



CONE CHEMISTRY + LIPID CONTROL, LIQUID – 2 LEVEL KIT

Product	Lot Number	Contents	Expiration Date
CONE Liquid Chemistry + Lipid Control, 2 Level Kit	4650F001	2 Levels x 6 Vials	18 months DOM
CONE Liquid Chemistry + Lipid Control, Level 1	4651F001	6 Vials x 1 mL	18 months DOM
CONE Liquid Chemistry + Lipid Control, Level 2	4652F001	6 Vials x 1 mL	18 months DOM

INTENDED USE

CONE Liquid Chemistry + 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 Chemistry + 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 Chemistry + Lipid Control, store unopened at $\leq -20^{\circ}\text{C}$ 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 $2-8^{\circ}\text{C}$.

PROCEDURE

CONE Liquid Chemistry + 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 $2-8^{\circ}\text{C}$. Follow instructions for the testing determination method being used. Dispose of product after

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 Chemistry + 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 Chemistry + 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 #4650F001 (Representative Values)

Containing Vial Lots L1 #4651F001 & L2 #4652F001

Analyte - Instrument		LEVEL 1 – 4651F001			LEVEL 2 – 4652F001		
Albumin	UNITS	MEAN	Expected Range		MEAN	Expected Range	
Abaxis Piccolo	g/dL	3.1	2.4	3.8	4.4	3.4	5.4
Alkaline Phosphatase							
Abaxis Piccolo	U/L	97	73	121	376	282	470
ALT/SGPT							
Abaxis Piccolo	U/L	42	33	52	178	137	219
Amylase							
Abaxis Piccolo	U/L	67	47	87	272	232	381
Aspartate Aminotransferase							
Abaxis Piccolo	U/L	81	62	100	309	238	381
Bilirubin – Direct							
Abaxis Piccolo	mg/dL	0.8	0.4	1.2	2.4	1.8	3.1
Bilirubin – Total							
Abaxis Piccolo	mg/dL	1.7	1.2	2.1	4.3	3.2	5.4
BUN (Urea Nitrogen)							
Abaxis Piccolo	mg/dL	20	16	25	52	47	57
Calcium, Total							
Abaxis Piccolo	mg/dL	7.2	6.2	8.2	12.3	11.0	13.7
Carbon Dioxide							
Abaxis Piccolo	mmol/L	14	9	19	21	15	27
Chloride							
Abaxis Piccolo	mmol/L	96	88	105	118	107	129
HDL Cholesterol							
Abaxis Piccolo	mg/dL	30	26	34	61	53	68
Total Cholesterol							
Abaxis Piccolo	mg/dL	156	134	177	292	251	333
Creatine Kinase							
Abaxis Piccolo	U/L	201	161	242	769	615	923
Creatinine							
Abaxis Piccolo	mg/dL	1.4	0.8	2.0	5.6	4.3	6.8
GGT							
Abaxis Piccolo	U/L	48	37	58	189	147	231
Glucose							
Abaxis Piccolo	mg/dL	69	58	80	277	233	322
Lactate							
Abaxis Piccolo	mmol/L	1.59	1.34	1.84	3.46	2.91	4.01
Lactate Dehydrogenase							
Abaxis Piccolo	U/L	109	89	128	461	378	544



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Analyte - Instrument		LEVEL 1 - 4651F001			LEVEL 2 - 4652F001		
Magnesium	UNITS	MEAN	Expected Range		MEAN	Expected Range	
Abaxis Piccolo	mg/dL	1.6	1.3	1.8	4.6	3.9	5.3
Phosphorus							
Abaxis Piccolo	mg/dL	3.1	2.6	3.7	6.9	5.7	8.2
Potassium							
Abaxis Piccolo	mmol/L	3.5	3.0	4.0	6.6	6.0	7.2
Protein, Total							
Abaxis Piccolo	g/dL	4.9	4.4	5.4	7.4	6.7	8.1
Sodium							
Abaxis Piccolo	mmol/L	123	116	131	149	140	158
Triglycerides							
Abaxis Piccolo	mg/dL	154	127	182	302	248	356
Uric Acid							
Abaxis Piccolo	mg/dL	3.4	2.9	3.8	10.7	9.2	12.2