

## DCA Vantage HbA1C: Daily Quality Control or Proficiency Test Procedure

### PURPOSE:

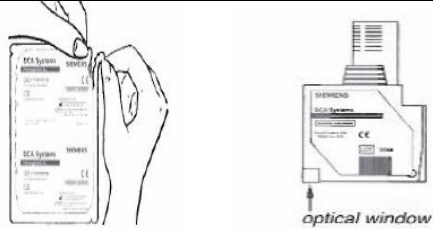


The procedure provides instructions for HbA1c Quality Control testing with the DCA Vantage.

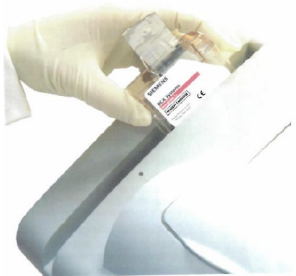
### Required Materials:

- 1) DCA Vantage® Analyzer
- 2) DCA HbA<sub>1c</sub> Reagent Cartridge
- 3) Capillary Holder
- 4) Daily QC - Siemens DCA Systems Normal Level and Abnormal Level QC.
- 5) Siemens DCA Systems HbA1c Quality Control Scan Card.
- 6) Monthly Proficiency QC - BIO-RAD Lyphochek Diabetes Control Bilevel – Level 1 and Level 2.
- 7) Lint-free tissue.

### PROCEDURE:

|           | <b>Action</b>  | <b>Related Documents Title Number</b>  |
|-----------|--|--|
| <b>1.</b> | Prepare DCA Vantage for a patient test.  | DCA Vantage HbA1C: Patient Test Flowchart  |
| <b>2.</b> | Prepare Quality Control (QC) specimen worksheet.   |  |
|           | Clinic   | Daily patient worksheet<br>Daily QC record form.<br>Monthly Proficiency Test form                  |
|           | Laboratory   | Call worksheet from Sunquest.<br>Function: WO<br>Worksheet: CA1POC,DCA1<br>Printer: 8049           |
| <b>3.</b> | Remove Quality Control solution from refrigerated (2-8°C) storage.<br><i>Note: Allow QC material to be at room temperature for a minimum of 10 minutes before use. QC is reconstituted in the laboratory for clinic use.</i> |  |
|           | Daily Quality Control  | <i>Siemens DCA Systems Normal Level &amp; Abnormal Level QC Quality Control Scan Card.</i>         |
|           | Monthly Proficiency Test   | <i>BIO-RAD Lyphochek Diabetes Control Bilevel – Level 1 &amp; Level 2 – Monthly Proficiency QC</i> |
| <b>4.</b> | Remove HbA1c Cartridges from 2-8°C storage for use with Quality Controls.  |  |
|           | <b>If test cartridge is</b>  | <b>Then bring to room temperature</b>  |
|           | In foil pouch  | minimum 10 minutes.  |
|           | Removed from foil pouch  | minimum 5 minutes.   |
|           | <i>Note the HbA1c cartridge is used:</i>   |  |
|           | <ul style="list-style-type: none"> <li>• Cartridge is at room temperature for a minimum of 10 minutes before use.</li> </ul>   |  |

|    | <b>Action</b>  | <b>Related Documents Title Number</b> |
|----|--|---------------------------------------|
|    | <ul style="list-style-type: none"> <li>Room Temperature expiry is (3) months.</li> <li>Use within (1) hour after opening the foil pouch.</li> </ul> <p><b>Caution:</b><br/>Do not touch the optical window of the cartridge.</p>   |                                       |
| 5. | <p>Remove capillary holder from blister package.</p> <p><i>Note: Capillary holders can be used with any lot of reagent cartridges.</i></p> <p><b>Caution: Discard capillary holder if a part is missing:</b><br/> a) glass capillary<br/> b) absorbent pad<br/> c) latching mechanism</p>    |                                       |
| 6. | Wear gloves.   |                                       |
| 7. | <p>Mix Quality Control material well for testing. Capillary vial holds 1uL.</p> <ul style="list-style-type: none"> <li>Aspirate a small amount of QC material into dropper and form a drop.</li> <li>Touch <b>ONLY</b> the tip of the glass capillary to the suspended QC drop.</li> <li>Avoid introducing air bubbles into the sample.</li> </ul> <p><b>Caution: Do Not allow QC material to touch the capillary holder.</b></p>  |                                       |
| 8. | <p>Use a lint free tissue and carefully wipe the outside of the glass capillary without allowing the tissue to touch the open end. Inspect the glass capillary for bubbles or blood on the capillary holder.</p> <p>Discard the capillary holder and repeat the sample application procedure if</p> <ul style="list-style-type: none"> <li>there are obvious bubbles or inadequate QC in the glass capillary.</li> <li>there is residual blood on the outside of the capillary holder.</li> </ul> <p><b>Caution: Once capillary is filled with sample, analyse within 5 minutes.</b></p> |                                       |
| 9. | <p>Insert capillary holder into the HbA1c cartridge. Holder will snap into place.</p>  <p><b>Caution:</b><br/>Do not touch the optical window of the cartridge.</p>   |                                       |

| <b>Action</b>  |   | <b>Related Documents Title Number</b> |
|--|---|---------------------------------------|
| <b>10.</b>   | Ready instrument for QC testing.  |                                       |
| Daily  | <ul style="list-style-type: none"> <li>• Locate the Siemens DCA control card.</li> <li>• Locate the barcode on the control card of the appropriate QC Level.</li> <li>• Hold the card so that the barcode faces to the right and scan.</li> </ul>   |                                       |
| Monthly Proficiency  | <ul style="list-style-type: none"> <li>• Press [Other Control] on Touch Screen.</li> <li>• Choose Level 1 or Level 2.</li> <li>• Press [Next].</li> </ul>   |                                       |
| <b>11.</b>   | Scan HbA1c cartridge.   |                                       |
|                             | <ul style="list-style-type: none"> <li>• Hold the reagent cartridge so that the barcode faces to the right.</li> <li>• Insert the reagent cartridge (above dot) into the barcode track and quickly slide the cartridge down past the dot.</li> <li>• Beep sounds with a successful scan.</li> <li>• View screen for display prompt to proceed with loading the cartridge.</li> </ul>  |                                       |
| <b>12.</b>   | Insert the HbA1c cartridge into the DCA for testing.  |                                       |
|  | <ul style="list-style-type: none"> <li>• Open the compartment door.</li> <li>• Hold the reagent cartridge so that the barcode faces to the right.</li> <li>• Insert the reagent cartridge until a gentle snap is heard or felt.</li> <li>• Hold cartridge with left hand.</li> <li>• With right hand, pull the flexible plastic pull-tab completely out of the reagent cartridge. Use a smooth, continuous motion.</li> <li>• Dispose the pull-tab.</li> <li>• Close compartment door.</li> </ul> |                                       |
| <p style="color: blue;"><b>Note: if the compartment door is accidentally closed before the pull-tab is</b></p> |   |                                       |

Medical Approval: Dr Benjamin Jung

Version: 1.2

Folder Name: CW\Point of Care\Hemoglobin A1C

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|     | <b>Action</b>   | <b>Related Documents Title Number</b> |
|-----|---|---------------------------------------|
|     | removed you have up to 5 seconds to re-open the door and pull the tab.  |                                       |
| 13. | A beep sounds at the end of the test cycle.   |                                       |
| 14. | Remove the test cartridge.  |                                       |
|     | <ul style="list-style-type: none"> <li>• Open the compartment door.</li> <li>• Locate the button on the right side of the cartridge compartment.</li> <li>• Push button down and hold with right hand.</li> <li>• With left hand, gently push the tab on the cartridge to the right of the cartridge compartment. This unlocks the cartridge.</li> <li>• Pull the cartridge up to remove.</li> <li>• Close the compartment door.</li> </ul>   |                                       |
|     | <p><b>Note:</b><br/>           To cancel a test at any time during the testing process press [ESCAPE].<br/>           At the display prompt [CANCEL TEST?], press [ENTER] within 15 seconds.<br/>           Discard the cancelled test.</p>   |                                       |
| 15. | Result screen displays when the system finishes analyzing the sample. <ul style="list-style-type: none"> <li>• The screen displays result values and demographics for each test.</li> <li>• At this time you can edit the sample demographics and comments at the Sample Data screen.</li> </ul>  |                                       |
| 16. | Print the result. For each HbA1c QC result the following is displayed.  |                                       |
|     | <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <pre> <b>DCA Vantage™</b> HbA1c Patient Test Print Date 06.04.2010 14:19 Serial No. S015762  Test Date 06.04.2010 14:12 Sequence No. 005 Cartridge Lot 0811  HbA1c Primary NGSP  Primary HbA1c = 5.4 %  Sample ID T12319 Patient ID 9862718192 Last Name ADIRIM                     </pre> </div> <div style="width: 50%;"> <ul style="list-style-type: none"> <li>• QC name</li> <li>• Print date</li> <li>• DCA Vantage Serial number</li> <li>• Test date</li> <li>• Sample Sequence number</li> <li>• Cartridge Lot #</li> <li>• HbA1c % QC Result</li> <li>• User ID</li> </ul> </div> </div> |                                       |
| 17. | Review Results. Record displayed test result on the appropriate QC Record Sheet.  |                                       |
|     | <p><b>Reporting Range for Quality Control &amp; Proficiency Testing Material.</b><br/> <b>See current Lot number information for QC ranges.</b></p>   | 2.5 – 16.0 HbA1c %                    |

|            | <b>Action</b>   | <b>Related Documents<br/>Title<br/>Number</b> |
|------------|---|---|
|            | <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• If result is not within QC range, repeat calibration of reagent cartridge and repeat the analysis procedure.</li> <li>• A second result not within QC range would require repeating the analysis with freshly made Quality Control material.</li> <li>• Confirm expiry dates of HbA1c Test Cartridge.</li> <li>• Notify Complex Chemistry Supervisor.</li> </ul> <p><b>Clinic Use:</b> Notify POCT Technologist <a href="mailto:POCTLab@cw.bc.ca">POCTLab@cw.bc.ca</a> Local: 7521</p> |   |
| <b>18.</b> | Follow instructions on the display screen to return to Home Page for testing.   |   |

**REFERENCES:**

**DCA Vantage Analyzer Operator’s Guide REF 06489264 Rev. B,2008-06**

## REVISION & APPROVAL LOG

| Version | Revision Type | Description of Change  | Revision Date | Technical Approval | Medical Approval   |
|---------|---------------|--|---------------|--------------------|--------------------|
| 1.0     |               | New document   | 21 Nov 2014   | Elvira Kozak       | Dr. Cathy Halstead |
| 1.1     | Minor         | Document title and number change. Upload to QMS document control | 28 Dec 2016   |                    | Dr. Benjamin Jung  |
| 1.2     | Minor         | Updated POCT Contact information                                 | July 1, 2019  | Calvin Lee         |                    |

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