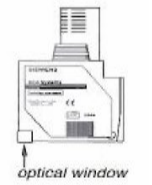
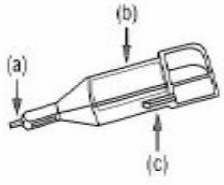
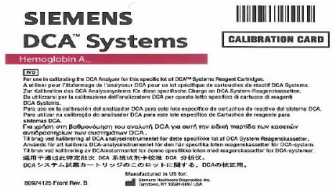
DCA Vantage HbA1C: Appendix C - Reagent Cartridge Kit

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. Rm. 2F57 Local:7520 or POCTLab@cw.bc.ca local 7521.

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.

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 µL.
- 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:

≤ 5 years	< 9 % HA1c
5-12 years	< 8 % HA1c
13 - adult	< 7 % HA1c

Reproducibility:

- 95% confidence limit of 2 SD is 4.3% to 5.7% at the non-diabetic range
- Measurement of Uncertainty for HA1c test is available upon request

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/vAb-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 packager 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

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0		New document	31 Dec 2013	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	POCTLab contact added, reformatted	July 1, 2019	Calvin Lee	

Attention: This document is published on the ePOPS website

Revisions made to this document require an update to the corresponding document published on ePOPS website