CONE CHEMISTRY LINEARITY, LYOPHILIZED – 7 LEVEL KIT

Product	Lot Number	Contents	Expiration Date
CONE Lyophilized Chemistry Linearity, 7 Level Kit	**5476F001**	**7 Levels x 1 Vial**	**12/01/2017**
CONE Lyophilized Chemistry Linearity, Level 1	**5431F001**	**1 Vial x 5 mL**	**12/01/2017**
CONE Lyophilized Chemistry Linearity, Level 2	**5432F001**	**1 Vial x 5 mL**	**12/01/2017**
CONE Lyophilized Chemistry Linearity, Level 3	**5433F001**	**1 Vial x 5 mL**	**12/01/2017**
CONE Lyophilized Chemistry Linearity, Level 4	**5434F001**	**1 Vial x 5 mL**	**12/01/2017**
CONE Lyophilized Chemistry Linearity, Level 5	**5435F001**	**1 Vial x 5 mL**	**12/01/2017**
CONE Lyophilized Chemistry Linearity, Level 6	**5436F001**	**1 Vial x 5 mL**	**12/01/2017**
CONE Lyophilized Chemistry Linearity, Level 7	**5437F001**	**1 Vial x 5 mL**	**12/01/2017**

INTENDED USE
CONE Lyophilized Chemistry Linearity 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 Linearity 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 Linearity 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 Linearity 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 Linearity 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.

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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.

For In Vitro Diagnostic Use Only

Assigned Values and Ranges Lot #5476F001 (Representative Values)

Containing Vial Lots L1-L7: 5431F001;5432F001;5433F001;5434F001;5435F001;5436F001;5437F001

Expected Ranges are ± 15% of Mean Values

Analyte - Instrument		LEVEL 1 5431F001	LEVEL 2 5432F001	LEVEL 3 5433F001	LEVEL 4 5434F001	LEVEL 5 5435F001	LEVEL 6 5436F001	LEVEL 7 5437F001
ALT / SGPT	**UNITS**	**MEAN**	**MEAN**	**MEAN**	**MEAN**	**MEAN**	**MEAN**	**MEAN**
Beckman AU 400	U/L	10	191.7	373.3	555	736.7	918.3	1100
Albumin								
Beckman AU 400	g/dL	15	24.2	33.3	42.5	51.7	60.8	70
Alkaline Phosphatase (ALP)								
Beckman AU 400	U/L	10	191.7	373.3	555	736.7	918.3	1100
Total Bilirubin								
Beckman AU 400	mg/dL	0.3	4.1	8.0	11.8	15.7	19.5	23.4
Direct Bilirubin								
Beckman AU 400	mg/dL	0.2	2.1	4.0	5.9	7.9	9.8	11.7
Calcium								
Beckman AU 400	mg/dL	4	6.7	9.3	12.0	14.7	17.3	20
Chloride								
Diamond SmartLyte	mmol/L	50	71.7	93.3	115	136.7	158.3	180
Creatine Kinase								
Beckman AU 400	U/L	10	191.7	373.3	555	736.7	918.3	1100
Creatinine								
Beckman AU 400	mg/dL	0.1	2.9	5.7	8.5	11.3	14.2	17
Gamma-Glutamyl Transferase (GGT)								
Beckman AU 400	U/L	10	191.7	373.3	555	736.7	918.3	1100
Glucose								
Beckman AU 400	mg/dL	18	105.1	192.2	279.3	366.4	453.5	541
Lactate Dehydrogenase(LDH)								
Beckman AU 400	U/L	10	191.7	373.3	555	736.7	918.3	1100

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Magnesium	**UNITS**	**MEAN**	**MEAN**	**MEAN**	**MEAN**	**MEAN**	**MEAN**	**MEAN**
Beckman AU 400	mg/dL	0.7	1.8	2.9	4.0	5.1	6.2	7.3
Phosphorus								
Beckman AU 400	mg/dL	1.2	3.1	5.0	6.8	8.7	10.5	12.4
Potassium								
Diamond SmartLyte	mmol/L	2.0	3.0	4.0	5.0	6.0	7.0	8.0
Total Protein								
Beckman AU 400	g/dL	4.0	5.0	6.0	7.0	8.0	9.0	10.0
Sodium								
Diamond SmartLyte	mmol/L	110	123.3	136.7	150	163.3	176.6	190
Urea								
Beckman AU 400	mg/dL	2.8	16.3	29.9	43.4	57	70.5	84
Uric Acid								
Beckman AU 400	mg/dL	0.3	3.1	5.8	8.6	11.3	14.1	16.8
Total Cholesterol								
Beckman AU 400	mg/dL	39	128.7	218.8	308.9	399	489.1	579
Triglyceride								
Beckman AU 400	mg/dL	44	154.9	265.5	376.1	486.7	597.3	708
HDL Cholesterol								
Beckman AU 400	mg/dL	19	67.6	115.8	164.1	212.4	260.6	309
LDL Cholesterol								
Beckman AU 400	mg/dL	19	67.6	115.8	164.1	212.4	260.6	309
Amylase								
Beckman AU 400	U/L	15	195.8	376.7	557.5	738.3	919.2	1100
AST / SGOT								
Beckman AU 400	U/L	10	191.7	373.3	555	736.7	918.3	1100
CO2 / Bicarbonate								
Beckman AU 400	mmol/L	5	12.5	20.0	27.5	35.0	42.5	50
Lactate								
Beckman AU 400	mmol/L	0.5	2.1	3.7	5.3	6.8	8.4	10
α-Hydroxybutyrate Dehydrogenase (a-HBDH)								
Beckman AU 400	U/L	30	125	220	315	410	505	600
Copper								
Laboratory Test	µg/dL	30	58.3	86.7	115	143.3	171.7	200
Iron								
Beckman AU 400	µg/dL	10	141.7	273.3	405	536.7	668.3	800
Lithium								
Laboratory Test	mmol/L	0.3	0.8	1.2	1.7	2.1	2.6	3.0
TIBC								
Beckman AU 400	µg/dL	80	166.7	253.3	340	426.7	513.3	600
Zinc								
Laboratory Test	µg/dL	80	133.3	186.7	240	293.3	346.7	400

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TBA	**UNITS**	**MEAN**	**MEAN**	**MEAN**	**MEAN**	**MEAN**	**MEAN**	**MEAN**
Beckman AU 400	µmol/L	2.0	18.3	34.7	51.0	67.3	83.7	100
Cholinesterase								
Beckman AU 400	U/L	300	2250	4200	6150	8100	10050	12000
Lipase								
Beckman AU 400	U/L	10	58.3	106.7	155	203.3	251	300

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