Performing a Hemoglobin A_{1c} Test on the DCA Vantage™ Analyzer

SIEMENS

DCA Vantage™ Analyzer

READ THIS GUIDE BEFORE PERFORMING A TEST.
TEST QUALITY CONTROLS AS DIRECTED ON REVERSE SIDE.
Note information regarding CLIA waiver on reverse side.

For the quantitative measurement of the percent concentration of Hemoglobin A_{1c} in blood.

Getting Started

- If the screen saver is on, select any part of the touchscreen.
- If an error message displays, select **OK** and follow the messages.
- No special skills are required.
- A Calibration Card is provided with each Reagent Kit.
- Refer to the Operator's Guide and Package Inserts for more information on entering calibration, analyzing controls, handling and disposal of biohazardous material, and more system details.

Note: Help You can select Help at any time for further assistance.

Testing Materials
- DCA Systems HbA_{1c} cartridge
- Capillary holder
- Tissue



STEP **1**

Collecting a Blood Sample

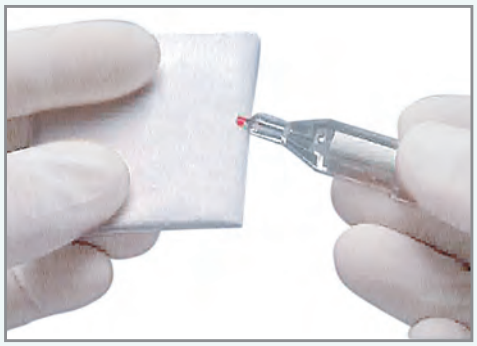
Touch the tip of the capillary to a small drop of blood until the capillary is filled.



STEP **2**

Cleaning the Capillary

Wipe the side of the capillary tube with a tissue.



STEP **3**

Inserting the Capillary

Insert the capillary holder into a cartridge (flat side toward cartridge) until the holder snaps into place.



Bring the cartridge to room temperature before use, if refrigerated. Refer to the Reagent Kit package insert for product limitations, interferences, storage, and expiration date. Do not use the cartridge past the expiration date.

If an error occurs, follow screen prompts or consult the DCA Vantage Operator's Guide.

For technical support questions or comments, call (877) 229-3711.

Continues on Reverse Side

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STEP 4

Scanning the Cartridge

1. **Hold** the cartridge so that the barcode faces to the right.
2. **Insert** the cartridge into the barcode track above the dot.
3. Quickly and smoothly, **slide** the cartridge down. A **beep** and display change indicate a successful scan; repeat if not successful.



STEP 5

Inserting the Cartridge

1. **Hold** the cartridge so that the barcode faces to the right.
2. **Open** the door and **insert** the cartridge into the compartment until a click is heard.
3. Slowly and firmly **pull** to remove the flexible tab.
4. **Close** the door to start the test.

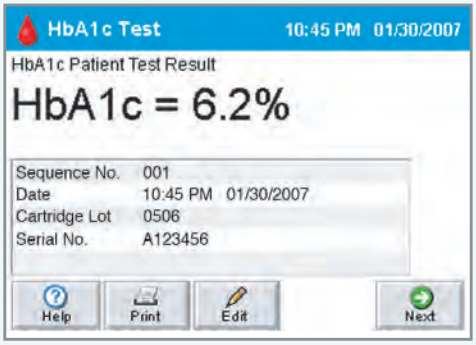


STEP 6

Recording the Results

1. **Wait** until the test is complete (approximately 6 minutes).
2. To change the patient information, select **Edit.**
3. To return to the patient result screen, select **Next.**
4. To print the results, select **Print.**

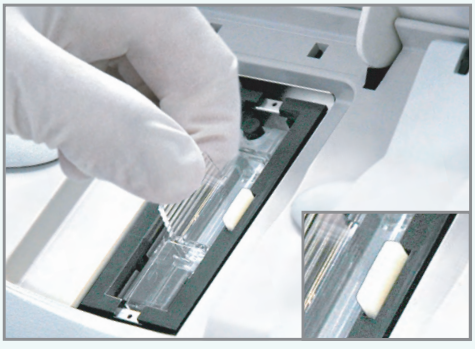
Note: You can select Help at any time for further assistance.



STEP 7

Removing the Cartridge

1. Select **Next**, then open the door.
2. **Push** and hold down the button on the right side.
3. To unlock, gently **push** the tab on the cartridge to the right.
4. **Pull** out the cartridge.
5. **Discard** the cartridge to prevent injury or possible contamination to others.



Quality Control

It is recommended that quality control specimens be tested with each new lot of reagents, new shipment of reagents and monthly for reagents that has been stored for more than 30 days. QC testing is recommended to ensure reagent storage integrity, train and confirm performance acceptability for new users, and when patients' clinical conditions or symptoms do not match. Additional QC intervals may be required as per your laboratory procedures. Liquid ready-to-use controls are available; contact technical support for recommendations.

Compare QC results to those listed as acceptable by the QC manufacturer. If control results are not acceptable, do not test patient samples until the problem is resolved. Repeat control testing until results are acceptable.

For technical support assistance call (877) 229-3711.

Information Regarding CLIA Waiver

The DCA Vantage™ system is CLIA-waived only when used with Siemens-branded DCA 2000+™ or DCA systems HbA1c cartridges.

A certificate of CLIA waiver is required to perform the test in a waived setting.

To obtain a Certificate of Waiver, contact your state department of health or visit the CMS Web site for an application, form CMS-116.

Failure to adhere to the instructions for use, including instructions for limitations or intended use, and for performing QC testing, is considered as off-label use, resulting in the test being categorized as high complexity and subject to all CLIA regulations.

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