



## CONE CHEMISTRY + CRP CONTROL, LIQUID – 2 LEVEL KIT

Product	Lot Number	Contents	Expiration Date
CONE Liquid Chemistry + CRP Control, 2 Level Kit	5280F001	2 Levels x 6 Vials	12/01/2017
CONE Liquid Chemistry + CRP Control, Level 1	5281F001	6 Vials x 1 mL	12/01/2017
CONE Liquid Chemistry + CRP Control, Level 2	5282F001	6 Vials x 1 mL	12/01/2017

### INTENDED USE

CONE Liquid Chemistry + CRP 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 + CRP Control is prepared from human serum to which biochemical material (human and animal origin), chemicals, stabilizers and preservatives are added. The control is in a prepackaged liquid form to avoid potential error or contaminate being introduced during reconstitution.

### STORAGE AND STABILITY

This product will be stable until the expiration date when stored  $\leq -20^{\circ}\text{C}$ . To achieve maximum shelf life, store vials away from the light. Do not store in a frost free freezer.

Thawed and Unopened: Chemistry Control is stable for up to 30 days when stored unopened at  $2-8^{\circ}\text{C}$ .

Thawed and Opened: Chemistry Control is stable for up to 14 days after opening, when stored tightly capped at  $2-8^{\circ}\text{C}$ . For optimum Bilirubin and  $\text{CO}_2$  stability avoid prolonged exposure of the Control vials to ambient air / room temperatures / light.

### PROCEDURE

The control should be treated the same as a patient sample and run according to the instructions accompanying the instrument, kit, or reagent being used. Before sampling the control should be mixed thoroughly but gently.

Thaw CONE Liquid Chemistry + CRP Control at room temperature ( $18-25^{\circ}\text{C}$ ) for 15 minutes or until completely thawed. Mix the vial thoroughly by inverting several times, before sampling gently swirl until homogeneous with no visible signs of precipitate. Avoid vigorous shaking. After sampling, the Control should be promptly re-capped and stored at  $2-8^{\circ}\text{C}$ .

### 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 + CRP 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 + CRP 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 #5280F001 (Representative Values)

Containing Vial Lots L1 #5281F001 & L2 #5282F001

*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
<b>*Alkaline Phosphatase (ALP)*</b>							
Abaxis Piccolo	U/L	97	73	121	376	282	470
<b>*Alanine Aminotransferase (ALT)*</b>							
Abaxis Piccolo	U/L	42	33	52	178	137	219
<b>*Amylase*</b>							
Abaxis Piccolo	U/L	67	47	87	272	232	312
<b>*Aspartate Transaminase (AST)*</b>							
Abaxis Piccolo	U/L	81	62	100	309	238	381
<b>*Calcium*</b>							
Abaxis Piccolo	mg/dL	7.2	6.2	8.2	12.3	11.0	13.7
<b>*Creatinine Kinase*</b>							
Abaxis Piccolo	U/L	201	161	242	769	615	923
<b>*CRP*</b>							
Abaxis Piccolo	mg/dL	41	35	46	108	93	123
<b>*Chloride*</b>							
AVL	mmol/L	96	88	105	118	107	129
<b>*CO<sub>2</sub>*</b>							
Abaxis Piccolo	mmol/L	14	9	19	21	15	27
<b>*Creatinine*</b>							
Abaxis Piccolo	mg/dL	1.4	0.8	2.0	5.6	4.3	6.8
<b>*Direct Bilirubin*</b>							
Abaxis Piccolo	mg/dL	0.8	0.4	1.2	2.4	1.8	3.1
<b>*Gamma-Glutamyl Transferase (GGT)*</b>							
Abaxis Piccolo	U/L	48	37	58	189	147	231
<b>*Glucose*</b>							
Abaxis Piccolo	mg/dL	71	66	75	287	267	307
<b>*HDL Cholesterol*</b>							
Abaxis Piccolo	mg/dL	76	71	80	31	29	33
<b>*Lactate*</b>							
Abaxis Piccolo	mmol/L	5.45	5.00	5.90	1.88	1.60	2.16
<b>*Lactate Dehydrogenase (LDH)*</b>							
Abaxis Piccolo	U/L	133	128	138	309	293	324



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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	6.0	7.2
*Potassium*							
AVL	mmol/L	3.5	3.0	4.0	6.6	6.0	7.2
*Sodium*							
AVL	mmol/L	123	116	131	149	140	158
*Total Bilirubin*							
Abaxis Piccolo	mg/dL	1.7	1.2	2.1	4.3	3.2	5.4
*Total Cholesterol*							
Abaxis Piccolo	mg/dL	156	134	177	292	251	333
*Total Protein*							
Abaxis Piccolo	g/dL	4.9	4.4	5.4	7.4	6.7	8.1
*Triglyceride*							
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
*Urea (BUN)*							
Abaxis Piccolo	mg/dL	20	16	25	52	47	57