



CONE CHEMISTRY CONTROL, LYOPHILIZED – 2 LEVEL KIT

Product	Lot Number	Contents	Expiration Date
CONE Lyophilized Chemistry Control, 2 Level Kit	5644F001	2 Levels x 3 Vials	12/01/2019
CONE Lyophilized Chemistry Control, Level 1	5641F001	3 Vials x 3 mL	12/01/2019
CONE Lyophilized Chemistry Control, Level 2	5642F002	3 Vials x 3 mL	12/01/2019

INTENDED USE

CONE Lyophilized Chemistry 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 Lyophilized Chemistry Control is prepared from human serum to which biochemical material (human and animal origin), chemicals, stabilizers and preservatives are added. The control is provided in lyophilized form for increased stability.

STORAGE AND STABILITY

To achieve maximum shelf life for the CONE Lyophilized Chemistry Control, store unopened at 2-8°C until the expiration date. Store vials away from the light. The control can be used for up to 7 days at 2-8°C after reconstitution. After reconstituting and freezing the control, all analytes will be stable for 30 days at -20°C. Upon thawing, do not refreeze. Discard remaining control.

PROCEDURE

CONE Lyophilized Chemistry Control should be treated in the same manner as patient samples in accordance with instructions for the testing determination method being used. Reconstitute product using a volumetric pipette with 5.0mL DI water. Replace the stopper, and allow product to sit for 15 minutes after reconstitution. Gently swirl occasionally. After reconstitution, store tightly capped at 2-8°C for up to 7 days. Before each use, gently swirl to ensure equal mixture of product. 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 Lyophilized Chemistry 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 Lyophilized Chemistry 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 CHEMISTRY CONTROL, LYOPHILIZED – 2 LEVEL KIT

For In Vitro Diagnostic Use Only
Assigned Values and Ranges Lot #5644F001 (Representative Values)
Containing Vial Lots L1 #5641F001 & L2 #5642F001

Analyte - Instrument		LEVEL 1 – 5641F001			LEVEL 2 – 5642F001		
α-1-Antitrypsin	UNITS	MEAN	Expected Range		MEAN	Expected Range	
Beckman AU 400	mg/dL	181	171	191	119	112	127
Albumin							
Beckman AU 400	g/dL	4.6	4.4	4.9	3.0	2.7	3.2
Alkaline Phosphatase (ALP)							
Beckman AU 400	U/L	114	103	125	336	324	348
Alanine Aminotransferase (ALT)							
Beckman AU 400	U/L	25	21	28	250	237	262
Apolipoprotein A-1							
Beckman AU 400	mg/dL	196	174	218	94	90	99
Apolipoprotein B							
Beckman AU 400	mg/dL	84	80	88	45	30	59
Amylase							
Beckman AU 400	U/L	59	55	63	264	245	282
Aspartate Transaminase (AST)							
Beckman AU 400	U/L	26	23	29	283	268	298
Calcium							
Beckman AU 400	mg/dL	5.9	5.6	6.3	11.2	10.5	11.7
Cholinesterase							
Beckman AU 400	U/L	7678	7306	8050	3581	3404	3759
Complement C3							
Beckman AU 400	mg/dL	167	158	175	103	96	109
Complement C4							
Beckman AU 400	mg/dL	32	30	34	18	17	19
Creatinine Kinase							
Beckman AU 400	U/L	100	96	104	288	278	298
Chloride							
AVL	mmol/L	119	117	122	97	93	100
CO₂							
Beckman AU 400	mmol/L	31	27	34	18	12	24
Copper							
Beckman AU 400	µg/dL	131	118	144	78	70	86
Creatinine							
Beckman AU 400	mg/dL	1.24	1.15	1.32	5.51	5.03	5.99
Direct Bilirubin							
Beckman AU 400	mg/dL	0.42	0.40	0.43	1.57	1.52	1.62



CONE CHEMISTRY CONTROL, LYOPHILIZED – 2 LEVEL KIT

Analyte - Instrument		LEVEL 1 – 5641F001			LEVEL 2 – 5642F001		
Gamma-Glutamyl Transferase (GGT)	UNITS	MEAN	Expected Range		MEAN	Expected Range	
Beckman AU 400	U/L	39	38	40	207	200	213
Glucose							
Beckman AU 400	mg/dL	71	66	75	287	267	307
HDL Cholesterol							
Beckman AU 400	mg/dL	76	71	80	31	29	33
Haptoglobin							
Beckman AU 400	mg/dL	139	128	149	86	83	90
Immunoglobulin A (IgA)							
Beckman AU 400	mg/dL	220	200	240	128	122	134
Immunoglobulin G (IgG)							
Beckman AU 400	mg/dL	1105	1000	1210	681	647	714
Immunoglobulin M (IgM)							
Beckman AU 400	mg/dL	114	108	121	69	65	72
Iron							
Beckman AU 400	ug/dL	261	256	265	62	57	66
Potassium							
AVL	mmol/L	2.5	2.4	2.6	5.1	4.8	5.3
Lactate							
Beckman AU 400	mmol/L	5.45	5.00	5.90	1.88	1.60	2.16
Lactate Dehydrogenase (LDH)							
Beckman AU 400	U/L	133	128	138	309	293	324
LDL Cholesterol							
Beckman AU 400	mg/dL	115	108	121	57	54	60
Lipase							
Beckman AU 400	U/L	48	44	52	290	276	304
Lithium							
Beckman AU 400	mmol/L	0.33	0.30	0.36	1.65	1.49	1.82
Magnesium							
Beckman AU 400	mg/dL	2.1	1.8	2.5	4.3	4.1	4.5
Sodium							
AVL	mmol/L	145	143	148	120	116	124
Phosphorus							
Beckman AU 400	mg/dL	3.7	3.5	3.8	8.5	7.5	9.5
Total Bile Acid (TBA)							
Beckman AU 400	umol/L	17	11	22	110	105	114
Total Bilirubin							
Beckman AU 400	mg/dL	0.8	0.7	0.9	4.7	4.4	4.9
Transferrin							
Beckman AU 400	mg/dL	289	276	301	185	175	195
Triglyceride							
Beckman AU 400	mg/dL	178	170	186	82	78	87



CONE CHEMISTRY CONTROL, LYOPHILIZED – 2 LEVEL KIT

Analyte - Instrument		LEVEL 1 – 5641F001			LEVEL 2 – 5642F001		
Iron, TIBC	UNITS	MEAN	Expected Range		MEAN	Expected Range	
Beckman AU 400	ug/dL	354	319	389	228	205	251
Iron, UIBC							
Beckman AU 400	ug/dL	93	84	103	166	156	176
Total Protein							
Beckman AU 400	g/dL	7.9	7.5	8.4	5.0	4.7	5.2
Uric Acid							
Beckman AU 400	mg/dL	4.5	4.1	4.8	7.5	6.8	8.2
Urea (BUN)							
Beckman AU 400	mg/dL	20	18	22	58	54	61
Zinc							
Beckman AU 400	ug/dL	187	168	206	134	121	147