Title: DCA Vantage HgbA1C Procedure
Cross References: DCA Vantage HgbA1C Training and Competency Assessment Record
DCA Vantage Operator Training Checklist
DCA Vantage Maintenance Log
DCA Vantage Optical Test Cartridge Results Log

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Written By: Nancy Toscano MT (ASCP) Date: 1/6/2012
Last Approved by: Kent Lewandrowski, MD Date: 3/2/2012

Title (with LTR): DCA Vantage HgbA1C Procedure (LTR19683)
Last Approved: Gregory, Kimberly (Electronic Signature Timestamp: 8/11/2014 3:13:51 PM)
Purpose

This document outlines policies and procedures pertaining to Hemoglobin A1C testing by DCA Vantage. In an effort to be concise, some information may be excluded from the manufacturer’s procedure. It is recommended that operators familiarize themselves with the manufacturer’s product information that accompanies each reagent kit and the operators’ manual if one exists.

Scope

Level of Personnel: All RN’s, medical assistants, and MD’s who have successfully completed initial training and maintained annual competency.

Testing Site: All sites approved and on file with the Pathology Service POCT Division.

Policy and Procedure Statement

The DCA Vantage Analyzer™ is a semi-automated bench top system used for the quantitative determination of hemoglobin A\textsubscript{1c} in blood. The measurement of hemoglobin A\textsubscript{1c} concentration is recommended for monitoring the long-term care of persons with diabetes. This assay provides a convenient method for the \textit{in vitro} measurement of percent concentration of hemoglobin A\textsubscript{1c} in blood.

Test Principle

The DCA Vantage Analyzer™ uses a spectrophotometer to analyze the intensity of the light transmitted through the cartridge optical window. Whole blood is added to the reagent cartridge, the cartridge is inserted into the DCA Vantage™ Analyzer, and meaningful results are available in 6 minutes. All measurements and calculations are performed automatically by the DCA Analyzer, and the screen displays percent HbA\textsubscript{1c} at the end of the assay. The following chemical reaction occurs within the cartridge:

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

For the measurement of specific HbA\textsubscript{1c}, an inhibition of latex agglutination assay is used. An agglutinator (synthetic polymer containing multiple copies of the immunoreactive portion of HbA\textsubscript{1c}) causes agglutination of latex coated with HbA\textsubscript{1c} specific mouse monoclonal antibody. This agglutination reaction causes increased scattering of light, which is measured as an increase in absorbance at 531 nm. HbA\textsubscript{1c} 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. The HbA\textsubscript{1c} concentration is then quantified using a calibration curve of absorbance versus HbA\textsubscript{1c} concentration. The percent HbA\textsubscript{1c} in the sample is then calculated as follows:

\[
\% \text{HbA}_{1c} = \frac{[\text{HbA}_{1c}]}{[\text{Total Hemoglobin}]} \times 100
\]

Both the concentration of hemoglobin A\textsubscript{1c} specifically and the concentration of total hemoglobin are measured, and the ratio reported as percent hemoglobin A\textsubscript{1c}.

Regulatory Requirements

I. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.

II. All test results must be maintained in patient records with all required information for four years

Required information:

1. Patient’s name
2. Medical Record Number
3. Patient’s gender
4. Patient’s age or date of birth
5. Date & time test collected, performed and reported  
6. Ordering Physician  
7. Responsible physician (if not 6)  
8. Reference or Target Range  
9. Test Performed  
10. Test units  
11. Lab name  

III. Additional information that must be retained for four years:  

1. Testing personnel records  
2. Quality control results  
3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on quality control and any remedial action  
4. QC charts, maintenance sheets, reference and critical ranges  

IV. Other  

1. Universal precautions must be observed when handling any patient specimen.  
2. A physician’s order or standing order is required prior to performing test.  
3. The Hospital Hand Hygiene policy must be adhered to at all times.  

**Competency Assessment**  

All operators must read the procedure manual and complete the “DCA Vantage Analyzer™ Training Checklist” during initial training. Competency is assessed at orientation and annually thereafter using at least two of the following methods:  

1. Performing a test on a blind specimen.  
2. Supervisor observes performance of routine work.  
3. Each user’s quality control performance is monitored.  
4. Written testing specific to the method.  

The name and operator ID of new operators trained on the DCA Vantage must be provided to the POCT program for entry into Telcor to allow instrument access. Only approved operators are allowed to use the machine.  

**Expired Operators:**  

Operators that fail to meet competency requirements within 365 days will be locked out of the system. They will be required to undergo retraining and competency assessment according to above.  

**Limitations/Interferences**  

<table>
<thead>
<tr>
<th>Interferent</th>
<th>Concentration</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s total hemoglobin</td>
<td>&lt;7 g/dL &amp; &gt;24 g/dL</td>
<td>Test by another method</td>
</tr>
<tr>
<td>Hemoglobin F</td>
<td>&gt;10%</td>
<td>Decreases HbA1c</td>
</tr>
<tr>
<td>Hemolytic anemia, polycythemia, homozygous Hb S &amp; Hb C, Thalassemia</td>
<td>N/A</td>
<td>Decreases HbA1c</td>
</tr>
<tr>
<td>Highly lipemic specimens stored for long periods of time or frozen</td>
<td>N/A</td>
<td>Test by another method</td>
</tr>
</tbody>
</table>

**Test Kit/Supplies/Equipment**  

The DCA Vantage™ system consists of 4 functional areas:  

1. **Reagent cartridge compartment:** Test is performed once cartridge is inserted.
2. **Onboard barcode scanner**: Used to calibrate the system and scan reagent and control cartridges
3. **Display screen**: An integrated touch screen. Do not use anything hard or pointed on the touch screen
4. **Printer**: Internal thermal printer for test results

When the system is not in use for more than 30 minutes, the Power Save Mode automatically turns on. Touch any location on the screen to resume operation.

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer #</th>
<th>People Soft</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCA 2000 Hgb A1c Reagent Kit</td>
<td>Siemens #5035C</td>
<td>Order through Fisher Cat #23-312-018</td>
<td>Refrigerated: 2°-8°C (36°-46°F) until expiration date on pkg. Rm. Temp: Up to 3 months. Record date on carton when taken out of refrigerator.</td>
</tr>
<tr>
<td>DCA 2000 Hgb A1c Control Kit</td>
<td>Siemens #5068A</td>
<td>Order through Fisher Cat #AM-5068</td>
<td>Unreconstituted: Refrigerate at 2°-8°C (36°-46°F) until expiration date on bottle. Reconstituted: 90 days refrigerated. May remain at room temp for 30 minutes during testing, but must be returned to the refrigerator.</td>
</tr>
<tr>
<td>Air Filter Holder</td>
<td>06498417</td>
<td>Special request</td>
<td>Contact POCT program</td>
</tr>
<tr>
<td>Cartridge Return Spring</td>
<td>06489248</td>
<td>Special request</td>
<td>Contact POCT program</td>
</tr>
<tr>
<td>Fuse: T-1.25 A, Slow Blow; 250 volt</td>
<td>04469001</td>
<td>Special request</td>
<td>Contact POCT program</td>
</tr>
<tr>
<td>Cleaning Sticks (10)</td>
<td>06488209</td>
<td>Special request</td>
<td>Contact POCT program</td>
</tr>
<tr>
<td>Optical Test Cartridge</td>
<td>06489221</td>
<td>Special request</td>
<td>Contact POCT program</td>
</tr>
<tr>
<td>Air Filter (2 pack) Replacement Kit</td>
<td>122521</td>
<td>Special request</td>
<td>Contact POCT program</td>
</tr>
<tr>
<td>Printer Paper (5 pack)</td>
<td>5773</td>
<td>Special request</td>
<td>Contact POCT program</td>
</tr>
<tr>
<td>Printer Paper (self adhesive, 5 pack)</td>
<td>1759</td>
<td>Special request</td>
<td>Contact POCT program</td>
</tr>
</tbody>
</table>

**Calibration**

Before using a new lot of reagent cartridges, scan the calibration card into the analyzer. The values for the calibration parameters are encoded onto the calibration card provided with each lot of reagent cartridges.

The reagent cartridge barcode (containing lot number and test name) is scanned before samples are analyzed. This accesses the appropriate calibration parameter values (calibration curve) for the particular lot number of reagent cartridges in use. If no calibration curve is in the instrument for the particular lot number of cartridges in use, the instrument prompts the user to scan the calibration card.

The instrument can store two calibrations for the DCA HbA1c Assay. Each of the two calibrations is for a different lot number.

1. Locate the dot on the instrument next to the barcode track.
2. Hold the card so that the barcode faces to the right. Insert the Calibration card into the top of the barcode track above the dot.
3. Hold the Calibration card gently against the right side of the track and smoothly slide the card down. A beep sounds to signal a successful scan.

**NOTE:** If no beep sounds, repeat the scanning procedure. To return to the Home screen, select OK.

**Quality Control: Electronic**

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.

**Quality Control: Liquid**

Run Liquid QC under the following conditions:

- Every day that patient testing is performed
- With each new shipment of reagents.
- With each new lot of reagents.
- Run QC monthly for reagents that have been stored longer than 30 days.
- When results do not match the patient’s clinical condition or symptoms.
- Following maintenance or repair procedures.

**Control Preparation:**

1. Follow hand hygiene protocol and put on gloves.
2. Remove the appropriate control bottle from the refrigerator just prior to reconstitution.
3. Gently tap the bottom of the control bottle on the counter to collect as much material as possible on the bottom of the bottle.
4. Add 6 drops of reconstitution fluid to the control bottle.
   
   **Note:** Discard the first drop to ensure a constant volume of drops thereafter.
5. Carefully replace the cap, not the eyedropper, and swirl the control bottle several times. Let stand at room temperature for 15 minutes.
6. Rotate and swirl the control bottle. Replace bottle cap with Eyedropper Cap.

**Adding Control to Cartridge:**

1. Upon removal from the refrigerator allow a reagent cartridge to warm up to room temperature for 10 minutes in the unopened foil pouch, or five minutes if removed from the foil pouch. After opening the foil pouch, the reagent cartridge must be used within one hour.
2. Remove and unwrap the capillary holder from the Reagent Kit.
3. Thoroughly mix the control solution by inversion. Insert the tip of the dropper into the control solution and aspirate a small amount.
   
   **Note:** Avoid introducing air bubbles into the sample.
4. Fill the glass capillary tube by touching it to the tip of the dropper (Touch only the tip of the capillary tube to the control material. If an air bubble is present in the filled tube, discard the capillary holder and fill a new one. See Specimen Collection, below)
   
   ◀ **Analysis must begin within 5 minutes after filling the glass capillary.**
5. Return any excess control material in the dropper to the control bottle.
6. Wipe any control solution off the sides of the glass capillary tube using a lint-free tissue. *(see step 4 under Specimen Collection, below)*
7. Inspect the capillary holder for the presence of any bubbles. If present, discard the capillary and repeat
8. Prevent the control material from coming in contact with the plastic part of the capillary holder. If control material comes in contact with the capillary holder, discard the capillary holder.
9. Insert the capillary holder into the reagent cartridge until the holder gently snaps into place. *(see step 3 under Test Procedure, below)*

**Running the controls**

A. Scan the control card in the barcode track

▶ **One side of the control card is for a normal control and the other side is for an abnormal control.**

1. Locate the dot next to the barcode track on the instrument.
2. Hold the card so that the barcode faces to the right.
3. Insert the control card into the top of the barcode track.
4. Hold the control card gently against the right side of the track and quickly slide the card down.
5. A beep sounds to signal a successful scan. If no beep sounds, repeat the scanning procedure
6. Scan the reagent card containing control solution using the same procedure as above.

B. Insert the reagent cartridge into the instrument:
1. Open the cartridge compartment door.
2. Hold the reagent cartridge so that the barcode is on the right.
3. Insert the reagent cartridge into the cartridge compartment until a gentle snap is heard or felt.

► The cartridge is designed to fit only one way into the system. Do not force the cartridge into the system.
4. Using a smooth, slow, continuous motion, pull the flexible pull-tab completely out of the reagent cartridge.
5. Close the door and dispose of the flexible pull-tab. Five seconds after the door is closed, a beep sounds and the assay begins.

► If you accidentally close the door before you pull the flexible plastic tab, you have 5 seconds to re-open the door and pull the tab.

Results
The Normal and Abnormal Controls should give values within the ranges shown on the Control Card when run according to instructions.

Troubleshooting Out-of-Range QC Values

- Use a new reagent cartridge to repeat the quality control procedure.
- If the new reagent cartridge fails to give results within the expected values, use a fresh control solution to repeat the quality control procedure.
- Review these instructions to ensure that the test was performed according to the procedure
- Verify that the materials are not expired.
- Verify that required maintenance was performed.
- If unable to resolve the problem contact the POCT Program: 6-1462; 3-5392; 6-3858

Specimen Collection
To remove the capillary holder from the blister package, remove the white plastic film from the clear plastic blister. Do not push the capillary holder out of or through the plastic. Inspect the capillary holder for the presence of the following parts:

1. Glass Capillary
2. Absorbent pad
3. Latching mechanism

Discard the capillary holder if any of the above parts is missing.

A. Filling the capillary with blood obtained by fingerstick:
1. Follow hand hygiene protocol and put on gloves.
2. Perform fingerstick according to protocol.
3. With the capillary holder at an angle, touch only the tip of the capillary to a small drop of blood on the finger until the capillary fills.
4. Using a lint-free tissue, carefully wipe the outside of the glass capillary.
NOTE: Do not allow the tissue to touch the open end of the glass capillary. Contact with the open end of the capillary could result in loss of sample. If sample loss is obvious, discard the capillary holder and repeat the procedure using a new capillary holder.

5. If any bubbles are present in the glass capillary, discard the capillary holder and repeat the procedure using a new capillary holder.

6. Analysis must begin within 5 minutes after filling the glass capillary.

B. Filling the capillary with blood obtained by venipuncture:

1. Follow hand hygiene protocol and put on gloves.

2. Perform venipuncture according to protocol. (Acceptable anticoagulants include EDTA, heparin, fluoride/oxalate, and citrate.)

3. Invert the tube of blood several times to prevent separation of red blood cells and plasma.

4. Remove the stopper from the blood collection tube so that a small sample of blood remains on the stopper.

5. Holding the capillary holder at an angle, touch only the tip of the capillary to a small drop of blood on the stopper until the capillary fills.
   **NOTE:** Do not attempt to fill the capillary by inserting the capillary holder into the blood collection tube. This will result in blood touching the capillary holder. If blood touches the capillary holder, discard the capillary holder.

6. Using a lint-free tissue, carefully wipe the outside of the glass capillary.
   **NOTE:** Do not allow the tissue to touch the open end of the glass capillary. Contact with the open end of the capillary could result in loss of sample. If sample loss is obvious, discard the capillary holder and repeat the procedure using a new capillary holder.

7. Inspect the glass capillary for the presence of bubbles. If bubbles are obvious, discard the capillary holder and repeat the procedure using a new capillary holder.

8. When the glass capillary is filled with the sample, analysis must begin within 5 minutes
Test Procedure

Ensure that the system is in the **Home** screen, which displays the status of the system and is the starting point for Patient and Control Test Sequences. If the system is in the **Not Ready** state and you cannot initiate a Patient or Control Test Sequence, an alert message displays explaining why the system is not ready. The **Recall menu** and the **System menu** can also be accessed from the Home Screen.

1. Remove a reagent cartridge from the refrigerator and allow it to warm up to room temperature. (10 minutes in the unopened foil pouch, or 5 minutes if removed from the foil pouch.)
   
   a. To open the foil pouch, tear down from the corner notch until the entire long side of the pouch is open. Do not use scissors. After opening the foil pouch, the **reagent cartridge must be used within one hour**.
   
   b. When handling the reagent cartridge, do not touch or otherwise contaminate the optical window (1) or erroneous test results may occur.

   c. Discard the reagent cartridge if any of the following conditions exist:
      - The **flexible pull-tab is loose or missing.** (2)
      - The **desiccant bag is missing or open.** (3)
      - The cartridge is damaged.
      - Loose desiccant particles are found inside the foil package.
      - If the foil package is open for more than 60 minutes.

2. Collect the sample using the capillary holder.

3. Insert the capillary holder containing the sample into the reagent cartridge until the holder snaps into place. The open side of the capillary holder should face the foil pull tab.

4. Scan the **Reagent Cartridge**: Hold the reagent cartridge so that the barcode faces to the right. Insert the reagent cartridge above the “dot” located on the side of the instrument barcode track. Quickly and smoothly, slide the reagent cartridge down. A beep sounds to signal a successful scan.

5. With the barcode facing to the right, insert the reagent cartridge into the cartridge compartment until a gentle a snap is heard or felt.

   **NOTE:** The cartridge is designed to fit only one way into the system. Do not force the cartridge into system.

6. Using a slow, continuous motion, pull the **flexible pull-tab** completely out of the reagent cartridge and discard.

7. Close the door. 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 and pull the tab.

8. The **Sample Data menu** screen displays when the instrument detects the system door closes, and indicates a test is in progress after the 5-second delay.

9. Follow the prompts to enter patient’s CSN (scan CSN from EPIC label on tube) and operator ID #.

10. The **Result screen** displays when the system finishes analyzing the sample. Press the “print” button on the screen to print results.

11. Remove the **Reagent Cartridge**

12. Open the cartridge compartment door.
13. Locate the button on the right side of the cartridge compartment.

14. Push and hold it down with your right hand.

15. With your left hand, gently push the tab on the cartridge to the right to release the cartridge.


**NOTE:** You can cancel a test any time. To cancel a test, select Cancel. If a test in progress is cancelled, you must discard the sample.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>result preceded by a less than (&lt;) sign</td>
<td>concentration is below the lower limit of the test (i.e. &lt;2.5%)</td>
</tr>
<tr>
<td>result preceded by a greater than (&gt;) sign</td>
<td>Concentration is above the upper limit of the test (i.e. &gt;14.0% for patient samples; &gt;16.0% for control samples.)</td>
</tr>
<tr>
<td>result followed by a minus sign (-)</td>
<td>result is below the Reference Range</td>
</tr>
<tr>
<td>result followed by a plus sign (+)</td>
<td>result is above the Reference range.</td>
</tr>
</tbody>
</table>

### Reference ranges

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference Range</th>
<th>Critical Value Range (Approved by Med Poll Committee)*</th>
<th>Analytical Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>HgbA1C</td>
<td>3.8 – 6.4%</td>
<td>None</td>
<td>3.0 – 10.0%</td>
</tr>
</tbody>
</table>

The tested ranges are those ranges that were tested during functional sensitivity and linearity testing.

* Clinical policy and Procedure Manual

Laboratory Results: Guidelines for Retreiving and Reporting.

### Maintenance

**Turn the power off and disconnect the power cord before cleaning.** (You can leave the DCA Vantage system on always, except during maintenance and cleaning procedures.)

**Turning the system off**

1. At the Home screen, select **Turn Off**. A message displays asking if you want to shut down the system.
2. Select **Yes**.
3. Turn the power switch to the off position when the system shut down is complete.
### Weekly (or as needed)

**Cleaning:**

- **Barcode Window:** Clean the barcode window with a lint-free cloth dampened with water or ethanol.

- **Exterior:** Clean the exterior with a lint-free cloth dampened with water or ethanol. Do not allow liquid to drip into the system.

**NOTE:** To disinfect the exterior of the system, expose the surface to 0.5% sodium hypochlorite for 10 minutes. Remove any visible blood on the system before disinfection. Do not use any other type of solvent, oil, grease, or silicone spray on any part of the system.

### Quarterly (or as needed)

- **Removing and Cleaning the Cartridge Spring:** See Operator’s Manual for instructions

- **Changing the Air Filter:** See Operator’s Manual for instructions

- **Running the Optical Test**
  - See Operator’s Manual for instructions

Document all instrument maintenance and cleaning on the appropriate log sheets.

### Connectivity and Downtime procedure

1. The DCA Vantage analyzer is connected to Telcor (POCT management system) through an interface on the network.

2. In the event of connectivity failure, document the results on the patient’s chart with the units and reference ranges. Results can be re-transmitted in the “Recall Results” menu.

3. Contact the POCT program for assistance (ext. 6-1462, 3-5392 or 6-3858)

### Technical Assistance

- Siemens Medical Solutions Technical Care Center: 1-877-229-3711
- Customer Service: 1-800-255-3232
- Serial Number:
- Customer Account Number:

### References


### Cross – References

- DCA Vantage HgbA1C Training and Competency Assessment Record
- DCA Vantage Maintenance Log
- DCA Vantage Operator Training Checklist
- DCA Vantage Optical Test Cartridge Results Log