CONE LIPID CONTROL, LIQUID – 2 LEVELS

Product	Lot Number	Contents	Expiration Date
CONE Liquid Lipid Control, 2 Level Kit	**5479F001**	**2 Levels x 3 Vials**	**1 Year DOM**
CONE Liquid Lipid Control, Level 1	**5477F001**	**3 Vials x 3 mL**	**1 Year DOM**
CONE Liquid Lipid Control, Level 2	**5478F001**	**3 Vials x 3 mL**	**1 Year DOM**

INTENDED USE
CONE Liquid 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 Liquid Lipid Control is prepared from human serum to which human biochemical material, chemicals, stabilizers and preservatives are added. The control is provided as a refrigerated liquid for user convenience.

STORAGE AND STABILITY
To achieve maximum shelf life for the CONE Liquid Lipid Control, store unopened at ≤-20°C until the expiration date. Store vials away from the light. Thawed and unopened vials are stable for 30 days. Upon opening, the control is stable for up to 14 days when stored tightly capped at 2-8°C.

PROCEDURE
CONE Liquid Lipid Control should be treated in the same manner as patient samples and in accordance with local, state, and/or federal regulations or accreditation requirements. Before each use, allow product to reach room temperature and gently swirl to ensure equal mixture of product. Replace cap immediately after sampling and store product at 2-8°C. Follow instructions for the testing determination method being used. 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 Liquid 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 Liquid 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.

1012 N. Austin Street, Seguin, TX 78155 USA – P: 830-379-0197 – F: 830-379-0471 – sales@conebio.com – www.conebio.com
(REV 12/01/2017)

CONE LIPID CONTROL, LIQUID – 2 LEVELS

For In Vitro Diagnostic Use Only

Assigned Values and Ranges Lot #5479F001 (Representative Values)

Containing Vial Lots L1 #5477F001 & L2 #5478F001

Analyte - Instrument		LEVEL 1 – 5477F001			LEVEL 2 – 5478F001		
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	94	90	99	196	174	218
Lp(a)							
Beckman AU 400	mg/dL	45	30	59	84	80	88
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

1012 N. Austin Street, Seguin, TX 78155 USA – P: 830-379-0197 – F: 830-379-0471 – sales@conebio.com – www.conebio.com

(REV 12/01/2017)