



CONE LIPID CONTROL, LYOPHILIZED – 2 LEVELS

Product	Lot Number	Contents	Expiration Date
CONE Lyophilized Lipid Control, 2 Level Kit	4810F001	2 Levels x 3 Vials	1 Year DOM
CONE Lyophilized Lipid Control, Level 1	4811F001	3 Vials x 4 mL	1 Year DOM
CONE Lyophilized Lipid Control, Level 2	4812F001	3 Vials x 4 mL	1 Year DOM

INTENDED USE

CONE Lyophilized Lipid Control is intended for use as quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

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 Lipid Control is prepared from human serum to which human biochemical material, chemicals, stabilizers and preservatives are added. The control is provided in lyophilized form for increased stability.

STORAGE AND STABILITY

To achieve maximum shelf life for the CONE Lyophilized Lipid Control, store unopened at 2-8°C until the expiration date. Store vials away from the light. The control can be used for up to 14 days at 2-8°C after reconstitution. After reconstituting and freezing the control, all analytes will be stable for 30 days at -20°C. Upon thawing, do not refreeze. Discard remaining control.

PROCEDURE

CONE Lyophilized Lipid Control should be treated in the same manner as patient samples in accordance with instructions for the testing determination method being used. Reconstitute product using a volumetric pipette with 4.0mL DI water. Replace the stopper, and allow product to sit for 15 minutes after reconstitution. Gently swirl occasionally. After reconstitution, store tightly capped at 2-8°C for up to 14 days. Before each use, gently swirl to ensure equal mixture of product. Dispose of product after expiration according to local waste authority procedures.

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 Lipid 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 Lyophilized Lipid 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.

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.

This product contains 0.09% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive compounds. Flush with copious amounts of water upon disposal.



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For In Vitro Diagnostic Use Only

Assigned Values and Ranges Lot #4810F001 (Representative Values)

Containing Vial Lots L1 #4811F001 & L2 #4812F001

Analyte - Instrument		LEVEL 1 – 4811F001			LEVEL 2 – 4812F001		
Apolipoprotein A	UNITS	MEAN	Expected Range		MEAN	Expected Range	
Beckman AU 400	mg/dL	181	171	191	119	112	127
Apolipoprotein B							
Beckman AU 400	mg/dL	4.6	4.4	4.9	3.0	2.7	3.2
Apolipoprotein E							
Beckman AU 400	mg/dL	114	103	125	336	324	348
HDL Cholesterol							
Beckman AU 400	mg/dL	25	21	28	250	237	262
LDL Cholesterol							
Beckman AU 400	mg/dL	196	174	218	94	90	99
Lp(a)							
Beckman AU 400	mg/dL	84	80	88	45	30	59
Total Cholesterol							
Beckman AU 400	mg/dL	59	55	63	264	245	282
Triglyceride							
Beckman AU 400	mg/dL	26	23	29	283	268	298