DCA Vantage HbA1C: Appendix C - Reagent Cartridge Kit

**CONTENTS OF THE PACK**

- HA1c reagent cartridges -10ea.
- Capillary Holders – 12 ea.
- Cartridge Calibration card.
- 2 Package inserts.

**LABORATORY**

- With a shipment, the temperature indicator card must be within guidelines.

Note: **DO NOT USE cartridges if the indicator has turned red. Notify Complex Chemistry Supervisor for a replacement shipment. Rm. 2F57 Local:7520**

**STABILITY AND STORAGE OF THE REAGENT CARTRIDGE**

**Laboratory:**

- Store reagent cartridge refrigerated at 2° - 8°C. Walk in fridge Room 2F50.

**Clinic Use:**

- Obtain from the laboratory walk-in fridge Rm. 2F50. Sign Reagent Cartridge Utilization Form.

Note: **Cartridge room temperature storage is (3) months, or up to printed expiry date. Cartridge is used within (1) hour after opening the foil pouch.**

**STABILITY AND STORAGE OF THE CAPILLARY HOLDER:**

- Store Capillary holders at room temperature.
- 15 - 30°C. Keep at workbench. Open just prior to use.

**CALIBRATION CARD:**

- Each calibration card belongs to a particular lot number of reagent cartridges.
- See procedure for new lot number calibration.
- Up to two different lot # of reagent cartridge can be stored in memory.

Note: **The DCA Vantage must be calibrated with a particular Lot # prior to using that particular lot number.**

**ADDITIONAL MATERIALS REQUIRED:**

- Blood collection supplies as per institutional requirements.

**SAMPLE MATERIAL:**

**Capillary:**

- Use only fresh capillary blood from a fingertip.
- Apply the second drop of blood to the glass capillary. Volume is 1 uL.
- Analysis must begin within 5 minutes of filling the sample capillary.

**Venous:**

- Recommended anticoagulants are EDTA, heparin, fluoride/oxalate, and citrate.
- Whole blood storage is -70°C to 5°C for two weeks, or up to 25°C for one week.

Note: **DO NOT REFREEZE Stored blood for testing purposes.**
INTEGRATED QUALITY CONTROL FUNCTION.

- Each reagent cartridge has an integrated quality control function.
- DCA System performs 48 optical, electronic, mechanical, and reagent system checks during the course of each specimen assay.
- If an assay or system error occurs during any individual measurement, the system automatically reports a message, preventing the reporting of erroneous patient results.
- Refer to manual for Daily Quality Control Test

MEASURING RANGE, THERAPEUTIC RANGE, AND REPRODUCIBILITY

Measuring Range:

- Patient test Reporting Range: 2.5% to 14.0% HA1c. Test is linear.
- Quality Control Reporting Range: 2.5% - 16.0% HA1c. Test is linear.

Therapeutic Range package insert:

- 3-6% non-diabetics; 6-8% controlled diabetics; >8% poorly controlled diabetics.

PHSA Therapeutic Range:

<table>
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<tr>
<th>&lt; 5 years</th>
<th>&lt; 9 % HA1c</th>
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<tr>
<td>5-12 years</td>
<td>&lt; 8 % HA1c</td>
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<td>13 - adult</td>
<td>&lt; 7 % HA1c</td>
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Reproducibility:

- 95% confidence limit of 2 SD is 4.3% to 5.7% at the non-diabetic range

PRINCIPLE OF THE TEST

- HA1c and total hemoglobin are measured, with the ratio reported as % HA1c.
- An inhibition latex agglutination assay is used for the measurement of HA1c.
- Potassium ferricyanide is used to oxidize hemoglobin in the sample to methemoglobin. Methemoglobin complexes with thiocyanate to form thiocyan-methemoglobin. The colored complex is measured at 531 nm.

REAGENT CARTRIDGE COMPOSITION AND ACCURACY

- Antibody Latex: HA1c-specific mouse monoclonal antibody adsorbed onto latex particles. 10 uL dried – 2.5% w/v Ab-latex in 10 mM glycine buffer.
- Agglutinator: 10 uL dried - 0.005% w/v aspartic acid polymer in 20 mM sodium citrate buffer with 0.1% bovine serum albumin.
- Buffer: 0.6 mL each - 8.1% w/v lithium thiocyanate, 0.01% digitonin in 200 mM glycine buffer.
- Oxidant: 10 mL dried – 1.5% w/v potassium ferricyanide in water.

TEST LIMITATIONS:

- Blood drop is a minimum of 1 uL in volume.
- Patient Results < 2.5% are rare. May indicate sample contains > 10% fetal hemoglobin or patients not within a hemoglobin range of 7 – 24 g/dL.
- Falsely decreased results with hemolytic anemia and polycythemia.
- Falsely increased results with lipemic samples.

PRECAUTIONS AND WARNINGS:

*For in vitro diagnostic use only. Use as per most current version of manufacturer’s most recent package insert. See below.*
REFERENCES
SIEMENS DCA Systems  Hemoglobin A1c Reagent Kit package insert. Siemens Healthcare Diagnostics Ltd. Frimley, Camberley, UK GU16 8QD

REVISION & APPROVAL LOG

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<th>Description of Change</th>
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<td>Elvira Kozak</td>
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