SIEMENS

# DCA™ Systems

**For Use With DCA™ Analyzers**

**Microalbumin/Creatinine Low and High Control Kit**

[10468975VD]

## SUMMARY AND EXPLANATION

The DCA™ Microalbumin/Creatinine Control Kit contains both Low Controls CONTROL LOW and High Controls CONTROL HIGH. Each control is a buffered aqueous solution containing known amounts of human albumin and creatinine. The resulting mixture is then lyophilized to ensure stability. The DCA Microalbumin/Creatinine Control Kit has been designed for use with the DCA Microalbumin/Creatinine Reagent Kit.

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 Microalbumin/Creatinine Control Kit has been developed as acceptable control material for the DCA Microalbumin/Creatinine Reagent Kit.

For additional information and instructions for running DCA Microalbumin/Creatinine Controls on the DCA Analyzer, refer to the Operator's Guide.

The DCA Microalbumin/Creatinine Low and High Controls should give DCA values within the ranges shown on the Control Card when run according to instructions. The DCA Microalbumin/Creatinine Low and High Controls are intended for use as controls and must not be used as calibrators.

## REAGENTS

The DCA Microalbumin/Creatinine Low Controls and High Controls included in the DCA Microalbumin/Creatinine Control Kit contain stable lyophilized materials. Each vial, when reconstituted, contains enoughControl Solution to run approximately 65 DCA Microalbumin/Creatinine Control tests. The Reconstitution Fluid (deionized water) contains 0.09% w/v sodium azide as a preservative.

## KIT CONTENTS:

2—DCA Microalbumin/Creatinine Low Control (3.6 mL each when reconstituted)
2—DCA Microalbumin/Creatinine High Control (3.6 mL each when reconstituted)
4—Reconstitution Fluid (3.6 mL each)
4—Reconstitution Fluid Transfer Pipettes
4—Dropper Tip Assemblies
2—Package inserts
1—DCA Microalbumin/Creatinine Low and High Control Card (double-sided)

***CAUTION***

IVD ***IN VITRO* DIAGNOSTIC MEDICAL DEVICE**

**SAFETY GLASSES, GLOVES AND LAB COAT ARE RECOMMENDED WHEN USING DCA ANALYZERS.**

**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 to hepatitis C (HCV), and antibodies to Human Immunodeficiency Viruses (HIV-1 and HIV-2), and found to be negative (was not repeatedly reactive).

**CAUTION:** 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—Second Edition, Approved Guideline (2001),* Document M29-A2, 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

2°C–8°C **Unreconstituted** DCA Microalbumin/Creatinine Low Control and High Control should be stored at 2°–8°C (36°–46°F) and can be used until the last day of the expiration month shown on the vial. **Appearance of moisture in the vial, prior to reconstitution, is an indication of deterioration of the material and renders the material unsatisfactory for use.**

**Reconstituted** DCA Microalbumin/Creatinine Low Control and High 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 vial from the refrigerator just prior to reconstitution.
2. Gently tap the bottom of the control vial on the counter to collect as much material as possible on the bottom of the vial.
3. Carefully remove the foil crimp and stopper from the control vial.
4. From the Reconstitution Fluid vial, transfer the entire contents into the control vial using the provided transfer pipette. **Do not draw the control back into the transfer pipette.** Dispose of the pipette.
5. Carefully replace the control vial stopper and swirl the vial several times. Let stand at room temperature for 15 minutes.
6. After 15 minutes, coat all surfaces of the control vial and stopper by rotating and inverting the vial to get all the lyophilized material into solution. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.
7. Remove and discard stopper. Replace with Dropper Tip Assembly (snap it onto the vial).

## PROCEDURE

Following reconstitution according to the instructions, the control needs no further dilution or processing. Use the DCA Microalbumin/Creatinine Low Control and High Control in the same manner as urine specimens. The procedure used to collect aliquots of reconstituted control for testing is as follows:

1. From a DCA Microalbumin/Creatinine Reagent Kit, remove a capillary holder and plunger from the plastic wrap.
2. Remove the white cap from the Dropper Tip Assembly. Tilt the control vial to allow control solution to fill the dropper. **Squeeze air bubbles out of the dropper, if necessary, to ensure that no bubbles are trapped in the dropper.**
3. Insert the end of the glass capillary tube 3 mm (1/8 in) *into* the tip of the dropper and fill the capillary tube with control solution by gently squeezing the dropper. If an air bubble 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 Control Solution in the glass capillary tube. This may cause an invalid control result. **If Control Solution comes in contact with the plastic of the Capillary Holder, discard the Capillary Holder.**

4. Do not touch the dropper to any other surfaces. Carefully replace the white cap back onto the control vial dropper tip.
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 Microalbumin/Creatinine Reagent Cartridge until the holder **gently snaps** into place.
   See DCA Analyzer 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 Microalbumin/ Creatinine 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 Low Control and one side for the High Control, is used in exactly the same way as the Reagent Calibration Card (see Operator's Guide).

## RESULTS

An ongoing quality control program is important in assessing and maintaining the integrity of the DCA Microalbumin/Creatinine Assay System. Keep a permanent record of all quality control results.

**NOTE:** If the Control Card was scanned to input control data, the 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 representative.

## EXPECTED VALUES

The values for albumin and creatinine have been assigned to this lot of control. Calibrators used to determine the calibration parameter values are made using a liquid preparation of albumin known to consist of ≥99% monomer, which is the form of albumin found in urine. The calibrators have been assayed against the Reference Preparation for Proteins in Human Serum (RPPHS*) and National Institute of Standards and Technology (NIST) Creatinine, and have been shown to produce identical results. The DCA Microalbumin/Creatinine Low and High 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.

**IMPORTANT NOTE: The DCA Microalbumin/ Creatinine Low and High Controls are for use only with the DCA Microalbumin/Creatinine Reagent Kit. Other Albumin or Creatinine assay systems may produce different values.**

## AVAILABILITY

The DCA Microalbumin/Creatinine Control Kit, containing 2 vials of Low Control and 2 vials of High Control, is available as REF 6012A.

***RPPHS is a certified reference material developed conjointly through the College of American Pathologists (CAP), the Bureau Communita de Reference (BCR) and the International Federation of Clinical Chemists (IFCC).**

Lot specific Mean [MEAN] and Control Range [RANGE] Values for Albumin [A] and Creatinine [C] are found on the control card in the control kit.

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