CONE CHEMISTRY+LIPID VERIFICATION, LIQUID – 3 LEVELS

Product	Lot Number	Contents	Expiration Date
CONE Chemistry + Lipid Verification, 3 Levels	**4640F001**	**3 Levels x 3 Vials**	**18 months DOM**
CONE Chemistry + Lipid Verification, Level 1	**4641F001**	**3 Vials x 3 mL**	**18 months DOM**
CONE Chemistry + Lipid Verification, Level 2	**4642F001**	**3 Vials x 3 mL**	**18 months DOM**
CONE Chemistry + Lipid Verification, Level 3	**4643F001**	**3 Vials x 3 mL**	**18 months DOM**

INTENDED USE
CONE Chemistry + Lipid Verification is intended for use to validate analyzer performance according to CLIA guidelines.

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 Chemistry + Lipid Verification 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 Chemistry + Lipid Verification, 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 14 days when stored tightly capped at 2-8°C. For optimum Bilirubin and CO2 stability, avoid prolonged exposure of the verification sample vials to ambient air / room temperature / light.

PROCEDURE
CONE Chemistry + Lipid Verification 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 Chemistry + Lipid Verification 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 Chemistry + Lipid Verification 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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(REV 12/01/2017)

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For In Vitro Diagnostic Use Only

Assigned Values and Ranges Lot #4640F001 (Representative Values)

Containing Vial Lots L1 #4641F001 & L2 #4642F001 & L3 #4643F001

Analyte - Instrument		LEVEL 1 – 4641F001			LEVEL 2 – 4642F001			LEVEL 3 – 4643F001		
Albumin	**UNITS**	**MEAN**	**Expected Range**		**MEAN**	**Expected Range**		**MEAN**	**Expected Range**	
Abaxis Piccolo	g/dL	1.6	1.1	2.1	3.9	3.5	4.3	5.9	5.4	6.4
Alkaline Phosphatase										
Abaxis Piccolo	U/L	25	15	35	856	770	942	2000	1700	2300
ALT/SGPT										
Abaxis Piccolo	U/L	25	15	35	677	609	745	1600	1400	1800
Amylase										
Abaxis Piccolo	U/L	25	15	35	1059	953	1200	2400	2100	2700
Aspartate Aminotransferase										
Abaxis Piccolo	U/L	20	13	27	755	679	831	1600	1400	1800
Bilirubin, Direct										
Abaxis Piccolo	mg/dL	0.6	0.68	0.92	4.3	3.7	4.9	5.0	4.0	6.0
Bilirubin, Total										
Abaxis Piccolo	mg/dL	25	18	32	100	85	115	5.0	4.0	6.0
BUN (Urea Nitrogen)										
Abaxis Piccolo	mg/dL	85	70	100	210	180	240	125	105	145
Calcium										
Abaxis Piccolo	mg/dL	4.6	4.1	5.1	10.7	9.8	11.5	15	14.5	15.5
Carbon Dioxide										
Abaxis Piccolo	mmol/L	36	33	39	27	24	30	8.0	5.0	11.0
Chloride										
Abaxis Piccolo	mmol/L	85	81	89	107	96	118	130	125	134
HDL Cholesterol										
Abaxis Piccolo	mg/dL	21	18	24	55	49	61	80	70	90
Total Cholesterol										
Abaxis Piccolo	mg/dL	55	30	80	253	228	278	400	350	450
Creatine Kinase										
Abaxis Piccolo	U/L	35	20	50	1600	1400	1800	3500	3000	4000
Creatinine										
Abaxis Piccolo	mg/dL	0.6	0.3	0.9	8.0	7.0	9.0	17	15	19
GGT										
Abaxis Piccolo	U/L	18	10	25	1130	930	1300	2500	2100	2900
Glucose										
Abaxis Piccolo	mg/dL	30	20	40	335	300	370	650	620	680
Lactate										
Abaxis Piccolo	mmol/L	0.35	0.25	0.45	5.7	5.1	6.3	9.8	8.8	10.8

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Analyte - Instrument		LEVEL 1 – 4641F001			LEVEL 2 – 4642F001			LEVEL 3 – 4643F001		
LDH	**UNITS**	**MEAN**	**Expected Range**		**MEAN**	**Expected Range**		**MEAN**	**Expected Range**	
Abaxis Piccolo	U/L	70	50	90	372	335	410	800	700	900
Magnesium										
Abaxis Piccolo	mg/dL	0.6	0.3	0.9	3.3	3.0	3.6	7.0	6.5	7.5
Phosphorus										
Abaxis Piccolo	mg/dL	16	14	18	8.3	7.5	9.1	1.0	0.5	1.5
Potassium										
Abaxis Piccolo	mmol/L	2.0	1.5	2.5	5.0	4.5	5.5	7.5	7.0	8.0
Total Protein										
Abaxis Piccolo	g/dL	3.0	2.3	3.7	6.6	5.9	7.3	10.5	8.5	12.5
Sodium										
Abaxis Piccolo	mmol/L	116	111	121	140	126	154	164	160	168
Triglycerides										
Abaxis Piccolo	mg/dL	40	20	60	218	196	240	350	320	380
Uric Acid										
Abaxis Piccolo	mg/dL	1.0	0.5	1.5	7.1	6.4	7.8	14	12	16

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