

DCA Vantage HbA1C: Appendix A - Quality Control Solution

INTENDED USE:

To monitor the performance of the HA1C Reagent Cartridges with the Siemens DCA System.

TEST LIMITATIONS:

HA1C 2.5 – 16.0 %

SIEMENS DCA HA1C LIQUID CONTROL KIT:

- 2 – DCA HA1C NORMAL Control
- 2 – DCA HA1C ABNORMAL Control
- 1 – Reconstitution Fluid (2.0 mL); deionized water with 0.09% sodium azide preservative.
- 4 – Eyedropper Cap assemblies.
- 3 - Package Inserts.
- 1 – DCA NORMAL and ABNORMAL Control Card (double sided).

RUNNING SIEMENS DCA HA1C LIQUID CONTROL KIT:

To test the integrity of the DCA System. Prepared as hemolysate from human blood.

- Run each time a new shipment of cartridges are received.
- Run each time a new lot number is started.
- Run daily with Patient Testing, both Normal and Abnormal Levels of Liquid QC.
- Refer to Daily Liquid Quality Control Procedure – DCA Procedure Manual HA1C.

STORAGE:

Unconstituted:

- DCA HA1C Liquid Control Kit is stored at 2°C to 8 °C..
- Stock supply is in the walk-in fridge Room 2F50.

Reconstituted:

- Current reconstituted Liquid QC Control Kit is stored in the Complex Chemistry fridge Room 2F57, contact POCTLab@cw.bc.ca or local 7521.
- Clinic obtains bottles of reconstituted Liquid QC Normal and Abnormal levels on a quarterly basis from the laboratory. Lab notifies clinic to pick up.

STABILITY:

- Store Controls upright and tightly capped.
- Reconstituted controls are stable for 3 months when stored refrigerated, 2°C to 8 °C.
- Controls are not to be left at room temperature for more than 30 minutes when in use.

PRECAUTIONS AND WARNINGS:

- For use only with the Siemens DCA HA1C Testing System.
- Do not use past expiry date. Do not use if cloudy or discolored.
- Do not use if the bottles have leaked. Recap reagents tightly after each use.
- Use Universal Standard Precautions.
- Source material is of human origin. Donors were tested and found to be negative for HIV1, HIV 2, and HCV antibody; HBsAg. No known test method can offer total assurance that HIV, hepatitis C virus, hepatitis B virus or other infectious agents are absent.
- When disposing of the reagents, always flush the drain with large volumes of water to prevent azide build-up. (Sodium azide is used as a preservative).

REFERENCES

SIEMENS DCA Systems Hemoglobin A1c Normal and Abnormal Control 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 and reformatted	July 1, 2019	Calvin Lee	

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