



CONE HbA1c CONTROL, LIQUID – 2 LEVEL KIT

Product	Lot Number	Contents	Expiration Date
CONE Liquid HbA1c Control, 2 Level Kit	5286F001	2 Levels x 2 Vials	2 Years DOM
CONE Liquid HbA1c Control, Level 1	5257F001	2 Vials x 1 mL	2 Years DOM
CONE Liquid HbA1c Control, Level 2	5258F001	2 Vials x 1 mL	2 Years DOM

INTENDED USE

CONE Liquid 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 Liquid HbA1c Control is prepared from human whole blood to which biochemical material (human and animal origin), chemicals, stabilizers and preservatives are added. The product is provided in liquid form for user convenience and is ready to use as is. **No further dilution of the control solution is needed for A1cNow and DCA instrument methods.**

STORAGE AND STABILITY

Kits may be received thawed but should be stored frozen (-15°C to -25°C) immediately upon receipt. Unopened CONE-TROL Liquid HbA1c Control is stable until the expiration date printed on the container when stored frozen.

Refrigerated **OPEN or CLOSED** vials are stable for 180 days for use with immunoassay methods, (i.e. DCA or A1CNOW). **The date refrigerated storage starts or “outdates” should be noted on the kit box.**

Refrigerated **OPEN or CLOSED** vials are stable for 30 days when used with HPLC methods, (i.e. Tosoh G8 or Primus Ultra 2)

Aliquots made immediately from freshly open vials which have been stored frozen may be frozen one time and stored until expiration date printed on the container. Thawed aliquots cannot be refrozen.

PROCEDURE

CONE Liquid HbA1c Control should be treated in the same manner as patient samples in accordance with instructions for the A1c assay method being used. No further dilution of the control solution is needed for A1cNow and DCA test methods.

(A) Frozen controls should be thawed to 2-8°C and mixed by gentle inversion several times prior to use.

(B) Refrigerated controls should be mixed by gentle inversion prior to use. Do not shake vigorously.

Do not warm up refrigerated control material to room temperature before using. 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 Liquid HbA1c Control should not be used past its expiration date or after improper handling. Microbial contamination will affect performance of this product.

ANALYTE VALUES

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

SPECIFIC PERFORMANCE CHARACTERISTICS

CONE Liquid 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 #5286F001 (Representative Values)
Containing Vial Lots L1 #5257F001 & L2 #5258F001

Analyte - Instrument		LEVEL 1 – 5257F001			LEVEL 2 – 5258F001		
HbA1c	UNITS	MEAN	Expected Range		MEAN	Expected Range	
A1CNow+	%	5.4	4.3	6.5	9.5	7.6	11.4
Siemens DCA Vantage	%	5.8	4.6	7.0	10.7	8.6	12.8
Tosoh G8	%	5.7	4.6	6.8	10.0	8.0	12.0