**CLIA-waived Glycated Hemoglobin A1c (HbA1c) Testing and Quality Control Procedure**

**DCA Vantage® Analyzer**

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| *Prepared By:* |  | | *Date:* |  | |
| *Approved By:* |  | | *Date:* |  | |
| *Effective Date:* |  | | | | |
| *Discontinued Date:* |  | *(retain this procedure for at least two years)* | | | |
| *Supersedes an Earlier Procedure:* |  | | | | *(Y or N)* |
| *Earlier Procedure Discontinuance Date:* |  | | | | |

The medical/laboratory director or the director’s designee should review all copies of this procedure at least once a year. The director should keep a log of the copies being maintained.

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Title:

Hemoglobin A1c (HbA1c) in Blood on the DCA Analyzer®

# Principle of the Test

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 HbA1c, an inhibition of latex agglutination assay is used. An agglutinator (synthetic polymer containing multiple copies of the immunoreactive portion of HbA1c) causes agglutination of latex coated with HbA1c specific mouse monoclonal antibody. This agglutination reaction causes increased scattering of light, which is measured as an increase in absorbance at 531 nm. 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:

% HbA1c = ([HbA1c] / [Total Hemoglobin]) x 100

Both the concentration of hemoglobin A1c specifically and the concentration of total hemoglobin are measured, and the ratio reported as percent hemoglobin A1c.

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

# Clinical Application and Usefulness

This assay provides a convenient, quantitative method for *in vitro* diagnostic use to measure the percent concentration of hemoglobin A1c in blood. The measurement of hemoglobin A1c concentration is recommended for monitoring the long-term care of persons with diabetes.

Hemoglobin A1c is formed by the non-enzymatic glycation of the N-terminus of the β-chain of hemoglobin Ao. The level of hemoglobin A1c is proportional to the level of glucose in the blood over a period of approximately two months. Thus, hemoglobin A1c is accepted as an indicator of the mean daily blood glucose concentration over the preceding two months. Studies have shown that the clinical values obtained through regular measurement of hemoglobin A1c leads to changes in diabetes treatment and improvement of metabolic control as indicated by a lowering of hemoglobin A1c values.

The Diabetes Control and Complications Trial (DCCT) showed the importance of improved glycemic control in reducing the risk and progression of the complications of diabetes.Glycemic control was determined by the measurement of hemoglobin A1c. The American Diabetes Association (ADA) recommends measurement of hemoglobin A1c levels two to four times per year, less frequently in patients with stable control.

Pre-analytic Process

# Specimen Collection and Handling

Specimen Collection

Important: After the glass capillary is filled with sample, analysis must begin within 5 minutes.

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|  |  | BIOHAZARD  All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing. |

* Collect blood in the provided glass capillary (within plastic capillary holder).
* The glass capillary holds 1 µL of whole blood.
* The blood sample may be obtained by fingerstick or venipuncture.
* Acceptable anticoagulants are EDTA, heparin, flouride/oxalate, and citrate.

Specimen Storage and Stability

* Preserved whole blood may be stored at -70°C to 5°C (-94°F to 41°F) for two weeks, or up to 25°C (77°F) for one week.
* Do not refreeze previously frozen blood samples or store in a self-defrosting freezer.
* Allow blood sample to reach room temperature. Mix blood sample thoroughly before use.

Specimen Rejection Criteria

* Extremely short specimens
* Specimens that are clotted
* Specimens collected in the incorrect tube/method

# Reagents

Storage and Stability

Upon receipt of the kit, check the temperature indicator located on the front of the carton. If the indicator has turned red, do not use the reagent cartridges. Note time and date received, and for assistance in obtaining a replacement kit, refer to instructions given on the carton.

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

**IMPORTANT:** Do not use reagent cartridges after the last day of the expiration month.

Ingredients

DCA HbA1c Reagent Cartridges contain the following ingredients:

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| --- | --- | --- |
| Reagent | Volume (Amount) | Ingredients |
| Antibody Latex | 10 µL dried in each reagent cartridge | HbA1c-speciﬁc mouse monoclonal antibody adsorbed onto latex particles. 2.5% w/v antibody-latex in 10 mM glycine buffer; 16% w/v nonreactive ingredients. |
| Agglutinator | 10 µL dried in each reagent cartridge | 0.005% w/v poly (aspartic acid) polymer covalently attached to the HbA1c hapten in 20 mM sodium citrate buffer containing 0.1% w/v bovine serum albumin and 1% w/v nonreactive ingredients. |
| Buffer Solution | 10 mL dried in each cartridge | 8.1% w/v lithium thiocyanate, 0.01% digitonin in 200 mM glycine buffer (0.6 mL in each cartridge). Oxidant: 1.5% w/v potassium ferricyanide in water with 21% w/v nonreactive ingredients. |

# Reagents Special Preparation and Handling

**Reagent Cartridges**

To open the foil pouch, tear down from the corner notch (until the entire long side of the pouch is open).

Discard the reagent cartridge if any of the following conditions exist:

* The cartridge is damaged.
* The flexible pull-tab is loose or missing.
* The desiccant bag is missing or open.
* Loose desiccant particles are found inside the foil package.
* If the foil package is open for more than 60 minutes.

Upon removal from refrigerated storage, allow the reagent cartridge to warm up at 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.

**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. To remove the capillary holder, remove the white plastic film from the clear plastic blister. DO NOT PUSH the capillary holder out of or through the plastic.

Before use, inspect the capillary holder for the presence of the following parts:

* absorbent pad
* glass capillary
* latching mechanism

If the capillary holder is missing any of the above parts, discard the capillary holder.

# Calibration

For detailed procedural information about performing a calibration, refer to the DCA Vantage Operator’s Guide.

The DCA Vantage analyzer is calibrated by the manufacturer. Thereafter, the instrument automatically self-adjusts during the 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.

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

Before you analyze samples, the reagent cartridge barcode (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 DCA Vantage system stores 16 distinct calibrations for the DCA Vantage Hemoglobin A1c Assay. Each calibration is for a different lot. Scan the lot number and test name before you analyze the sample reagent cartridge barcode. This allows access to the appropriate calibration parameter values and calibration curve for the particular lot of reagent in use.

When reagent cartridges are stored and used properly, acceptable performance up to the expiration date is ensured. To verify proper functioning of the DCA System, analyze DCA HbA1c Controls (refer to Quality Control section).

Calibration Interval

Before using a new lot of reagent cartridges, scan the calibration card in to the analyzer.

Calibration Procedure

You must scan the calibration card for a lot of HbA1c cartridges before you can use the lot on the DCA Vantage system. Scanning the calibration card enters the information on the DCA Vantage system.

1. Locate the dot on the system next to the barcode track.
2. Locate the barcode on the calibration card.
3. Hold the card so that the barcode faces to the right.
4. Insert the Calibration card into the top of the barcode track.
5. 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. If you repeatedly fail to hear a beep, refer to the Troubleshooting section in the DCA Vantage Operator’s Guide.

1. To return to the Home screen, select OK.

Accessing Calibration Data

Use the Calibration Data screen to access calibration data including scan date and time, and lot number for DCA HbA1c.

1. At the Recall menu, select Calibration Data. The Calibration Data screen displays.
2. Select HbA1c.

The HbA1c calibration data displays.

1. Highlight the calibration data that you want to display, and select View. The Calibration Data screen displays.
2. To print the calibration data, select Print.
3. To return to the Recall menu, select Recall.

# Quality Control (QC)

For detailed QC procedural information, refer to the DCA Vantage Operator’s Guide and the HbA1c instructions for use.

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.

QC Materials

DCA HbA1c Normal & Abnormal Control Kit, 5068A.

QC Frequency

Run quality control specimens under the following conditions:

* With each new shipment of reagents.
* With each new lot of reagents.
* Each time a calibration card is scanned. (Performing a calibration)
* To train and confirm performance acceptability for new analysts.
* When results do not match the patient’s clinical condition or symptoms.
* Following maintenance or repair procedures.

Defining QC Materials

Use the Control Test Data Entry screen to specify the data and comments you enter when you run a control test, and what data is required or optional. Only the data you select as Enabled displays. If you select Required, you have to enter a value for that specific data before you can exit the screen.

1. At the System Settings menu, select Additional Settings. The Additional Settings screen displays.
2. Select Control Tests. The Control Tests screen displays.
3. Select Data Entry. The Control Sample Data Entry screen displays.
4. Select Enabledor Enabled and Requiredfor each of the following options:

* User ID
* Comments 1-3

1. To save the settings, select Save.

Troubleshooting Out-of-Range QC Values

If the control results fall outside the values stated in the package insert, the following sources of error may have occurred:

* Deterioration of the reagent cartridge test areas due to exposure to light, ambient moisture, or heat.
* Deterioration of the control solution.
* Use a new reagent cartridge to repeat the quality control procedure.
* Use a fresh box of reagent cartridges, or a new lot. If the new reagent cartridge fails to give results within the expected values, proceed to the next possible cause.
* Use a fresh control solution to repeat the quality control procedure.
* Review these instructions to ensure that the test was performed according to the procedures recommended by Siemens Medical Solutions.
* Verify that the materials are not expired.
* Verify that required maintenance was performed.

Analytic Process

# Instrument Operation and System Description

The DCA Vantage is a semi-automated, benchtop system. It is designed to quantitatively measure the percent of Hemoglobin A1c in blood.

The DCA Vantage system is intended for professional use in a physician’s office or hospital laboratory. Tests performed using the DCA Vantage system are intended for *in vitro* diagnostic use. As with all diagnostic tests, do not base a definitive diagnosis on the results of a single test. A physician should make a diagnosis after all clinical and laboratory findings are evaluated.

The system is a spectrophotometer that analyzes the intensity of the light transmitted through the cartridge optical window and reports the results in clinically meaningful units. No calculations are required by the user. When an operator swipes a calibration card, the barcode reader reads the card and the system automatically performs the calibration.

All testing takes place at the DCA Vantage system. The DCA Vantage system consists of 4 functional areas: the reagent cartridge compartment, the onboard barcode reader, the display screen, and the printer. The barcode reader is used to calibrate the system and scan the reagent cartridges and control cards. The reagent cartridges are placed in the reagent cartridge compartment where the tests are run, and when testing is complete, an internal thermal printer can print the test results.

The DCA Vantage system provides an easy-to-navigate and intuitive user interface. 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.

The Home screen displays after the DCA Vantage system completes its initialization. The Home screen displays the state 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.

If the system is in the Ready state, you can start a patient test and scan an HbA1c test cartridge. You can access the Recall menu and the System menu from the Home screen. Notifications or error messages display at the Home screen and provide you with information about the state of the DCA Vantage system.

You test whole blood for the percent concentration of HbA1c. Results are available in 6 minutes.

NOTE:You can use DCA 2000 and DCA 2000 Systems cartridges on the DCA Vantage analyzer.

# Daily Start-up and Maintenance

Running Control Tests

You must perform required control tests when they are scheduled. Patient test is disabled until the required control is performed and passed.

Use the Control Test Data entry screen to specify if the User ID and Comments are displayed as required or optional during data entry for control tests.

Use the Control Test Reminders screen to access the Control Test Log and to change the schedule for Control Tests.

1. Locate the control card.

NOTE:One side of the control card is for a normal control and the other side is for an abnormal control.

1. Locate the dot on the system next to the barcode track.
2. Locate the barcode on the Control card.
3. Hold the card so that the desired control level barcode faces to the right.
4. Insert the Control card into the top of the barcode track.
5. Hold the Control card gently against the right side of the track and quickly slide the card down.
6. A beep sounds to signal a successful scan.

NOTE:If no beep sounds, repeat the scanning procedure. If you repeatedly fail to hear a beep, refer to the Troubleshooting section in the DCA Vantage Operator’s Guide.

1. Scan the reagent cartridge containing the control to be run. (See Performing the HbA1c Test)

Performing the HbA1c Test

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|  |  | BIOHAZARD  All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing. |

NOTE:You can save unused capillary holders and use them with any lot of DCA Hemoglobin A1c reagent cartridges.

1. Open the plastic wrap of the capillary holder by tearing the wrap at the serrated edge with the arrow.
2. Inspect the capillary holder for the presence of the following parts:

* absorbent pad
* glass capillary
* latching mechanism

If the capillary holder is missing any of the above parts, discard the capillary holder.

Filling the Capillary with Whole Blood from a Fingerstick

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

NOTE:1 µL of blood is required to fill the capillary.

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.

Skip to step 5 in next section: “Filling the Capillary with Blood obtained by Venipuncture”.

Filling the Capillary with Blood obtained by Venipuncture:

1. Mix the sample well (by inversion or use of a tube mixer) to prevent separation of red blood cells and plasma.
2. Remove the stopper from the blood collection tube in such a way that a small sample of blood remains on the stopper.
3. Hold the capillary holder at an angle.
4. Touch only the tip of the capillary to the blood sample on the stopper.

NOTE: Do not attempt to fill the capillary by touching the glass capillary to blood in a blood collection tube. Attempting to fill the capillary in this manner most often results in blood touching the capillary holder. If blood touches the capillary holder, discard the capillary holder.

1. 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.

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

Inserting Capillary Holder into Reagent Cartridge

****CAUTION

Avoid harsh insertion of the capillary holder. Do not dislodge the sample from the glass capillary or erroneous results may occur.

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

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. If a beep repeatedly fails to sound, refer to the Troubleshooting section in the DCA Vantage Operator’s Guide.

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 system.

1. Using a smooth, slow, continuous motion, pull the flexible pull-tab completely out of the reagent cartridge.
2. 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.

Entering Sample Data

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

NOTE:You can only enter data during the test if you have configured to enable data entry. For more information, see the DCA Vantage Operator’s Guide.

You can enter the following sample demographic information:

* Sample ID
* Patient ID
* Last Name
* First Name
* User ID
* Comments 1-8

1. Select Sample ID. The Sample ID screen displays.
2. Enter theSample ID.
3. Select Enter. The Sample ID displays next to the Sample ID button.
4. Select Patient ID. The Patient ID screen displays.
5. Enter the Patient ID**.**
6. Select Enter. The Patient ID displays next to the Patient ID button.
7. Select Last Name. The Last Name screen displays.
8. Select First Name. The First Name screen displays.
9. Select User ID. The User ID screen displays.
10. Select Comments 1-8. The Comment(s) screen display.

Removing the Reagent Cartridge

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.

1. Pull the reagent cartridge out of the compartment.
2. Close the system door.
3. Discard the cartridge in a proper container, according to your standard laboratory procedures.

Cancelling a test

You can cancel a test anytime.

To cancel a test, select Cancel.

NOTE:If a test in progress is cancelled, you must discard the sample.

Using the Patient Tests Menu

Use the Patient Tests menu to access the screens that specify the data you enter with patient tests, and to view what factors control how some patient test results are calculated.

Use the Patient Data Entry screen to specify the data and comments you enter when you run a patient test, and what data is enabled or required. Only the data you select as enabled displays. If you select required, you have to enter a value for that specific data before you can exit the screen.

1. At the Additional Settings menu, select Patient Tests. The Patient Tests screen displays.
2. Select Data Entry. The Patient Data Entry screen displays.
3. Select either Enabled or Enabled and Required for each of the following options:

* Sample ID
* Patient ID
* Last Name
* First Name
* User ID
* Comments 1-8

1. To save the settings, select Save.

Setting the HbA1c Reference Range

The reference Range screen can be used to specify the upper and lower reference range values for HbA1c results.

NOTE:If you are a user of version 3.0 software or higher, you will need to select if you wish to display, print and transmit the reference range with each test. Once you “enable” or “disable” this feature you can select the “Set Range” button. (Debbie, please have someone use the v 3.0 software if you want to add in more detail as to where to find the enable/disable screen.

NOTE:You cannot set the lower limit higher than the upper limit, or allow a difference of less than 0.5% between the upper and lower limits.

1. At the Additional Settings menu, select Patient Tests. The Patient Tests screen displays.
2. Select Reference Range.

The HbA1c Reference Range screen displays.

1. Use the up and down arrows to set the upper and lower limits.
2. To set the reference range to the default values, select Reset Default Values.

This resets the Lower % to 4.0 and the Upper % to 6.0.

1. To save the HbA1c reference range, select Save.

The range is saved.

Setting the HbA1c User Correction

Use the HbA1c User Correction screen to adjust the slope and the offset for HbA1c values.

If results are within the instrument operating range and a user correction is applied, the corrected results are reported with an asterisk (\*). Corrected results are not saved in the DCA system memory. Only the original, uncorrected results are saved. Saved data when recalled is displayed as uncorrected if no correction is set in the system, or if a correction is set in the DCA system that correction is applied.

1. Select Patient Tests from the Additional Settings menu. The Patient Tests screen displays.
2. Select HbA1c User Correction. The HbA1c User Correction screen displays.
3. Change the slope, if needed:
4. Select Edit. The HbA1c Slope screen displays.
5. Enter the slope.
6. Select Enter. The HbA1c User Correction screen displays.
7. Change the offset, if needed:
8. Select Edit. The HbA1c Offset screen displays.
9. Enter the offset.
10. Select Enter. The HbA1c User Correction Screen displays.
11. To reset the settings to the default values, select Reset Default Values. This resets the slope to 1.000 and the offset to 0.0.
12. Select Back. The Patient Tests screen displays.

Post-analytic Process

# Reporting Results

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results.

**Result preceded by a less than sign (<):**

A less than sign in the display indicates a concentration below the lower limit of the test (under range). Report the result as being less than 2.5% HbA1c. This method does not provide for re-assay using a larger sample aliquot. Results less than 2.5% HbA1c are rare and may indicate that the sample contains substantial amounts of fetal hemoglobin (does not react in the immunoassay); or that the patient may be suffering from hemolytic anemia or polycythemia (conditions which often result in a significant decrease in the life span of red blood cells).

**Result preceded by a greater than sign (>):**

A greater than sign in the display indicates a concentration above the upper limit of the test (over range). Report the result as being more than 14.0% HbA1c. This method does not provide for re-assay using a diluted sample. To obtain a more quantitative test value, use another test method.

All laboratory tests are subject to random error. If the test result is questionable, or if clinical signs and symptoms appear inconsistent with test results, re-assay the sample or conﬁrm the result using another method.

Reference Interval

HbA1c concentrations in the following range are reported: 2.5% to 14.0% HbA1c.

The test is linear throughout this range.

Units for Reporting Results

The system reports results by percentage.

Acceptable Results

Patient test results are acceptable and may be reported when:

* Proper quality controls have been performed, are in range, and have been documented
* Proper maintenance had been performed and documented

Corrective Action

Patient test results must be repeated and corrective action taken when:

* Result appears to not match the history of the patient
* The assay appears to not have functioned properly

# Procedure Notes

Calculations

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

Disposal

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner, and in compliance with all federal, state, and local requirements.

# Method Limitations

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

Glycated hemoglobin F is not measured by the DCA HbA1c assay.

At levels of hemoglobin F less than 10%, the DCA system accurately indicates the patient’s glycemic control. However, at very high levels of hemoglobin F (>10%), the amount of HbA1c is lower than expected because a greater proportion of the glycated hemoglobin is in the form of glycated hemoglobin F. HbA1c results for such patients do 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 HbC, can result in decreased life span of the red blood cells, which causes HbA1c results to be lower than expected, regardless of the method used, and not be related to glycemic control, when using published reference ranges.

Bilirubin, up to a level of 20 mg/dL, does not interfere with 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 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, Dymelor, glipizide.

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Reportable Range

The displayed test result requires no further calculation. HbA1c concentrations in the following range are reported: 2.5% to 14.0% HbA1c.

The test is linear throughout this range.

# Version 3.0 Software Users

POCTI-A and ASTM Standards

* The DCA Vantage system uses the POCT1-A standard to link to laboratory information systems. The POCT1-A standard automates transmission of such information as date and time, result, patient ID, and Operator ID, to support a full electronic patient record. POCTI-A is the default setting.

/i\ CAUTION

* If you are using the default POCT1-A to communicate with an LIS, the Patient ID field is required. if you do not provide a Patient ID in the test result, POCTI -A does not transmit the result to the US. An error message does not display at the analyzer.
* If you recall a patient record, ensure that there is a value in the Patient ID field before resending that record; otherwise, the record is not sent to the LIS.
* Earlier versions of the DCA Vantage software used the ASTM protocol, which allows a blank Patient ID field. You may still select ASTM as your ethernet protocol.
* The DCA Vantage system supports the ASTM Specification E1381, Low-Level Protocol to transfer messages between Clinical Laboratory Instruments and Computer Systems.
* The system also supports the ASTM Specification E1394, Standard Specification for transferring Information between Clinical Instruments and Computer Systems.

Improved Security Using Operator Levels and Modes

User ID is now Operator ID. The Operator ID has multiple levels to provide secure access to test and system options.

The System Access screen enables you to set the level of access to system features. There are 4 types of system access:

Unrestricted (default)

Restricted

Restricted Plus

Fully Restricted

Adding an Operator

The system verifies if a Level I operator is configured in the system. If not, you will be prompted to add this operator first. At the initial system installation, there are no operators or access codes created.

The first operator added to the system must be a Level I operator. There must be at least one Level I operator in the system at all times. The system prevents the last Level 1 operator from being deleted, or the Level changed.

The access code field is alphanumeric with the alpha characters entered as uppercase A-Z and 0-9. The access code can be up to 13 characters.

1. At the Home screen, select Menu.
2. Select System Settings from the Menu screen.
3. At the System Settings menu, select Additional Settings.
4. Select General.
5. Select System **Access.**
6. Select the system access level (Unrestricted, Restricted, Restricted Plus, or Fully Restricted).

The Operator button enables after selecting a system access level.

1. Select Operator.
2. To add an operator, select ADD.

Use the alphanumeric keypad to enter an Operator ID in the Name field. The Operator ID can include letters and numbers. The maximum number of characters for an Operator ID is 16.

1. Select Enter to save the Operator ID.
2. To add an access code, select Edit to the right of the ID field. Use the alphanumeric keypad to enter an access code. Note: Operator and access codes must be unique.
3. Select Enter.
4. At the Add Operator screen, select Save. The operator information is saved.

Editing an Operator

To change the Operator ID, access code, or level for an operator, follow these procedures:

1. At the Home screen, select Menu.
2. Select System Settings from the Menu screen.
3. At the System Settings menu, select Additional Settings.
4. Select General.
5. Select System Access.
6. At the System Access menu, select Operators. The Operators screen displays.
7. Highlight the operator you want to edit.
8. Select Edit.
9. Edit the Operator ID or the Access code.
10. Select Save.

Displaying an Operator

To display a list of Operator IDs on the system, follow these procedures:

1. At the Home screen, select Menu.
2. Select System Settingsfrom the Menu screen.
3. At the System Settings menu, select Additional Settings.
4. At the Additional Settings menu, select General.
5. Select System Access.
6. At the System Access menu, select Operators. A list of operators displays.

Deleting an Operator

To delete an Operator ID from the system, follow these procedures:

1. At the Home screen, select Menu.
2. SelectSystem Settingsfromthe Menu screen.
3. At the System Settings menu, select Additional Settings.
4. At the Additional Settings menu, select General.
5. Select System Access.
6. At the System Access menu, select Operators. A list of operators displays.
7. Highlight the Operator ID you want to delete.
8. Select Delete.

A message displays verifying that you want to delete the Operator ID.

1. Select Yes to delete the Operator ID.

# Version 2.0

Designating the Primary and Secondary HbA1~ Reporting Units Algorithm

A Supervisor can designate the primary and secondary HbA1~ using the following procedure:

1. At the Home screen, select Menu.
2. Select System Settings.
3. Select Additional Settings.
4. Select HbA1c Reporting Units.

The Supervisor ID Entry screen displays.

1. Enter the Supervisor ID.
2. Select Enter.

The HbA1c, Reporting Units screen displays.

1. Select the Primary.
2. Select the optional Secondary.
3. Select Save.

# Introduction to Version 1.1

Setting Analyzer to Require a QC or Display a QC Reminder for New Reagent Lots

**Setting a Required QC or Optional Reminder**

To set a reminder, use the following procedures:

1. At the Home screen, select Menu.
2. Select System Settings.
3. Select Additional Settings.
4. Select Control Tests.
5. Select New Lot Reminders.

NOTE: The New Lot Reminders screen displays. At the New Lots Reminders screen, checkboxes labeled Enabled and Required display for each of the following control tests:

HbA1, Normal

HbA1, Abnormal

A/C Low

A/C High

1. To activate a QC reminder for the selected reagent test, select the Enabled checkbox. To require a QC to be performed for the selected reagent test, select the Enabled and Required checkboxes. The Enabled checkbox must be selected before the Required checkbox.

NOTE:Repeat step 6 for any additional tests, as needed.

1. Select Save.
2. The next time a calibration card for a new lot of reagent cartridges is scanned, the following occurs:

* If you activated a reminder, a message displays prompting you to perform a QC.
* If you required a QC, a message displays requiring you to perform a QC.

NOTE: You cannot proceed to perform the selected test until the required QC is performed.

Customizing QC Reminders

1. At the Home screen, select Menu.
2. Select System Settings.
3. Select Additional Settings.
4. Select Control Tests.
5. Select Control Test Reminder.
6. At the Control Test Reminder screen, select I of the: following options:

* HbA1c, Normal
* HbA1c, Abnormal
* A/C Low
* A/C High

Once selected, the Schedule button to the right of the control test you selected becomes active.

1. Select Schedule for the selected test.
2. Select Change.
3. Select Optional or Required, and then select Next.
4. Select Custom.

A screen displays that enables you to select a number between 7 and 60 by pressing up or down arrow keys. The selected number displays above the arrow keys. The default value is 14.

Both up and down arrow keys cycle continuously through the 7 to 60 number range. For example, if 7 displays, pressing the down arrow key displays 60. Press the down arrow again to display 59, then 58, and so on.

1. Press an arrow key to cycle to the number.
2. Select Next.
3. Select the time in hours and minutes, using the arrow keys.
4. Select AM or PM.
5. Select Next.

You are returned to the Settings screen. Verify that the settings you entered are correct. if any setting is incorrect, select **Change**, and reenter settings, as needed.

1. Select **Save**.

The Control Test Reminders screen displays.

1. Repeat steps 6 to 16 to set additional QC reminders, as needed.

Selecting HbA1c Reference Range Limits

To change the HbA1~ Reference Range, use the following procedure:

1. Select Menu.
2. Select System Settings.
3. Select Additional Settings.
4. Select Patient Tests.
5. SelectReference Range.
6. Use the up and down arrow keys, which display under the Lower % and Upper % columns, to select reference range limit values.

Each selection increments the reference range by 0.1%.

The default reference range is 4.0 to 6.0%, which is set by selecting Reset Default Values.

1. Select Save.

Selecting a Bar Code Check Digit

To select a check digit, follow the procedure below.

1. At the Home screen, select Menu.
2. Select System Settings.
3. Select Additional Settings, and then select the down arrow key.
4. Select External Barcode.
5. If using an Interleaved 2 of *5* bar code, select the l2of5 checkbox. If using any other bar code, select the Other checkbox.
6. Select the Check Digit checkbox.
7. Select Save.

Selecting a Baud Rate

To change the Baud Rate, use the following procedure:

1. At the Home screen, select Menu.
2. Select System Setting.
3. Select Additional Settings, and then select the down arrow key.
4. Select Serial Port.

If the Serial Port is not active, you must select Enable Serial Port before selecting Serial Port.

1. Select Baud Rate.
2. Select a baud rate.
3. Select Save.

Removal of LIS Software Handshaking Protocol

Applies to analyzers using an LIS.

With the introduction of DCA Vantage version 1.1 software, selecting Xon/Xoff to support software handshaking protocol is not an available option. Removal of this option may affect the ASTM (American Society for Testing and Materials) LIS interface. The software sets the default Flow Control setting to Disabled. The Flow Control screen, at which the Xon/Xoff options displayed, has been removed.

# Equipment and Supplies

The accessory items available for the DCA Vantage system are listed below.

**Hemoglobin A1c**

|  |  |
| --- | --- |
| **Part Number** | **Description** |
| 5035C | DCA Reagent Kit |
| 5068A | DCA Normal & Abnormal Control Kit |

**Replacement Parts**

The replacement parts available for the DCA Vantage system are listed below.

|  |  |
| --- | --- |
| **Part Number** | **Description** |
| 00142617F | NA Power Cord for System |
| 00171415A | Euro Power Cord for System |
| 06498298 | UK Power Cord for System |
| 06498417 | Air Filter Holder |
| 06489248 | Cartridge Return Spring |
| 04469001 | Fuse: T-1.25 A, Slow Blow; 250 volt |
| 06488209 | Cleaning Sticks (10) |
| 06489221 | Optical Test Cartridge |
| 122521 | Air Filter (2 pack) Replacement Kit |
| 5773 | Printer Paper (5 pack) |
| 1759 | Printer Paper (self adhesive, 5 pack) |

# References

1. Siemens Medical Solutions DCA Hb1Ac, 5051GD Rev. 02/07.
2. Siemens Medical Solutions DCA Vantage Operator’s Guide, Ref 06489264 Rev. A, 2007-05.
3. Clinical and Laboratory Standards Institute. *Laboratory Documents: Development and Control; Approved Guideline⎯Fifth Edition*. CLSI document GP2-A5 [ISBN 1-56238-600-X]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.
4. Siemens Healthcare Diagnostics Inc, *Customer Bulletin 2010-12.*

# Technical Assistance

Siemens Healthcare Diagnostics Technical Care Center: 1-877-229-3711, Prompt 14, 1

Customer Service: 1-800-255-3232

Serial Number:

Customer Account Number:

# Trademark Information

DCA Vantage is a trademark of Siemens Healthcare Diagnostics

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