CONE CARDIAC CONTROL, LIQUID – 3 LEVELS

Product	Lot Number	Contents	Expiration Date
CONE Liquid Cardiac Control, 3 Levels	**4621F001**	**3 Levels x 3 Vials**	**3 Years DOM**
CONE Liquid Cardiac Control, Level 1	**4219F001**	**3 Vials x 3 mL**	**3 Years DOM**
CONE Liquid Cardiac Control, Level 2	**4220F001**	**3 Vials x 3 mL**	**3 Years DOM**
CONE Liquid Cardiac Control, Level 3	**4221F001**	**3 Vials x 3 mL**	**3 Years DOM**

INTENDED USE
CONE Liquid Cardiac 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. Three levels of control are available to allow performance monitoring within the clinical range.

REAGENT
CONE Liquid Cardiac 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 Cardiac Control, store unopened at ≤-20°C until the expiration date. Store vials away from the light. Upon opening, the control can be used for up to 7 days when stored tightly capped at 2-8°C. For optimum stability, avoid prolonged exposure of the control vials to ambient air / room temperature / light.

PROCEDURE
CONE Liquid Cardiac 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 Cardiac 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 Cardiac 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.

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For In Vitro Diagnostic Use Only

Assigned Values and Ranges Lot #4621F001 (Representative Values)

Containing Vial Lots L1 #4219F001 & L2 #4220F001 & L3 #4221F001

Analyte - Instrument		LEVEL 1 – 4219F001			LEVEL 2 – 4220F001			LEVEL 3 – 4221F001		
CKMB	**UNITS**	**MEAN**	**Expected Range**		**MEAN**	**Expected Range**		**MEAN**	**Expected Range**	
Tosoh AIA	ng/mL	87.5	79	96	33.1	29	37	16.6	14.6	18.6
Myoglobin										
Tosoh AIA	ng/mL	199.5	179	220	159.1	143	175	75.5	67	84
Troponin I										
Tosoh AIA	ng/mL	21.1	19	23	9.9	8.9	11	0.94	0.7	1.1

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