



<p style="text-align: center;">  Clinical Laboratories</p>	<p style="text-align: center;">Point of Care Testing</p>
---	---

HEMOGLOBIN A1C BY THE DCA VANTAGE

I. PURPOSE AND PRINCIPLE

DCA VANTAGE is intended for the monitoring of hemoglobin A1c levels only. The measurement of hemoglobin A1c concentration is recommended for monitoring the long term care of patients with diabetes. The assay, using whole blood samples, is based on a latex immunoagglutination inhibition methodology.

Hemoglobin A1c is formed by the non-enzymatic glycation of the N-terminus of the Beta chain of hemoglobin A. The level of hemoglobin A1c is proportional to the level of glucose in the blood over a 2 month period. Therefore, hemoglobin A1c is an acceptable indicator of the average daily glucose levels over the preceding two months. Recent studies have shown, that the clinical values obtained through regular measurement of the hemoglobin A1c leads to changes in diabetes treatment and improvement of metabolic control by lowering hemoglobin A1c values.

Both the concentration of hemoglobin A1c 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 Hemoglobin A1c Reagent Cartridge. For the measurement of total hemoglobin, potassium ferricyanide is used to oxidize the hemoglobin present in the sample to methemoglobin. The methemoglobin, then complexes with thiocyanate to form thiocyan-methemoglobin. This colored compound is measured spectrophotometrically in the DCA Vantage instrument at 531nm.

For the measurement of hemoglobin A1c, an inhibition of latex agglutination is used. A synthetic polymer containing multiple copies of the immunoreactive portion of hemoglobin A1c causes agglutination of latex coated with hemoglobin A1c-specific murine monoclonal antibody. This causes an increase of the light scattering which is measured as an increase of absorbance at 531nm. Hemoglobin A1c in whole blood samples competes for a limited number of binding sites causing an inhibition of agglutination and a decrease in light scatter. This decrease in scattering is measured as a decrease in absorbance at 531nm. The hemoglobin A1c concentration is then quantified using a lot-specific calibration curve of absorbance

versus hemoglobin A1c concentration. The percentage of hemoglobin A1c is calculated by dividing the concentration of hemoglobin A1c by the patients' total hemoglobin. The DCA Vantage analyzer performs all of the measurements and calculations.

II. SCOPE

This test is performed in both inpatient and ambulatory settings.

III. PERSONNEL

Intended for use by clinical personnel who have received training and demonstrated competency in this procedure. In the hospital setting, this includes Clinical Laboratory Scientists, Registered Nurses, Nurse Practitioners, Physician Assistants, Physicians, Respiratory Tech. and Perfusionists. In the ambulatory setting, this includes the aforementioned personnel as well as Medical Assistants, Licensed Vocational Nurses and other licensed Technologists.

IV. REAGENTS, EQUIPMENT, MATERIALS AND STORAGE

A. Reagents

1. Siemens DCA Systems Hemoglobin A1c Reagent Kit (PMM# 12815, Mfr # 5035C, Cat # 23-312-018). Contents include:
 - a. 10 Hemoglobin A1c test cartridges
 - b. 10 capillary holders
 - c. Calibration card
2. Liquid Quality Controls
 - a. Siemens DCA Systems controls kit (PMM# 192671, Mfr # 5068, Cat # AM-5068). Contents include:
 - i. Two vials of Normal Control. The hemolysate is prepared from normal subjects and then lyophilized.
 - ii. Two vials of Abnormal Control. The hemolysate is prepared from diabetic human subjects and then lyophilized.
 - iii. Control reconstituting fluid.
 - iv. Control card.
3. Equipment
 - a. DCA Vantage instrument
 - b. optical check cartridge
4. Materials
 - a. Transfer pipets
 - b. Gloves
 - c. Refrigerator 2° – 8° C (36° – 46° F)
 - d. Thermometer for refrigerator

- e. Lancet for finger stick
- f. Kimwipes or gauze
- g. Sharps container QC logs
- h. Cotton tipped applicator
- i. Printer paper roll (optional)

B. Storage and Handling

1. Siemens DCA Systems Hemoglobin A1c Reagent Kit

- a. Reagent cartridges refrigerated at 2° – 8° C (36° - 46° F) remain stable and may be used until the expiration date on the box.
- b. Regent cartridges may also be stored at room temperature (15° - 30° C).
- c. Cartridges stored at room temperature are good for 90 days anytime before the expiration date. Record on the box, the date the box was placed at room temperature and the new expiration date.
- d. Capillary holders may be stored refrigerated or at room temperature (15 ° - 30 ° C / 59 ° – 86 ° F).
- e. Each box of reagent cartridges has a temperature indicator on the lid. If the indicator is RED, do not use the box of reagent. Inform the Nurse Manager.
- f. Upon removal from refrigerator, allow the cartridge to warm up at room temperature for 10 minutes (in the unopened foil pouch) or five minutes (if removed from the foil pouch).
- g. After opening the foil pouch, the reagent cartridge must be used within 1 hour.
- h. Precautions
 - i. For in-vitro diagnostic use only.
 - ii. Handle patient samples and control material as potentially infectious. Though the control material has been tested and found to be negative for HIV, HCV, and Hepatitis B surface antigen; Standard Precautions are to be used at all times.
 - iii. Do not allow reagent cartridges to be exposed to temperatures over 40.6° C (105° F) at any time.
 - iv. Do not use reagent cartridges after the last day of the month listed on the expiration date.

2. Liquid Quality Controls

- a. Store lyophilized control material at 2 – 8°C. When stored in this manner it may be used until the printed expiration date.
- b. Once prepared, the material may be used for up to 90 days after reconstitution if stored at 2 – 8°C. Be certain to note the date prepared on each bottle. Material stored otherwise must be discarded after one day of use.
- c. Precautions
 - i. Controls are prepared from human blood, treat as potentially infectious. Use Standard Precautions.

- ii. Do not allow control material to become frozen during storage.
- iii. Material should be "cherry red" in color and clear. If the control material is turbid or otherwise discolored, do not use.
- iv. Appearance of moisture in the bottle, prior to reconstitution, is an indication of deterioration of the material and renders the material

V. SAMPLE REQUIREMENT

- A. The blood sample may be obtained by finger stick or venipuncture. Acceptable anticoagulant is EDTA.
- B. Whole blood can be placed directly into the DCA Vantage pipette or collected in an appropriate microtainer or vacutainer.
- C. Samples not tested **immediately**, by person collecting the sample, must be labeled, in the presence of the patient, using two patient identifiers.
- D. Clotted samples are unacceptable.
- E. Sample **MUST** be analyzed within 5 minutes once placed into the DCA Vantage capillary pipet.

VI. DATA MANAGEMENT SYSTEM

Not applicable

VII. CALIBRATION VERIFICATION / LINEARITY

Not applicable

VIII. INSTRUMENT ALERT NOTIFICATION

- A. Event Log
- B. An Event Notification window displays at the Home Screen to alert operator when:

- | |
|---|
| <ul style="list-style-type: none">a. control is dueb. maintenance task is duec. optical check is dued. an error event occurs |
|---|

- C. At Home screen, **select Events**. Use the up and down arrows to scroll through the Events List Notifications. Note: The Events Notification Window closes after all events are cleared.

IX. QUALITY CONTROL

- A. Instrument Calibration:
Calibration is set initially at the factory. Thereafter, the instrument automatically self-adjusts during first-time power-up and during each assay. An error message is displayed when the machine is unable to make the internal adjustments. See “Error Codes and Troubleshooting Guide” or call technical support at 1-877-229-3711.
- B. Reagent calibration card is scanned:
 - 1. Upon opening a new box of reagent
 - 2. Prior to performing any control samples
- C. Quality Control Policy
 - 1. Run 2 levels of controls, normal and abnormal, for each day of patient testing.
 - 2. Run two levels of control upon opening a new box of reagent.
 - 3. Run two levels of controls, normal and abnormal, with each new lot of reagents.
 - 4. All opened reagent boxes/containers and control test vials must be dated and initialed when first opened.
- D. Quality Control Sample Preparation
 - 1. Remove normal and abnormal controls from the refrigerator.
 - 2. Tap control vial on counter to verify material is on bottom of vial.
 - 3. Remove stopper from vial and place vial on a flat surface.
 - 4. Holding the reconstituting fluid dropper vertically, discard the first drop and then dispense 6 (six) drops of fluid into the control vial.
 - 5. Replace the stopper, swirl, and allow to stand for 15 minutes.
 - 6. After 15 minutes invert and rotate vial to assure all material in the vial is in solution.
 - 7. Return diluting fluid to kit in refrigerator.
 - 8. Material is ready to use and requires no further preparation.
 - 9. The control solutions are good for 90 days after reconstitution.
 - 10. Mark vial(s) with initials, opening date, and new expiration date.

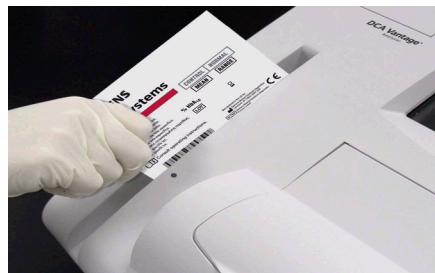
X. MAINTENANCE

- A. Optical test cartridge is run:
 - 1. Quarterly
 - 2. After cleaning the cartridge compartment and/or
 - 3. After changing the air filter:
 - a. Run the optical test cartridge by scanning the bar code on the cartridge and insert the cartridge into the analyzer. The cartridge will require 6 minutes to run. Record the results on the quality

- control log sheet. Compare the values obtained to the target values.
- b. If the values are out of range, repeat the test one time. If still out of range, call Siemens Technical support at 1-877-229-3711.
 - c. The optical test cartridge is reusable, do not discard.
- B. Preventive Maintenance (PM)
1. PM on the DCA Vantage requires the following:
 - a. Clean all spills as they occur. If the instrument becomes splashed with blood or other reagents, clean immediately with bleach toweled.
 - b. Clean the test chamber with a cotton tipped applicator on a monthly basis. This will prevent the buildup of dust in the cuvette area. Record this cleaning on the monthly optical cartridge log sheet.
 - c. Change air filter quarterly (located at the back of the instrument).
 - d. Clean the barcode window and the exterior as needed using a lint-free cloth dampened with alcohol.

XI. PROCEDURE

- A. Prepare a manual worksheet for each day of use. Each patient may be entered on the worksheet when the sample is received. If person collecting sample does not perform testing immediately, then sample must be labeled in the presence of the patient with two patient identifiers.
- B. Run two levels of **QUALITY CONTROL** samples each day of patient testing.
1. To reconstitute control samples, refer to Quality Control Sample Preparation, section IX, D.
 2. Remove cartridge and control solutions from the refrigerator and allow warming at room temperature for 15 minutes.
 3. Remove a test cartridge from its foil wrapper.
 4. Remove the control card from the control package and slide it past the bar code reader (blue dot) on the DCA Vantage. The “control level” will be on display.



Scanning the HbA1c control card

5. Remove a capillary pipette from its package.
6. Mix the control vial by inversion, then aspirate a small amount of the control solution with the vial dropper.

7. Touch the capillary end of the capillary tube to the sample and allow it to fill completely by capillary action.
⚠ Discard the capillary if any bubble is present and repeat the collection procedure using a new capillary holder.
8. Carefully remove the excess sample from the outside of the capillary with a Kimwipe.
9. Fully insert the capillary into the test cartridge, rounded side out until the holder gently snaps into place.



Inserting capillary holder into a reagent cartridge

10. Swipe the cartridge past the bar code reader (blue dot), the DCA Vantage will beep if done correctly.



Scanning the reagent cartridge

11. Open the cartridge compartment door and insert the cartridge in the holder, barcode towards the right side of the instrument. A gentle snap is heard or felt if the cartridge is fully seated in the holder.



Inserting the reagent cartridge into the cartridge compartment

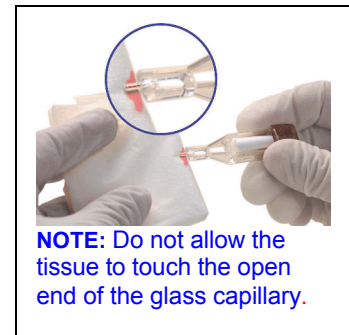
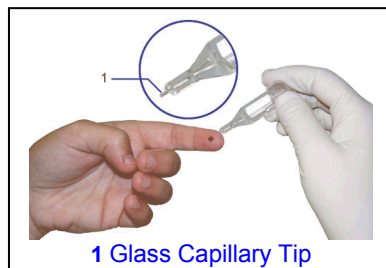
12. Pull the aluminum flexible pull tab completely out of the reagent cartridge.
13. Close the door. Sample analysis will begin immediately and will be complete in 6 (six) minutes.
14. The instrument will prompt you to enter operator ID and up to 3 custom comments. Then, press “next” and test time remaining will appear on screen.
15. When sample analysis is complete, the result will appear on the display. Record the results on the log sheet and compare with the expected results (see acceptable control range printed on the control card).
 - a. If results are within the acceptable range, continue with patient testing.
 - b. If the results are not within the acceptable range, check the expiration date of the reagent cartridge and control solution, environmental conditions and technique.
 - i. Re-run the control(s). Select Comment and enter “Repeat Test”.
 - ii. If QC still fails, repeat QC using a new reagent cartridge from another box or different lot # if available. Select Comment and enter “Used New Reagent Cartridge”.
 - iii. If QC still fails, repeat QC using a new vial of freshly reconstituted control solution.
 - c. See QC sample preparation (section **IX, D.**)
 - d. Select Comment and enter “Used New Control”.
 - e. If after using new cartridge and new control solution, the QC results continue to remain outside the acceptable range, contact POCT Coordinator or contact Siemens Diagnostics, Customer Service Department for technical support:
Technical Support: 1-877-229-3711
Customer Service: 1-800-255-3232
POCT Laboratory: 3-8750

16. Remove and discard used cartridge in a biohazard waste container. To remove cartridge, open door and depress gray button on right side. Move cartridge slightly to the right and pull out.

C. To run a **PATIENT TEST**:

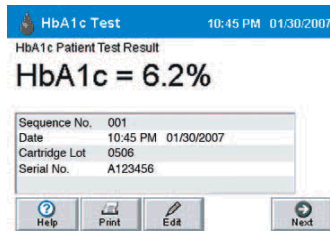
1. Using two patient identifiers, verify patient identification, and explain procedure to patient and /or family.
2. Remove a test cartridge from the reagent kit box and remove the cartridge from its foil wrapper.
3. Remove a capillary holder from its package. Holding the capillary holder at an angle, touch the tip of the capillary to a small drop of blood from the finger stick or on the stopper of vacutainer after inverting the tube and allow to fill completely. Remove any excess sample from the outside of the capillary.

⚠ Discard the capillary if any bubble is present and repeat the collection procedure using a new capillary holder.



Note: Once the capillary is filled with sample, analysis must begin within five minutes.

4. Fully insert the capillary holder into the test cartridge, rounded side out until the holder gently snaps into place.
5. Swipe the cartridge past the bar code reader (blue dot), the DCA Vantage will beep if done correctly. Note: If no beep sounds, repeat procedure.
6. Open the cartridge compartment door and insert the cartridge in the holder, barcode towards the right side of the instrument. A gentle snap is heard or felt if the cartridge is fully seated in the holder.
7. Pull the aluminum flexible pull tab completely out of the reagent cartridge.
8. Close the door. Sample analysis will begin immediately and will be complete in 6 (six) minutes.
9. Instrument will prompt you to enter Patient ID, User/Operator ID, and Comment (if needed, but not required).
10. When sample analysis is complete, the result will appear on the display.



11. Record the result on the patient's medical record chart.
12. Remove and discard used cartridge in a biohazard container. To remove cartridge, open door and depress gray button on right side. Move cartridge slightly to the right and pull out.

XII. RESULTS, RANGES, AND PANIC VALUES

- A. Results will be reported in percent (%) Glycated Hemoglobin.
- B. Reference or Normal Range is set at 4.2% – 6.0% based on reference interval studies conducted by the Clinical Laboratory.
- C. The instrument's Reportable Range is 2.5% – 14.0%.
- D. Results preceded by a < (less than) sign are below 2.5%. This is a rare condition and should be reported as "less than 2.5%". Results preceded by a > (greater than) sign are greater than 14.0% and should be reported as "greater than 14.0%".
- E. If a numeric answer is required by the ordering physician, submit the sample to the UCSF Clinical Laboratory.
- F. Depending on the method, non-diabetics have hemoglobin A1c levels ranging from 3% to 6%, controlled diabetics 6% to 9%, and as high as 20% in out of control diabetics.
- G. Panic values are not warranted for this procedure.
- H. Whenever a user identifies that an incorrect result has been reported, they are responsible for correcting/commenting the incorrect result (if possible), contacting the ordering provider, notifying them of the error, and documenting this notification, including the time and date, in the patient record.

XIII. NOTES

- A. Interfering Substances
 1. This method is useful for samples having between 7.0 and 24.0 g/dL of hemoglobin. Patients with severe anemia or polycythemia must not be tested with this assay.
 2. Hemoglobin F less than 10% will not affect the assay. Patients with high levels of Hgb F (e.g. HPFHgb-hereditary persistence of fetal hemoglobin) must be referred for another method.
 3. This method is not recommended for patients with Hemoglobin C or Hemoglobin S.
 4. Bilirubin up to 20.0 mg/dL does not interfere with this assay.

- 5. Triglycerides greater than 1347 mg/dL in fresh whole blood have been shown not to interfere with this assay.
- B. Samples that are noted to be severely lipemic or frozen for long periods of time are not recommended with this assay system.
- C. Rheumatoid factor, up to 1:5120 titer, does not interfere with the assay.
- D. Common oral diabetic medications (Diabinase, Orinase, Tolinase, Micronase, Dymelor, Glipizide) do not interfere with this methodology.
- E. In diabetic patients who have experienced recent blood loss, hemolysis or have elevated reticulocyte counts for other reasons the hemoglobin A1c level may be lowered and may not reflect actual glycemic control.

XIV. TROUBLESHOOTING ERROR CODES

An Error Code message with description of the problem will be on display if an operational or system problem occurs. Refer to DCA Vantage Operator's Manual Troubleshooting Guide for Error Code Translation and Corrective Action (Chapter 6, page 107) or contact POCT Coordinator.

Example of an Error Code:

Error Code	Description of Problem	Remedy
E104 - HbA1c Sample Error - low total hemoglobin	<ul style="list-style-type: none"> • The transmittance of the blood pickup reading is too high. • Possible causes: <ol style="list-style-type: none"> 1. No or low blood reaction. 2. No capillary holder was inserted. 3. Improper constitution of controls or use of non-DCA controls. 4. Hemoglobin <7g/dL = anemic patient. 5. Buffer tab is not removed. 	<ol style="list-style-type: none"> 1. Discard the sample. 2. Acknowledge the error. 3. Repeat the test with a new sample. <p>NOTE: Wait no more than 5 minutes after filling the capillary to start the test.</p> <ol style="list-style-type: none"> 4. If the error still occurs, contact your local technical support.

XV. BACK-UP

Should the DCA Vantage be unavailable, submit samples to the UCSF Clinical Laboratory for hemoglobin A1c assay.

XVI. RECORD MAINTENANCE

- A. Patient records are kept in their medical record charts
- B. Quality control logs must be kept in an accessible area for at least 3 years.
- C. Optical test cartridge results sheets are retained with the QC logs.

XVII. REFERENCES

- A. UCSF Clinical Laboratory Manual
- B. Siemens DCA Systems, Product Insert Hemoglobin A1c Normal and Abnormal Control Kit, Siemens Medical Solutions Diagnostics, Tarrytown, NY, USA, 10591-5097
- C. Siemens DCA Systems, Product Insert Hemoglobin A1c Reagent Kit, Siemens Healthcare Diagnostics, Inc., Tarrytown, NY, USA, 10591-5097, 8/2008 Rev. A
- D. Bodor, G.S., et. al., Standardization of glycohemoglobin determinations in the clinical laboratory: 3 Years of Experience, Clinical Chemistry, Vol. 38, 2414 - 2418, 1992.
- E. Burtis, C.A., and Ashwood, E.R, ed. Tietz Textbook of Clinical Chemistry, 2nd Ed., W. Saunders and Co., Philadelphia, Pa, 1994.
- F. Henry, J.B., ed., Clinical Diagnosis and Management by Laboratory Methods, 17th ed.W. Saunders and Co., Philadelphia, Pa., 1984
- G. DCA Vantage Analyzer Operator's Guide, Ref 06489264, Rev. 2008-06
- H. Siemens Healthcare Diagnostic Inc. Tarrytown, NY 10591-5097, U.S.A, 877-229-3711

Signature Manifest

Document Number: SOP-0020

Revision: 2

Title: DCA Vantage

All dates and times are in Pacific Standard Time.

DCA Vantage Procedure

SR Sup Review

Name/Signature	Title	Date	Meaning/Reason
Cynthia Ishizaki (024044224)	POC SR SUP	17 Jun 2013, 03:20:43 PM	Reviewed

Med Dir Apprvl

Name/Signature	Title	Date	Meaning/Reason
Tim Hamill (023335003)	PA CB MED DIRECTOR	19 Jun 2013, 09:24:24 AM	Approved