



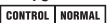

DCA™ Systems

For Use With DCA™ Analyzers


Hemoglobin A_{1c} NORMAL and ABNORMAL Control Kit

[6006GD]

SUMMARY AND EXPLANATION

The DCA™ Hemoglobin A_{1c} Control Kit contains both NORMAL Controls  and ABNORMAL Controls  which are prepared as a stabilized hemolysate from human blood. The hemolysate is then lyophilized to ensure stability. The DCA Hemoglobin A_{1c} Control Kit has been designed for use with the DCA Hemoglobin A_{1c} Reagent Kit. **CLIA Complexity: Waived (USA)**

Good laboratory practice dictates that a quality control program be established in all laboratories. This program consists of the routine assay of control material, evaluation of control results and acceptable limits on controls, as well as proper sample collection and handling practices and proper storage of Reagent Cartridges. The DCA Hemoglobin A_{1c} Control Kit has been developed as acceptable control material for the DCA Hemoglobin A_{1c} Reagent Kit. It is also acceptable for use with the RA/opeRA® HbA_{1c} Reagent Kit, ADVIA® Chemistry Systems HbA_{1c} Reagent Kit and the ADVIA IMS® HbA_{1c} Reagent Kit.

 For additional information and instructions for running DCA Hemoglobin A_{1c} Controls, refer to the Operator's Guide.*

The DCA Hemoglobin A_{1c} Normal and Abnormal Controls should give DCA values within the ranges shown on the Control Card when run according to instructions. For the RA and opeRA systems, ADVIA Chemistry Systems and ADVIA IMS systems, this control is provided as an unassayed material. Each laboratory should establish their own recovery value for this lot of control on these systems as part of their QC program. The DCA Normal Control and Abnormal Control are intended for use as controls and must not be used as calibrators.

REAGENTS

The DCA Hemoglobin A_{1c} NORMAL Controls and ABNORMAL Controls included in the DCA Hemoglobin A_{1c} Control Kit contain a stable lyophilized hemolysate of human blood. Each bottle, when reconstituted, contains enough Control Solution to run approximately 90 DCA Hemoglobin A_{1c} Control Tests. The Reconstitution Fluid (deionized water) contains 0.09% w/v sodium azide as a preservative.



KIT CONTENTS:


- 2—DCA Hemoglobin A_{1c} NORMAL Control (0.25 mL when reconstituted)
- 2—DCA Hemoglobin A_{1c} ABNORMAL Control (0.25 mL when reconstituted)
- 1—Reconstitution Fluid (2.0 mL)
- 4—Eyedropper Cap Assemblies
- 2—Package Inserts
- 1—DCA NORMAL and ABNORMAL Control Card (double sided)

to hepatitis C (HCV), and antibodies to Human Immunodeficiency Viruses (HIV-1 and HIV-2), and found to be negative (was not repeatedly reactive). Because no test method can offer complete assurance that HIV, hepatitis B or C viruses, or other infectious agents are absent, these products should be handled at the Biosafety Level II as recommended for any potentially infectious human blood specimen in *Protection of Laboratory Workers from Occupationally Acquired Infections — Third Edition, Approved Guideline (2005)*, Document M29-A3, promulgated by Clinical and Laboratory Standards Institute — CLSI (formerly NCCLS).

The Reconstitution Fluid contains sodium azide as an antimicrobial agent. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. If reagents containing sodium azide are to be disposed of via the sink, flush with large volumes of water to prevent accumulation of potentially explosive compounds. In addition, consult manual guide, "Safety Management No. CDC-22, Decontamination of Laboratory Sink Drains to Remove Azide Salts" (Center for Disease Control, Atlanta, GA, April 30, 1976).

STORAGE AND HANDLING

 **Unreconstituted** DCA Hemoglobin A_{1c} Normal Control and Abnormal Control should be stored at 2°–8°C (36°–46°F) or 220°C (24°F), and can be used until the last day of the expiration month  shown on the bottle. **Appearance of moisture in the bottle, prior to reconstitution, is an indication of deterioration of the material and renders the material unsatisfactory for use.**

 **Reconstituted** DCA Hemoglobin A_{1c} Normal Control and Abnormal Control should **not be frozen. Do not allow it to stand uncapped.** Control material may remain at room temperature for 30 minutes during testing, but should be stored in a refrigerator in an upright position and tightly capped at all other times. Discard any reconstituted control solution appearing turbid or obviously contaminated. The reconstituted control is stable for 3 months when stored refrigerated.

RECONSTITUTION

The following directions for reconstitution are recommended to minimize variation resulting from different reconstitution methods in different laboratories.

1. Remove the *appropriate* control bottle from the refrigerator just prior to reconstitution.
2. Gently tap the bottom of the control bottle on the counter to collect as much material as possible on the bottom of the bottle.
3. Carefully remove the cap from the control bottle.
4. Holding the Reconstitution Fluid dropper bottle **vertically**, add **six (6)** drops of fluid to the control bottle.

NOTE: Discard the first drop to ensure a constant volume of drops thereafter.

5. Carefully replace the cap, not the eyedropper, and swirl the control bottle several times. Let stand at room temperature for 15 minutes.
6. After 15 minutes, coat all surfaces of the control bottle by rotating and inverting the bottle. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.
7. Remove and discard cap. Replace with Eyedropper Cap Assembly.



CAUTION

FOR *IN VITRO* DIAGNOSTIC  USE.

SAFETY GLASSES, GLOVES AND LAB COAT ARE RECOMMENDED WHEN USING THE DCA SYSTEM.

THIS PRODUCT CONTAINS A SUBSTANCE KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER.

POTENTIALLY BIOHAZARDOUS MATERIAL


Human sourced materials were used in the manufacturing of this product. Each donor unit was tested for hepatitis B surface antigen (HB_sAg), antibodies

PROCEDURE

Following reconstitution according to the instructions, the control needs no further dilution or processing. Use the DCA Hemoglobin A_{1c} Normal Control and Abnormal Control in the same manner as whole blood. The DCA procedure used to collect aliquots of reconstituted control for testing is as follows:

1. From a DCA Hemoglobin A_{1c} Reagent Kit, obtain a Capillary Holder and remove it from the plastic wrap.
2. Unscrew the Eyedropper Cap Assembly. While applying only slight pressure to the bulb, insert the tip of eyedropper into the Control Solution (tilt bottle as necessary). Release pressure on bulb to aspirate a very small amount of Control Solution.
3. Hold the glass capillary tube to the Control Solution collected in the eyedropper and completely fill the 1 µL tube. Touch *only* the tip of the tube to the Control Solution. If an air bubble(s) is present in the filled tube, discard the Capillary Holder and refill a new one.

IMPORTANT: Do not allow the Control Solution to come in contact with the wider plastic part of the Capillary Holder. Any Control Solution adhering to the Capillary Holder may be transferred into the reaction buffer, along with the 1 µL Control Solution in the glass capillary tube. This may cause an invalid HbA_{1c} control result or possibly an error message. **If Control Solution comes in contact with the plastic of the Capillary Holder, discard the Capillary Holder.**

4. Do not touch the eyedropper to any other surfaces. Squeeze any excess Control Solution out of the eyedropper back into the Control Solution bottle. Carefully replace and screw the Eyedropper Cap Assembly back onto control bottle.
5. Using a lint-free tissue, **carefully wipe** any Control Solution off the sides of the glass capillary tube. **DO NOT ALLOW THE TISSUE TO TOUCH THE OPEN END OF THE TUBE.** Contact with the open end could result in loss of sample. If sample loss is obvious, discard the Capillary Holder, and refill a new one.
6.  Carefully insert the Capillary Holder into a DCA Hemoglobin A_{1c} Reagent Cartridge until the holder **gently snaps** into place. See the Quick Reference guide and the Operator's Guide for instructions on placing the Capillary Holder in the Reagent Cartridge.
7. Run the control as you would any sample according to the instructions in the DCA Hemoglobin A_{1c} Reagent Kit Package Insert. To automatically set up the DCA Analyzer for running the control and to store the result automatically in the control memory buffer,

use the DCA Control Card found in the Control Kit. The Control Card, one side for the Normal Control and one side for the Abnormal Control, is used in exactly the same way as the reagent Calibration Card (see the Quick Reference guide and the Operator's Guide).

RESULTS

An ongoing quality control program is important in assessing and maintaining the integrity of the DCA Hemoglobin A_{1c} Assay System. Keep a permanent record of all quality control results.

NOTE: If the DCA Control Card was scanned to input control data, the DCA instrument will automatically indicate (via the display screen) whether the control result is within or out-of-limits. If the result is not within the given range:

- a) Re-run the Control Solution. If the result remains outside the given range, check the Reagent Cartridge, control, instrument, environmental conditions and technique.
- b) If after re-running the control, the result continues to remain outside the given range, contact your local authorized Bayer representative.

EXPECTED VALUES

A DCA value (mean and range about the mean) has been assigned to this lot of control. Values of calibration parameters based on a Diabetes Control and Complications Trial (DCCT) reference method are determined which provide for optimal reagent performance. The DCA HbA_{1c} test method is National Glycohemoglobin Standardization Program (NGSP) Certified. The DCA HbA_{1c} test method is traceable to International Federation of Clinical Chemistry (IFCC) reference materials and test methods. Note: The DCA Analyzer reports NGSP HbA_{1c} numbers, which are aligned to DCCT results and are higher than IFCC HbA_{1c} numbers. The DCA Hemoglobin A_{1c} Normal and Abnormal Controls should give DCA values within the ranges shown on the Control Card when run according to instructions. Control limits can also be established based on day-to-day use of this test in your laboratory. Investigate any result that is outside the limits established by your laboratory.

AVAILABILITY

The DCA Hemoglobin A_{1c} Control Kit, containing 2 bottles of NORMAL Control and 2 bottles of ABNORMAL Control, is available as REF 5068A.

***Refer to the RA and opera Systems, ADVIA Chemistry Systems or ADVIA IMS Operating Manuals for specific procedures for use of the controls on the respective systems.**

Lot specific Control Mean **MEAN** and Range **RANGE** Values for HbA_{1c} are found on the control card in the control kit.

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