



## CONE HbA1c CONTROL, LYOPHILIZED – 2 LEVEL KIT

Product	Lot Number	Contents	Expiration Date
CONE Lyophilized HbA1c Control, 2 Level Kit	5379E001	2 Levels x 2 Vials	2 Years DOM
CONE Lyophilized HbA1c Control, Level 1	5377E001	2 Vials x 1 mL	2 Years DOM
CONE Lyophilized HbA1c Control, Level 2	5378E001	2 Vials x 1 mL	2 Years DOM

### INTENDED USE

CONE Lyophilized HbA1c Control is intended for use as quality control material to monitor the performance and precision of Hemoglobin A1c (HbA1c %) Immunoassay and HPLC test methods using protocols established in individual laboratories.

### SUMMARY AND PRINCIPLE

The use of independent quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control are available to allow performance monitoring within the clinical range.

### REAGENT

CONE Lyophilized HbA1c Control is prepared from human serum to which biochemical material (human and animal origin), chemicals, stabilizers and preservatives are added. The product is provided in Lyophilized form for increased stability.

### STORAGE AND STABILITY

Unopened CONE Lyophilized HbA1c Control is stable until the expiration date printed on the container when stored refrigerated between 2-8°C.

Reconstituted **OPEN or CLOSED** vials are stable for 30 days

### ANALYTE VALUES

In accordance with good laboratory practices, each laboratory should establish its own analyte means and acceptable performance ranges.

### PROCEDURE

CONE Lyophilized HbA1c Control should be treated in the same manner as patient samples in accordance with instructions for the A1c assay method being used.

- (1) Vials should be uncapped and reconstituted with exactly 1mL of deionized water by micropipette. Replace cap after adding water.
- (2) Allow vials to sit for 15 minutes, gently swirling on occasion. Do not shake, avoid formation of bubbles during handling.

**Do not warm up refrigerated control material to room temperature before using. NOD Lyophilized A1c control vials should be used, recapped and back in the refrigerator in approximately 5 minutes or less to preserve refrigerated stability.**

### LIMITATIONS

Different values from those obtained with reagents available at the time of assay may be obtained as a result of changes in manufacturer's reagents or lot-to-lot reagent variability. CONE Lyophilized HbA1c Control should not be used past its expiration date or after improper handling. Microbial contamination will affect performance of this product.

### SPECIFIC PERFORMANCE CHARACTERISTICS

CONE Lyophilized HbA1c Control is manufactured in accordance with industry guidelines and standards. To perform as intended, the control requires proper storage and handling as described in this package insert.



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### WARNINGS

Individual donor units used in the preparation of this product have been tested and found to be non-reactive for HBsAg, Anti-HIV I/II, Anti-HCV, HIV-1 RNA, and HCV RNA. Donors of human plasma units used in making this product were tested and found negative for syphilis. However, no test method can offer complete assurance that products derived from human source material will not transmit infectious diseases. Therefore, this product should be considered potentially infectious and be treated in the same manner as a patient specimen.

***For In Vitro Diagnostic Use Only***  
**Assigned Values and Ranges Lot #5379E001 (Representative Values)**  
**Containing Vial Lots L1 #5377E001 & L2 #5378E001**

*Analyte* - Instrument		LEVEL 1 – 5377E001			LEVEL 2 – 5378E001		
*HbA1c*	UNITS	MEAN	Expected Range		MEAN	Expected Range	
Tosoh G8	%	5.22	4.3	6.5	10.54	7.6	11.4
*Hemoglobin*							
Beckman DU520, Drabkin's Reagent	g/dL	21.19	18	22	19.49	18	22