

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 1 of 17
7.4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 05/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

<b>Purpose</b>	This document provides a convenient, quantitative method to ensure accurate bedside measurement of the percent concentration of hemoglobin A <sub>1c</sub> (HbA <sub>1c</sub> ) in blood using the DCA 2000 Analyzer. The measurement of HbA <sub>1c</sub> concentration is recommended for monitoring the long-term care of persons with diabetes.
<b>Audience</b>	The information in this document is applicable to all medical, nursing (RN, LVN, HTA, NA), and laboratory personnel.
<b>Policy</b>	A physician's order is required for this test. At the discretion of the provider, test results where clinical indication or departmental protocol suggest confirmatory testing, (specimen) may be sent to the laboratory.
<b>Test Principle</b>	HbA <sub>1c</sub> is formed by the non-enzymatic glycation of the N-terminus of the $\beta$ -chain of hemoglobin A <sub>o</sub> . The level of HbA <sub>1c</sub> is accepted as an indicator of the mean daily blood glucose concentration over the preceding two months. Recent studies have shown that the clinical values obtained through regular measurement of HbA <sub>1c</sub> leads to changes in diabetes treatment and improvement of metabolic control as indicated by a lowering of HbA <sub>1c</sub> values. This assay is based on a latex immunoagglutination inhibition methodology. Both the concentration of HbA <sub>1c</sub> specifically and the concentration of total hemoglobin are measured, and the ratio reported as percent HbA <sub>1c</sub> . For the measurement of total hemoglobin, potassium ferricyanide is used to oxidize hemoglobin in the sample to methemoglobin. The methemoglobin molecule then complexes with thiocyanate to form thiocyan-methemoglobin, which is measured photometrically at 531 nm. The extent of color is proportional to the concentration of total hemoglobin in the sample. All measurements and calculations are performed automatically by the DCA 2000 Analyzer, and the screen displays percent HbA <sub>1c</sub> at the end of the assay.
<b>Specimen</b>	<ul style="list-style-type: none"> <li>• The DCA 2000 Analyzer requires 1<math>\mu</math>l capillary or venous blood.</li> <li>• EDTA, heparin, fluoride/oxalate and citrate are acceptable anticoagulants for venipuncture. Do not use any other anticoagulants.</li> <li>• <b>NOTE:</b> Once the capillary is filled with sample, analysis <i>must</i> begin within 5 minutes.</li> </ul>

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 2 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Equipment and Supplies

DCA 2000 Analyzer (Bayer)  
 Capillary Holders  
 Calibration Card  
 Optical Test Cartridge (1 ea., Bayer Part No. 95002911)  
 Air filter (pack of 8, Bayer Part No. 95002117)  
 Gloves  
 lint-free tissue  
 Alcohol swab  
 Collection device

### Reagents

Reagent Cartridges

1. Antibody Latex: HbA<sub>1c</sub> -specific mouse monoclonal antibody adsorbed onto latex particles. 2.5% w/v antibody-latex in 10mM glycine buffer. 16% w/v nonreactive ingredients (10µL dried in each reagent cartridge).
2. Agglutinator: 0.005% w/v poly (aspartic acid) polymer covalently attached to the HbA<sub>1c</sub> 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 cartridge).
3. Buffer Solution: 8.1% w/v lithium thiocyanate, 0.01% digitonin in 200 mM glycine buffer (0.6 mL in each cartridge).
4. Oxidant: 1.5% w/v potassium ferricyanide in water with 21% w/v nonreactive ingredients (10µl dried in each cartridge).

#### WARNINGS AND PRECAUTIONS:

DCA 2000 HbA<sub>1c</sub> Reagent Cartridges are for *in vitro* diagnostic use and must be treated as potentially hazardous.

### Reagent Storage and Stability

#### REAGENT CARTRIDGES

##### Temperature Indicator:

Upon receipt of this kit, check the temperature indicator located on the inside of the top lid 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 instructions given on the carton.

##### Storage:

Store reagent cartridges refrigerated at 2° - 8°C (36° - 46°F). Capillary holders may be stored refrigerated or at room temperature, 15° - 30° C (59° - 86° F).

<b>UTMB POINT OF CARE TESTING PROCEDURES POLICY -</b>	<b>Policy 7.4.75</b> Page 3 of 17
<b>7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED</b>	<b>Effective: 5/97</b> <b>Revised: 01/09</b>

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Reagent Storage and Stability (continued)

#### Use Life:

Reagent cartridges can be kept for up to three months at room temperature before the expiration date. Record on the carton the date the carton was placed at room temperature.

#### Handling:

Discard the reagent cartridge if the cartridge is damaged, the pull-tab is loose or missing, the desiccant is missing, or if loose desiccant particles are found inside the foil pouch. Allow the reagent cartridge to warm up to room temperature for 10 minutes (in unopened foil pouch) or 5 minutes (if removed from foil pouch). After opening the foil pouch, the reagent cartridge must be used within one hour.

#### CONTROLS:

Store **lyophilized** DCA 2000<sup>®</sup> HbA<sub>1c</sub> Normal and Abnormal Controls at 2° - 8°C (36° - 46°F) or at -20° C (-40° F). **Reconstituted** DCA 2000 HbA<sub>1c</sub> Controls should not be frozen. **The reconstituted control is stable for 3 months when stored refrigerated.**

### Calibration

**Analyzer** - The DCA 2000 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.

**Reagent** - 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.** 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 card in use, the instrument prompts the user to scan the calibration card. The instrument can store two calibrations for the DCA2000 HbA<sub>1c</sub> Assay. Each of the two calibrations is for a different lot number.

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 4 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Calibration (continued)

Step	Action
1	Set the power switch to ON (right back), wait 2-8 minutes for the DCA 2000 analyzer to warm up. <b>CAUTION: The program card must be inserted or removed only when the power switch is set to OFF. If the card is inserted when the power is ON, the card can be permanently damaged.</b>
2	Use the calibration card provided. Locate the dot on the instrument next to the bar code track. With the bar code of the calibration card facing right, insert the calibration card into the bar code track.
3	Hold card gently against the right side of the track and quickly and smoothly slide the card down past the dot. A beep sounds to signal a successful calibration. If no beep sounds, repeat procedure.
4	To view the calibration status for the DCA 2000 Analyzer, press the MENU key, then repeatedly press the MENU/NEXT key until [VIEW CALIBRATION STATUS] is displayed. Press ENTER. The calibration status for the most recent calibration will be displayed. Press NEXT to recall a second stored calibration. To exit the menu, press ESCAPE twice or scan a bar code.
5	Record the new reagent cartridge lot number on the "Daily Log of Quality Control and Patient Results" form.

### Quality Control Frequency

UTMB adheres to manufacturer's quality control guidelines.

#### Quality control is to be performed:

- Each day of use before patient testing
- With each new lot of reagents.
- When results do not match the patient's clinical condition or symptoms.

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 5 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Quality Control Preparation

Lyophilized controls can be used until the last day of the expiration month shown on the vial.  
**Reconstituted controls are stable for 3 months when stored refrigerated.**

Step	Action
1	Remove control vial from refrigerator just prior to reconstitution. <b>Do not use if moisture is present in the vial, prior to reconstitution. This is an indication of deterioration of the control material and renders the material unsatisfactory for use.</b>
2	Write the "opened" and expiration (3 months after reconstitution) date on the vial.
3	Gently tap the bottom of the vial on the counter to collect as much material as possible on the bottom of the vial.
4	Carefully remove the cap from the vial.
5	Holding the Reconstitution Fluid dropper bottle <b>vertically</b> , add <b>six (6)</b> drops of fluid to the control vial. <b>NOTE:</b> Discard the first drop to ensure a constant volume of drops thereafter.
6	Carefully replace the cap, not the eyedropper, and swirl the control vial several times. Let stand at room temperature for at least 15 minutes.
7	After 15 minutes, coat all surfaces of the control vial by rotating and inverting the vial. Continue mixing until the solution is homogenous and all lyophilized material is reconstituted.
8	Remove and discard cap. Replace with Eyedropper Cap Assembly.

### Quality Control Testing

Do not allow controls to stand uncapped. Control material may remain at room temperature for 30 minutes during testing, but should be stored in a refrigerator in an upright position and tightly capped at all other times. Discard any reconstituted control solution appearing turbid or obviously contaminated.

Step	Action
1	Allow reagent cartridges to warm up naturally at room temperature for 10 minutes in the unopened foil pouch.
2	Remove controls from refrigerator for testing.

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 6 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Quality Control Testing (continued)

3	Record date in log book. NOTE: Calibration must be performed and recorded in log book each time a new lot of reagent cartridges is opened.
4	Remove the reagent cartridge from the foil pouch. NOTE: Do not use scissors to cut open the foil pouch. Scissors can damage the reagent cartridge, the flexible plastic pull-tab on the cartridge or the sack containing desiccant. To open foil pouch, tear down from corner notch (until entire <i>long</i> side of pouch is open) when handling the reagent cartridge, do not touch or otherwise contaminate the optical window or erroneous test results may occur. Discard the reagent cartridge if the cartridge is damaged, the flexible plastic pull-tab is loose or missing, the desiccant is missing, or if loose desiccant particles are found inside the foil pouch.
5	Obtain a capillary holder and remove it from the plastic wrap.
6	Unscrew the Eyedropper Cap Assembly. While applying only slight pressure to the bulb, insert the tip of eyedropper into the control solution (tilt bottle as necessary). Release pressure on bulb to aspirate a very small amount of control solution.
7	Hold the glass capillary tube to the control solution and completely fill the 1 µl tube. Touch <i>only</i> the tip of the tube to the control solution. If an air bubble(s) is present in the filled tube, discard the capillary holder and refill a new one. IMPORTANT: Do not allow the control solution to come in contact with the plastic part of the capillary holder. Any control solution adhering to the capillary holder may be transferred into the reaction buffer, along with the 1 µl control solution in the glass capillary tube. This may cause an invalid HbA <sub>1c</sub> control result or possibly an error message. <b>If control solution comes in contact with the plastic of the capillary holder, discard the capillary holder.</b>
8	Do not touch the eyedropper to any other surfaces. Squeeze any excess control solution out of the eyedropper back into the control solution vial. Carefully replace and screw the Eyedropper Cap Assembly back onto control vial.

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 7 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Quality Control Testing (continued)

9	Using a lint-free tissue, <b>carefully wipe</b> any control solution off the sides of the glass capillary tube. <b>DO NOT ALLOW THE TISSUE TO TOUCH THE OPEN END OF THE TUBE.</b> Contact with the open end could result in loss of sample. If sample loss is obvious, discard the capillary holder, and refill a new one.
10	Carefully insert the capillary holder into a DCA 2000 HbA <sub>1c</sub> Reagent Cartridge until the holder <b>gently snaps</b> into place.
11	Locate the dot on the instrument next to the bar code track. With the bar code of the control card facing right, insert the control card into the bar code track.
12	Hold card gently against the right side of the track and quickly and smoothly slide the card down past the dot. A beep sounds to signal a successful scan. Press ENTER. If no beep sounds, repeat procedure. If a beep repeatedly fails to sound, refer to Troubleshooting in the Operating Manual, Section 5.
13	At the display prompt, [LOAD CARTRIDGE/ PULL TAB/ CLOSE DOOR], open the cartridge compartment door. Hold the cartridge so that the bar code faces right. Insert the cartridge into the compartment until a subtle snap is heard/felt. Using a smooth, slow, continuous motion, pull the flexible plastic pull-tab completely out of the reagent cartridge. Close door and dispose of the plastic pull-tab.
14	Five (5) seconds after the door is closed, a beep sounds and the assay begins. NOTE: If you accidentally close the door before you pull the tab, you have 5 seconds to re-open the door (the display returns to "LOAD CARTRIDGE") and pull the tab.
15	Document the result on the "Daily Log of Quality Control and Patient Results" <i>before</i> removing the reagent cartridge.
16	NOTE: If "CONTROL OUT OF RANGE" is displayed, press ESCAPE to display value of out-of range control and record on QC log. <b>DO NOT</b> proceed with specimen analysis and refer to the next section.
17	Remove the cartridge by opening the cartridge compartment door. Push and hold down the button located on the right side of the compartment. While holding the button down, push plastic tab (on cartridge) to the right to unlock the cartridge. Pull test cartridge out of the compartment, and dispose in biohazard container according to hospital policy.

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 8 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Quality Control Corrective Action

If a control **does not** perform as expected: check controls, reagent cartridges, instrument, environmental conditions, and technique before proceeding.

Step	Action
1	Do not report the patient results.
2	Repeat control.
3	If the repeat does not fall within acceptable limits, the patient sample should be sent to the Clinical Laboratory for testing.
4	The Point of Care can be contacted at 747-2496 or 747-2497, or for additional assistance contact Bayer tech support at 1-877-229-3711. Refer to the troubleshooting guide in the Operator's Manual for further instructions.

### Recording Quality Control Data

Record results on appropriate log the following:

- Clinic name and instrument serial number
- Current cartridge lot number, and expiration date
- Lot number, expiration date, and acceptable ranges for normal and abnormal controls at the top of the page, information available in the package insert
- Date and time controls were tested, results and initials
- Record maintenance as performed in the maintenance column. Refer to page 15 of policy for a list of weekly, monthly, and as required maintenance.

### Review of Quality Control Data

Quality Control will be performed and reviewed by the operator. The operator who performs the test will document the results on the QC log, including any "out of range" values and corrective action. In addition, the TSM will submit a QC Data Tool on a monthly basis.

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 9 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Patient Preparation

Step	Action
1	The patient identification must be verified by the person collecting the sample. At outpatient settings, this can be achieved by checking the name on the chart against the patient's verbal identification statement.
2	Prior to testing the patient should be informed of the purpose of the test and the steps involved in the procedure.
3	If the specimen is going to be obtained from a fingerstick the patient should wash his/her hands prior to testing, if possible.

### Specimen Collection

Step	Action
1	Universal Precautions as stated in nursing policy must be followed when collecting and handling blood specimens.
2	See Patient Testing 1-5 in the next section before proceeding with specimen collection.
3	Fresh capillary whole blood samples are to be taken from the fingertip.
4	Cleanse the puncture site with an alcohol swab.
5	Allow the area to air dry.
6	Using a collection device obtain the blood sample. Specific instructions for blood collection can be found in the <u>Laboratory Survival Guide</u> located at every testing site or on-line at <a href="http://lablink.utmb.edu/pathology/manual.htm">http://lablink.utmb.edu/pathology/manual.htm</a> . Alternately, the NCCLS document H4-A3, <u>Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture</u> or NCCLS document H3-A3 <u>Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture</u> can be used.
7	Fingerstick: <ul style="list-style-type: none"> <li>Puncture the side of the tip of the finger to produce a free spontaneous flow of blood.</li> </ul>
8	Continue with #6 of Patient Testing in the next section.

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 10 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Patient Testing

Step	Action
1	Assemble required supplies at the patient's location. Allow reagent cartridges to warm up naturally at room temperature for 10 minutes in the unopened foil pouch.
2	Set the instrument power switch to ON. Allow time for the instrument to warm up (1-8 minutes). READY: SCAN BAR CODE is displayed and a beep is heard when the instrument is ready.
3	To assign a sequence number to the sample, press MENU/NEXT key until SET SEQUENCE NUMBER is displayed. Press the UP arrow or the DOWN arrow key to select the digit above the cursor. Press the NEXT key to move the cursor to the next digit. Repeat this procedure to select the second and third digits. Press ENTER to save changes. Press ESCAPE to exit the menu. To display the next menu item, press NEXT.
4	Remove the reagent cartridge from the foil pouch. <b>NOTE:</b> Do not use scissors to cut open the foil pouch. Scissors can damage the reagent cartridge, the flexible plastic pull-tab on the cartridge or the sack containing desiccant. To open foil pouch, tear down from corner notch (until entire <i>long</i> side of pouch is open.)
5	<b>NOTE:</b> When handling the reagent cartridge, do not touch (or otherwise contaminate) the optical window or erroneous test results may occur. Discard the reagent cartridge if the cartridge is damaged, the flexible pull-tab is loose or missing, the desiccant is missing, or if loose desiccant particles are found inside the foil pouch.
6	Obtain the blood sample by fingerstick or routine venipuncture. <b>Caution:</b> <u>Do not allow blood to contact the plastic part of the capillary holder.</u> Any blood touching the plastic will be transferred into the reaction buffer, along with the 1 µl of blood in the glass capillary. This will cause an invalid HbA <sub>1c</sub> result and possibly an error message. If blood contacts capillary holder, discard capillary holder. Fingerstick:

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 11 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Patient Testing (continued)

	<ul style="list-style-type: none"> <li>Puncture the side of the tip of the finger to produce a free spontaneous flow of blood.</li> <li><b>Hold</b> the capillary holder at an angle.</li> <li><b>Touch</b> <i>only</i> the tip of the capillary to a <i>small drop</i> of blood on the finger until the capillary is filled.</li> </ul> <p>Venipuncture:</p> <ul style="list-style-type: none"> <li>Anticoagulated blood should be <b>mixed well</b> (slowly <i>invert the tube ten times</i>) prior to testing.</li> <li><b>Remove stopper</b> from the tube.</li> <li><b>Hold</b> the capillary holder at an angle.</li> <li>Using the sample from the stopper, <b>touch</b> <i>only</i> the tip of the capillary to the blood sample on the stopper.</li> <li>NOTE: Do not attempt to fill capillary by touching glass capillary to blood in a blood collection tube. Attempting to fill capillary in this manner most often results in blood touching the capillary holder. <u>If blood touches the capillary holder, discard capillary holder.</u></li> </ul>
7	Using a lint-free tissue, <b>carefully wipe</b> the outside of the glass capillary. <b>Do not allow the tissue to touch the open end of the glass capillary.</b> Contact with the open end could result in loss of sample (by wicking into tissue). If sample loss is obvious, discard the capillary holder; then repeat procedure using a new capillary holder.
8	Carefully insert the capillary holder into the reagent cartridge until the holder <b>gently snaps</b> into place.
9	<b>Caution:</b> Avoid harsh insertion of capillary holder. It is important not to dislodge sample from glass capillary or erroneous results will occur.
10	Insert the reagent cartridge into the bar code track of the instrument (located above the dot) by holding it so that the bar code faces to the right. Quickly (within 1 second) and smoothly, slide the cartridge down past the dot. A beep sounds to signal a successful scan. If no beep sounds, repeat the procedure. If a beep repeatedly fails to sound, refer to Troubleshooting in the Operating Manual, Section 5.

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 12 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Patient Testing (continued)

11	At the display prompt, [LOAD CARTRIDGE/ PULL TAB/ CLOSE DOOR], open the cartridge compartment door. Hold the cartridge so that the bar code faces right. Insert the cartridge into the compartment until a subtle snap is heard/felt. Using a smooth, slow, continuous motion, pull the flexible plastic pull-tab completely out of the reagent cartridge. Close door and dispose of the plastic pull-tab.
12	Five (5) seconds after the door is closed, a beep sounds and the assay begins. NOTE: If you accidentally close the door before you pull the tab, you have 5 seconds to re-open the door (the display returns to "LOAD CARTRIDGE") and pull the tab.
15	After the test is completed, a beep sounds and the test result is displayed. Document the result on the "Daily Log of Quality Control and Patient Results" <i>before</i> removing the reagent cartridge.
16	Remove the cartridge by opening the cartridge compartment door. Push and hold down the button located on the right side of the compartment. While holding the button down, push plastic tab (on cartridge) to the right to unlock the cartridge. Pull test cartridge out of the compartment, and dispose in biohazard container according to hospital policy.
17	To cancel a test at any time during the testing process, press ESCAPE. At the display prompt CANCEL TEST, press ENTER within 15 seconds. Discard the canceled test.

### Reporting Result

- Results are reported as a percent of the total hemoglobin.
- When the measurement is complete, record the results shown on the display. No further calculation is required.
- The test linearity ranges from 2.5-14.0. Values outside the range are reported as less than 2.5 or greater than 14.0.
- For results obtained outside the instrument reportable range, the DCA 2000 Analyzer method DOES NOT provide for re-assay using a dilute (for >14.0 %) or a larger sample aliquot (for <2.5 %).
- Document the HbA<sub>1c</sub> test result in the patient chart and on appropriate log.
- Results recorded on log sheet are entered into the LIS system by POCT personnel.

<b>UTMB POINT OF CARE TESTING PROCEDURES POLICY -</b>	<b>Policy 7.4.75</b> Page 13 of 17
<b>7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED</b>	<b>Effective: 5/97</b> <b>Revised: 01/09</b>

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Normal Range

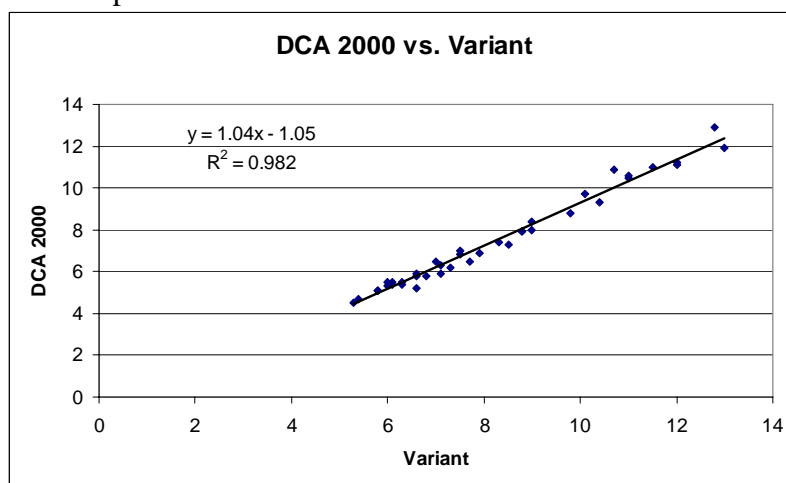
Normal Range: 4 - 6 %.  
ADA target for diabetics: < 7%

### Inter-pretation

The physician ordering the HbA<sub>1c</sub> shall be responsible for the interpretation of the result based on the patient's condition at the time of draw.

### Limitations

The DCA 2000 gives acceptable results, especially below the threshold of 7% HbA<sub>1c</sub>, and can be used to monitor the long term glucose control of diabetics. Caution, however, must be used when the DCA 2000 and central laboratory HbA<sub>1c</sub> (Variant II) are interspersed in the monitoring of diabetic patients.



The DCA 2000 HbA<sub>1c</sub> assay gives accurate and precise results over a range of total hemoglobin of 7 to 24 g/dL. Samples of patients with severe cases of anemia whose hemoglobin concentrations are lower than 7 g/dL, or those patients with polycythemia who may have hemoglobin concentrations above 24 g/dL, should be assayed by the laboratory. Glycated hemoglobin F is not measured by the DCA 2000 HbA<sub>1c</sub> assay. At levels of hemoglobin F less than 10%, the DCA 2000 will accurately indicate the patient's glycemic control. However, at a very high levels of hemoglobin F (>10%), the amount of HbA<sub>1c</sub> will be lower than expected because a greater proportion of the glycated hemoglobin will be in the form of glycated hemoglobin F. Hemoglobin A<sub>1c</sub> results for such patients will not accurately indicate the patient's glycemic control and should not be compared to published normal or abnormal values. Conditions such as hemolytic anemia, polycythemia, homozygous HbS and

<b>UTMB POINT OF CARE TESTING PROCEDURES POLICY -</b>	<b>Policy 7.4.75</b> Page 14 of 17
<b>7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED</b>	<b>Effective: 5/97</b> <b>Revised: 01/09</b>

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

HbC, can result in decreased life span of the red blood cells, which will cause HbA<sub>1c</sub> results to be related to glycemic control, when using published reference ranges.

### Interfering Substances

Bilirubin up to a level of 20 mg/dL, does not interfere this assay.  
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.  
Rheumatoid factor, up to 1:5120 titer, does not interfere with this assay.  
Expected serum levels of the following drugs, commonly prescribed to persons with diabetes do not interfere with this assay: Diabinese®, Orinase®, Tolinase®, Micronase®, Dylmelor®, glipizide.

### Specific Performance Characteristics

The precision and correlation data are results of studies conducted by staff at separate physician offices.

**Precision:** Multiple DCA 2000 HbA<sub>1c</sub> assays of two different commercially prepared whole blood controls were performed by three independent investigators. The assigned values listed were determined by the manufacturer. Within-run precision was evaluated by including Normal and Abnormal controls, in duplicate in each run of clinical specimens.

Control	Site No.	Assigned Value (HbA <sub>1c</sub> )	Mean Value (HbA <sub>1c</sub> )	No. Runs	No. Assays	Within Run S.D.	Within Run %C.V.	Between Run S.D.	Between Run % C.V.
Normal	1	5.2	4.95	21	42	0.16	3.3	Neg*	Neg*
	2	5.2	5.10	22	44	0.11	2.2	0.06	1.2
	3	5.2	5.11	22	44	0.12	2.3	0.06	1.1
Abnormal	1	11.9	11.32	21	42	0.34	3.0	Neg*	Neg*
	2	11.9	11.86	22	44	0.33	2.8	0.51	4.3
	3	11.9	11.81	22	44	0.44	3.7	0.11	0.9

### Specific Performance Characteristics

**Correlation:** The correlation of HbA<sub>1c</sub> in clinical specimens ranging from 3.8 % - 14.0 % HbA<sub>1c</sub> (both venous and capillary) was determined using the DCA 2000 HbA<sub>1c</sub> System (y) and ion exchange high performance liquid chromatography (HPLC) (x). Results are as follows:

UTMB POINT OF CARE TESTING PROCEDURES POLICY -	Policy 7.4.75 Page 15 of 17
7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED	Effective: 5/97 Revised: 01/09

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

Site No.	Sample Type	No. of Assays	Regression Line	Standard Error of Estimate	Correlation Coefficient
1	venous	50	$y = 0.91x + 0.26$	0.42	0.98
1	capillary	50	$y = 0.94x + 0.00$	0.51	0.98
2	venous	47	$y = 0.89x + 0.42$	0.39	0.98
2	capillary	47	$y = 0.91x + 0.34$	0.50	0.97
3	venous	49	$y = 0.94x + 0.34$	0.42	0.98
3	capillary	50	$y = 0.91x + 0.58$	0.52	0.98

### Specific Performance Characteristics (continued)

**Specificity:** Effect of Hemoglobin Variants: The antibody in the DCA 2000 HbA<sub>1c</sub> assay is specific for the first few amino acid residues of the glycosylated amino-terminus of the β-chain of hemoglobin A. Any glycosylated hemoglobin molecule having this same structure will be measured in the assay. Most glycosylated hemoglobin variants are immunoreactive in the DCA 2000 HbA<sub>1c</sub> assay (e.g., HbS<sub>1c</sub>, HbC<sub>1c</sub>, HbE<sub>1c</sub>). The point mutations in these molecules occur at the 6 position of the β-chain (HbS and HbC) and at the 26 position of the β-chain (HbE). Thus, the point mutations in these variants do not affect the binding of the antibody used in the DCA 2000 HbA<sub>1c</sub> assay. The DCA 2000 will report % HbA<sub>1c</sub> values that will reflect the glycemic control of patients with these hemoglobinopathies.

### Instrument Maintenance

**Weekly:** Clean the exterior of the instrument, including the display panel and bar code window with a lint-free cloth dampened with water. Turn off the power and unplug the power cord before cleaning exterior of instrument. Caution: Do not allow water or other cleaning fluid to drip inside instrument (bar code window area, program card area and key pad are especially vulnerable).

**Monthly:** Perform optical test cartridge, which monitors the performance of the optical system over time.

**Quarterly:** Clean cartridge compartment and change air filter, refer to the Operator's Manual, Instrument Care and Routine Maintenance.

**Document** maintenance on corresponding log kept on site.

<b>UTMB POINT OF CARE TESTING PROCEDURES POLICY -</b>	<b>Policy 7.4.75</b> Page 16 of 17
<b>7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED</b>	<b>Effective: 5/97</b> <b>Revised: 01/09</b>

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Monthly Sample Comparison

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A sample comparison to the UTMB High Volume Laboratory will be performed and submitted each month. Passing criteria is within ½ % HbA1C of the laboratory result.

### References

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Bayer Corporation, *DCA 2000 Analyzer Operator's Manual*, 1994, Elkhart, IN.  
Bayer Corporation, *DCA 2000 Hemoglobin A<sub>1c</sub> Reagent Kit Package Insert*, Revised 12/96, Elkhart, IN.

Bayer Corporation, *DCA 2000 Quality Control Kit Package Insert*, Revised 4/1998, Elkhart, IN.

<b>UTMB POINT OF CARE TESTING PROCEDURES POLICY -</b>	<b>Policy 7.4.75</b> Page 17 of 17
<b>7. 4.75 Hemoglobin A1C Measurement - DCA 2000 Analyzer CLIA WAIVED</b>	<b>Effective: 5/97</b> <b>Revised: 01/09</b>

## Hemoglobin A1C Measurement - DCA 2000 Analyzer

### Hemoglobin A1C Policy Revision Summary DCA 200 Analyzer

<b>Date</b>	<b>Page</b>	<b>Description</b>	<b>Signature</b>
<b>12/2004</b>		Addition: "At the discretion of the provider, test results where clinical indication or departmental protocol suggest confirmatory testing, (specimen) may be sent to the laboratory." to Policy section.	
		Addition: "UTMB adheres to manufacturer's quality control guidelines." to Quality Control section.	
<b>06-05</b>		Modified "Normal Range" section per Director's instructions.	
<b>06/30/06</b>	3 of 16	Addition: "Reagent Storage and Stability section, Handling"	
	3 of 16	Removed: "Calibrate once every six months, or each time a new lot number of reagent cartridges is used."	
	4 of 16	Addition: "QC Frequency" section.	
	16 of 16	Addition: "Monthly Sample Comparison" section	
<b>10/19/06</b>	4 of 16	Modified: QC requirements ("QC Frequency" section).	
<b>01/16/08</b>	13 of 17	Modified: "Limitations" section	
<b>01/31/09</b>	17	Added Signature Column	