



CONE IMMUNOLOGY CONTROL, LIQUID – 2 LEVEL KIT

Product	Lot Number	Contents	Expiration Date
CONE Liquid Immunology Control, 2 Level Kit	4959F001	2 Levels x 3 Vials	18 months DOM
CONE Liquid Immunology Control, Level 1	4969F001	3 Vials x 3 mL	18 months DOM
CONE Liquid Immunology Control, Level 2	4970F001	3 Vials x 3 mL	18 months DOM

INTENDED USE

CONE Liquid Immunology 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 Immunology 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 Immunology Control, store unopened at 2-8°C until the expiration date. Store vials away from the light. Upon opening, the control can be used for up to 60 days when stored tightly capped at 2-8°C.

PROCEDURE

CONE Liquid Immunology 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 Immunology 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 Immunology 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.



CONE IMMUNOLOGY CONTROL, LIQUID – 2 LEVEL KIT

For In Vitro Diagnostic Use Only

Assigned Values and Ranges Lot #4959F001 (Representative Values)

Containing Vial Lots L1 #4969F001 & L2 #4970F001

Analyte - Instrument		LEVEL 1 – 4969F001			LEVEL 2 – 4970F001		
Total Protein	UNITS	MEAN	Expected Range		MEAN	Expected Range	
Beckman AU, Sekisui Reagent	g/dL	7.0	6.5	7.5	15.5	15.1	15.9
IgG							
Beckman AU, Kamiya Reagent	mg/dL	880	730	1030	2065	1720	2410
IgA							
Beckman AU, Kamiya Reagent	mg/dL	194	153	235	434	367	500
C3							
Beckman AU, Kamiya Reagent	mg/dL	78	66	90	240	200	280
C4							
Beckman AU, Kamiya Reagent	mg/dL	17	12	21	46	35	57
CRP							
Beckman AU, Kamiya Reagent	mg/dL	0.6	0.68	0.92	4.3	3.7	4.9
RF							
Beckman AU, Kamiya Reagent	IU/mL	25	18	32	100	85	115
ASO							
Beckman AU, Kamiya Reagent	IU/mL	85	70	100	210	180	240