrations above 24 g/dL. Patients known to have these conditions should be assayed by a test employing a different assay principle if their hemoglobin concentrations are outside the acceptable range.

13.2. Glycated hemoglobin F (HbF) is not measured by the DCA VANTAGE® HbA1c assay. At levels of HbF less than 10%, the DCA VANTAGE® will accurately indicate the patient's glycemic control. However, at very high levels of HbF (>10%), the amount of HbA1c will be lower than expected because a greater proportion of the glycated hemoglobin will be in the form of glycated HbF. HbA1c results for such patients will not accurately indicate the patient's glycemic control and should not be compared to published normal or abnormal values.

13.3. Conditions such as hemolytic anemia, polycythemia, homozygous HbS and HbC, can result in decreased life span of the red blood cells, which will cause HbA1c results to be lower than expected, regardless of the method used, and not be related to glycemic control, when using published reference ranges.

13.4. Bilirubin, up to a level of 20 mg/dL, does not interfere with this assay.

13.5. Triglycerides, up to 1347 mg/dL in fresh whole blood, do not interfere with this assay. Highly lipemic blood samples stored for long periods of time and/or frozen should not be assayed using this method.

13.6. Rheumatoid factor, up to 1:5120 titer, does not interfere with this assay.

13.7. Expected serum levels of the following drugs commonly prescribed to persons with diabetes do not interfere with this assay: Diabinese®, Orinase®, Tolinase®, Micronase®, Dymelor®, and glipizide.

13.8. If the DCA Vantage becomes inoperable, send all specimens to the main lab for analysis.

14. REFERENCES (as applicable):

14.1. Siemens DCA Systems® Hemoglobin A1c Reagent Kit package insert.
14.2. Siemens DCA VANTAGE®+ Analyzer Operating Manual, Rev. E 2012-08.
14.3. Siemens DCA Systems® Hemoglobin A1c Control Kit package insert.

15. RELATED DOCUMENTS

Refer to QPulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms