DCA Vantage HbA1C: Appendix B - Monthly Proficiency 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 %

BIO-RAD LYPHOCHEK DIABETES CONTROL BILEVEL MINIPAK

- 2 – Level 1 Control 0.5 mL
- 2 – Level 2 Control 0.5 mL

RUNNING HA1C BIO-RAD LYPHOCHEK DIABETES CONTROL KIT:

Liquid Control Kit is a set of quality controls, one bottle each of a Level 1 and a Level 2 control. Used to test the integrity of the DCA System for HA1c. This product is prepared from human whole blood and contains preservatives and stabilizers. The control is provided in lyophilized form for increased stability.

- Run monthly. Refer to Monthly Proficiency Testing Control Procedure – DCA HA1c.

STORAGE:

Unconstituted:

- BIO-RAD Control Kit is stored at 2^{o} to 8^{o}C. Stock supply - Walk-in fridge Room 2F50.

Reconstituted:

- Liquid QC BIO-RAD Control is prepared monthly and run on the day of preparation.
- Clinic obtains an aliquot of reconsitituted Bio-Rad Lyphochek Diabetes Control Level 1 and Level 2 at the beginning of each month and should be analyzed within 7 days.
- Lab to notify the clinic for pick up.

STABILITY:

- *Controls are stable for up to 7 days once reconstituted.*
- *Store Controls upright and tightly capped.*
- *Controls are used at room temperature, if necessary, stored after use at 2^{o} to 8^{o}C.*
- *Controls are not to be left at room temperature for more than 30 minutes when in use.*

PRECAUTIONS AND WARNINGS: FOR INVITRO DIAGNOSTIC USE ONLY

- For use only with the Siemens DCA HA1c Testing System.
- 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 is of human origin.
- 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

BIO-RAD Lyphochek Diabetes Control Kit package insert. 2008.
United States, Bio-Rad Laboratories Clinical Diagnostics Group. Irvine, California 92618

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

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