



CONE HbA1c CONTROL – 5 LEVEL KIT

Product	Lot Number	Contents	Expiration Date
CONE HbA1c Control, 5 Level Kit	5810A20001	5 Levels x 1 Vial	10/2021
CONE HbA1c Control, Level 1	5734A20001	1 Vial x 1 mL	10/2021
CONE HbA1c Control, Level 2	5735A20001	1 Vial x 1 mL	10/2021
CONE HbA1c Control, Level 3	5736A20001	1 Vial x 1 mL	10/2021
CONE HbA1c Control, Level 4	5737A20001	1 Vial x 1 mL	10/2021
CONE HbA1c Control, Level 5	5738A20001	1 Vial x 1 mL	10/2021

INTENDED USE

CONE HbA1c Control, Lyophilized is intended for use as quality control material to demonstrate linearity throughout the reportable range of Hemoglobin A1c (HbA1c%) for Immunoassay and HPLC test methods using protocols established in individual laboratories.

SUMMARY AND PRINCIPLE

CONE HbA1c Control, Lyophilized is provided at five levels ranging across the reportable range of HbA1c to assist in calibration linearity procedures.

REAGENT

CONE HbA1c Control, Lyophilized is prepared from human whole blood to which stabilizers are added. The product is provided in lyophilized form for increased stability.

STORAGE AND STABILITY

Unopened CONE HbA1c Control, Lyophilized is stable until the expiration date printed on the container when stored at 2-8°C. Reconstituted control is stable for 14 days when stored tightly capped at 2-8°C.

RECONSTITUTION

Reconstitute each vial with 1.0mL of distilled or deionized water. Allow to sit for 15 minutes. Gently swirl to mix until in solution.

PROCEDURE

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

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

Do not warm up refrigerated linearity material to room temperature before using. Linearity 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 HbA1c Control, Lyophilized 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 HbA1c Control, Lyophilized is manufactured in accordance with industry guidelines and standards. To perform as intended, the linearity 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

Method	Units	Level 1 5734A20001 Average Values	Level 2 5735A20001 Average Values	Level 3 5736A20001 Average Values	Level 4 5737A20001 Average Values	Level 5 5738A20001 Average Values
Tosoh G8	%HbA1c	4.13	6.68	9.60	11.30	14.67