Bassett Healthcare Network  
Point of Care Testing  
Hemoglobin A1c DCA VANTAGE

A. PURPOSE
This assay provides a convenient, quantitative method for measuring the percent concentration of Hemoglobin A1c (HbA1c) in blood. The measurement of Hemoglobin A1c concentration is recommended for monitoring the long-term care of persons with diabetes. This assay is based on a latex immunoagglutination inhibition methodology. After loading the reagent test cartridge into the DCA Vantage, the test result will be displayed in six minutes. Results obtained are considered definitive for purposes of patient care and diagnosis.

B. PRINCIPLE
Both the concentration of Hemoglobin A1c specifically and the concentration of total hemoglobin are measured, and the ratio reported as percent Hemoglobin A1c. All of the reagents for performing both reactions are contained in the DCA Vantage Hemoglobin A1c Reagent 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 which is measured. The extent of color development at 531nm is proportional to the concentration of total hemoglobin in the sample.

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

The percent HbA1c in the sample is then calculated as follows

\[
\text{\% HbA1c} = \frac{(\text{HbA1c})}{(\text{Total Hemoglobin})} \times 100
\]

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

C. SPECIMEN REQUIREMENTS
The provided glass capillary (within plastic capillary holder) holds 1uL of whole blood. The blood sample may be obtained by fingerstick or venipuncture. (Refer to Phlebotomy Manual). Acceptable anticoagulants from venipuncture are EDTA, heparin, citrate and fluoride/oxalate. EDTA, heparin, fluoride/oxalate, and citrate preserved whole blood may be stored at -70° to 5° C (-94 to 41° F) for two weeks, or up to 46° C (77° F) for one week.
D. CALIBRATION

**Instrument:** 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.

Before the sample can be analyzed, the reagent cartridge bar code (containing lot number and test name) is scanned. 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 Vantage Hb A1c Assay. Each of two calibrations is for a different lot number of cartridges. The calibration data comes on a calibration card with each box of cartridges. When reagent cartridges are stored and used properly, acceptable performance up to the expiration date is ensured.

E. REAGENTS/MATERIALS/INSTRUMENTATION

- Siemens DCA Systems Hemoglobin A1c Reagent Kit – Order ref. 06162000 - Obtain from POC office
- Siemens DCA Systems Hemoglobin A1c Normal and Abnormal Control Kit - Order ref. 03714363. Obtain from POC office
- Lancet®, Roche – Warehouse Item
- Alcohol Swabs – Warehouse Item
- Zip-lock Bags – Warehouse Item
- Clorox Germicidal Wipes – Warehouse #554713
- Oxivir – Warehouse #554694

1. Storage, Stability and Handling

**Reagent Kit:**

Store DCA Systems Hemoglobin A1c Reagent Kit at 2º to 8ºC (36º - 46º F) until manufacturer’s expiration date.

Ready for use kits must equilibrate to room temperature. Once removed from the refrigerator (2º to 8ºC), the reagent cartridges may be stored at 15º to 30ºC for no more than 3 months, but not to exceed manufacturer’s expiration date. Upon removal from refrigerated storage, allow the reagent cartridge to warm up at room temperature for 10 minutes (in unopened foil pouch) or five minutes (if removed from foil pouch). After opening foil pouch, the reagent cartridge must be used within (1) hour. To open foil pouch, tear down from corner notch. Discard the reagent cartridge if:

- The cartridge is damaged
- The pull-tab is loose or missing
- The desiccant is missing
- Loose desiccant particles are found inside the foil pouch
- Beyond manufacturer’s expiration date
Date reagent cartridges for the new expiration date by completing expiration label on each box. Date individual cartridges that are removed from the original box. Use entire lot number from stock before opening another lot number. Use lot number with shortest outdate first when multiple lots are stocked.

**Capillary holders:**  
Unused capillary holders may be saved and used with any lot of reagent cartridges. Each capillary holder is packaged separately in a blister package. Discard the plastic capillary holder if any of the following are missing from the holder:

**Controls:**  
- **Unreconstituted** DCA System Hemoglobin A1c Normal and Abnormal Control Kit must be stored at 2° to 8°C (36°- 46° F), and can be used until the last day of the expiration month shown on the bottle. **Appearance of moisture in the bottle prior to reconstitution, is an indication of deterioration of the material and renders the material unsatisfactory for use.**
- **Reconstituted** DCA Hemoglobin A1c Normal and Abnormal Controls should **not be frozen.**

**Do not allow it to stand uncapped.** Control material may remain at room temperature for 20 minutes during testing, but should be stored in a refrigerator tightly capped in an upright position at all other times. Discard any reconstituted control solution appearing turbid, or obviously contaminated. The reconstituted control is stable for 3 months when stored refrigerated.

2. **Instrumentation**  
   - Power off (switch on back) on Friday or last day of weekly testing.  
   - Power on – Monday. Allow the instrument to warm up (approx. 5 minutes)

F. **QUALITY CONTROL**  
To assure quality of both testing procedures and patient results for Hemoglobin A1c, the DCA Vantage 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. Should an assay or system error occur during any individual measurement, the system automatically reports an error message, preventing the reporting of erroneous patient results.

Liquid QC - 2 levels of Quality Control must be run, assuring that each is within acceptable range only on days when patients are being run.

1. **Reconstitution**  
The following directions for reconstitution are recommended to minimize variation resulting from different reconstitution methods in different laboratories:
   - Remove the appropriate control bottle from the refrigerator just prior to reconstitution.  
   - Gently tap the bottom of the control bottle on the counter to collect as much material as possible on the bottom of the bottle.  
   - Carefully remove the cap from the control bottle.
c. Holding the Reconstitution Fluid dropper bottle vertically, add six (6) drops of fluid to control bottle. **Note:** Discard first drop to ensure a constant volume of drops thereafter.

d. Carefully replace the cap, not the eyedropper, and swirl the control bottle several times. Let stand at room temperature for 15 minutes.

e. After 15 minutes, coat all surfaces of the control bottle by rotating and inverting the bottle. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.

f. Replace the cap with appropriate colored eye dropper.

2. **Frequency for performing quality control:**
   a. Daily, when patient testing is performed (This is required for auto verification)
   b. With each lot of new reagent cartridges
   c. With each new shipment of existing lot of reagent cartridges
   d. When results do not match the patient’s clinical condition of symptoms

G. **PROCEDURE**

1. **Quality Control:** POC reviews the QC monthly in Beaker and documents the review there.
   a. Remove the QC material from the 2°-8°C refrigerator. Allow to equilibrate to room temperature (15 minutes).
   b. Mix the QC vial by rolling in the palm of hand for 15-20 seconds.
   c. Sample the QC in the same manner as a patient test sample. Follow the procedure outlined in **Test Procedure for Patient Sample**.
   d. Scan appropriate QC barcode (received in control kit) for level being run. The control identification is stored in the DCA Vantage.
   e. Scan the reagent cartridge barcode.
   f. The operator must verify that both levels of QC are within manufacturer’s acceptable range. The results automatically file into Beaker. Do not proceed with patient testing if QC is not within acceptable limits. Document all corrective action on the DCA Corrective Action Log. Notify the POC Office immediately when QC fails.
BEAKER WORK FLOW

1. User must log into **MIB ENDOCRINOLOGY** to have this functionality.
2. Go to Epic button – Patient Care – Encounter and enter patient’s MRN. You will then see a list of patient encounters, select the active one that the test should be documented on.
3. Place the order for the test by going to Order Entry.
4. Type in LAB 2850 to find the Med Clinic A1C and click Accept. Pend the orders and enter the ordering/authorizing provider.
5. From here, go to Snap Shot – Visit Orders

6. Click on Collect Specimens
7. This brings you to Order Inquiry, highlight the order for Hemoglobin A1C Medical Clinic for that day. Click Release (3).

8. While order is still highlighted, click Collect Specimens.
9. Click Print Labels (1)
10. Click Collect All (2)
11. Click Receive (3)

12. View Outstanding Test List – At completion of analyzing the sample, the results are auto verified and the specimen is removed from the list.
13. Verify the test results in the chart under Report Viewer.

14. Reprinting a label – If you need to reprint a label go to Labels and Docs. Select print.

2. Patient Sample
   a. Take the Beaker barcode label and sample collection supplies to patient’s room. Affix the Beaker barcode label on the Bassett Healthcare Network DCA Patient Information Sheet – yellow copy. Place an IDX sticker on the white copy.
   b. Open the plastic wrap of the capillary holder by tearing the wrap at the serrated edge with the arrow. Inspect the capillary holder for the presence of the following parts:
      - Absorbent pad
      - Glass capillary
b. Latching mechanism

c. Filling the glass capillary with blood from finger stick:
   1. Hold the capillary holder at an angle.
   2. Touch only the tip of the capillary to a small drop of blood on the finger until the capillary fills.
      **Note:** 1μL of blood is required to fill the capillary.
   3. 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 (by wicking into the tissue). If sample loss is obvious, discard the capillary holder. Repeat the procedure using a new capillary holder.
   4. 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.

d. Carefully insert the capillary into the reagent cartridge until the holder gently snaps into place. Avoid harsh insertion of the capillary holder. Do not dislodge the sample from the glass capillary or erroneous results may occur. Label reagent cartridge sample with the smallest Beaker label. Transport to testing area in a biohazard bag. Perform the test within 5 minutes of collection.

e. Scanning the reagent cartridge:
   1. Locate the dot (on the system) next to the barcode track.
   2. Locate the barcode on the reagent cartridge.
   3. Hold the reagent cartridge so that the barcode faces to the right.
   4. Insert the reagent cartridge (above dot) into the barcode track.
   5. Quickly and smoothly, slide the reagent cartridge down. A beep sounds to signal a successful scan.
      **Note:** If no beep sounds, repeat procedure.

f. Inserting the Reagent Cartridge into the System:
   1. Open the cartridge compartment door.
   2. Hold the reagent cartridge so that the barcode faces to the right.
   3. Insert the reagent cartridge into the cartridge compartment until a gentle snap is heard or felt.
      **Note:** 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.
      **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.
   6. When the cartridge is identified the instrument has started the test cycle. Select Patient ID. Scan the Beaker barcode, “enter”. If a barcode number is unavailable, enter the patient’s MRN (notify the POC Office). Select the following keys for manual entries, hit the “enter” button after keying in data:
      - Last name
      - First name
      - Operator ID
   The test cycle takes 6 minutes to complete.

g. Removing the Reagent Cartridge into the System:
1. Open the cartridge compartment door.
2. Locate the button on the right side of the cartridge compartment
3. Push and hold it down with your right hand.
4. With your left hand, gently push the tab on the cartridge to the right. This action releases (unlocks) the cartridge
5. Pull the reagent cartridge out of the compartment
6. Close the system door
7. Discard the cartridge in a proper container, according to your standard laboratory procedures.

h. End of Day
   • Clean the benchtop with Oxivir wipes.
   • Shut down analyzer (Fridays only).

H. REFERENCE RANGE

Pursuant to the 2010 American Diabetes Association recommendations for using HBA1c to diagnose and monitor diabetes, the Clinical laboratories are making the following change to the reference range for HBA1c. The Bassett Medical Center Endocrinologists have approved this change.

<table>
<thead>
<tr>
<th>% HBA1c</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5.7</td>
<td>Non-diabetic</td>
</tr>
<tr>
<td>5.7-6.4</td>
<td>Pre diabetes</td>
</tr>
<tr>
<td>6.5-7.0</td>
<td>Diabetes, Good control</td>
</tr>
<tr>
<td>7.1-7.5</td>
<td>Fair control</td>
</tr>
<tr>
<td>7.6-8.5</td>
<td>Poor control</td>
</tr>
<tr>
<td>8.6-9.5</td>
<td>Very poor control</td>
</tr>
<tr>
<td>&gt;9.5</td>
<td>Extremely poor control</td>
</tr>
</tbody>
</table>

I. MEASURING RANGE

4.0%-11.9%

J. RESULT DOCUMENTATION

The instrument display shows a test result that requires no further calculation. The instrument interface will report the Hgb A1c concentration directly into Beaker, manual entry is not needed. Results outside the measuring range will be reported in Beaker as <4.0 or >11.9. A confirmatory sample should be ordered and collected as a venipuncture lab sample. Lab order code – LAB90.

Results from the DCA Vantage are recorded manually on the patient information sheet. See addendum A. Billing for the test occurs through IDX.

K. LIMITATIONS

There are two major errors that can be seen on the analyzer: a cartridge error and a hemoglobin error. They have different causes and are handled differently. Cartridge errors
may be due to a sample error or an analyzer error. Another finger stick sample can be 
collected with a new cartridge. (See Addendum B).

Hemoglobin errors may occur if the patient’s hemoglobin is <7.0 or >24.0. In this case, the 
order should be canceled and a venous sample drawn and sent to the lab for testing. Refer to 
operator’s manual for troubleshooting or contact the Point of Care Office at 547-6728 or to 
Page, call 547-3555 and Page 1626.

L. MAINTENANCE/CLEANING/TROUBLESHOOTING

**Maintenance:**

**Daily:** by Endocrinology Staff
- Clean exterior of DCA Vantage daily with water
- Disinfect the exterior as needed with Clorox Germicidal Wipes

**Weekly:** by Endocrinology Staff
- Power OFF on Friday
- Power ON on Monday

**Quarterly:** by POC Staff
- Run and record Optical Cartridge:
  The provided optical test cartridge allows you to monitor the performance of the 
system over time. **Keep a permanent record of the results obtained** (i.e., Mean 
Transmittance Standard Deviation and Drift). These initial values will be used for 
comparison as in control charting. (See Operators Manual for procedure)
- Clean air filter (replace as needed)
- Clean barcode guide and cartridge compartment

**Unscheduled:** by POC Staff (as required)
- Document all maintenance on the DCA Vantage Maintenance Log.

**Troubleshooting:**
See section 6 of the Operation Manual

**Error Messages:**
See section 6 of the Operation Manual

**Technical Support:**
Siemens Medical Solutions Diagnostics 1-877-229-3711

**REFERENCES**
- DCA Vantage Operating Manual.
- Refer to operator’s manual for instructions on how to operate each function.
ADDENDUM A

Results within established range and no flags
Autoverify

ADDENDUM B

Hemoglobin Flag
Record error in action log
Repeat with a new fingerstick sample
Error continues, collect venous sample and send to lab. Order code Lab 90
Call POC to cancel test (Lab 2850)

Cartridge/Analyzer Error
Record error in action log
Repeat with a new fingerstick sample
Error continues, collect venous sample and send to lab. Order code Lab 90
Call POC to cancel test (Lab 2850)