



CONE CHEMISTRY CALIBRATOR, LYOPHILIZED

Product	Lot Number	Contents	Expiration Date
CONE Lyophilized Chemistry Calibrator	4672F001	6 Vial x 3 mL	12/01/2019

INTENDED USE

CONE Lyophilized Chemistry Calibrator is intended for use in the calibration of clinical chemistry assays on automated analyzers.

DESCRIPTION

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

STORAGE AND STABILITY

To achieve maximum shelf life for the CONE Lyophilized Chemistry Calibrator, store unopened at 2-8°C until the expiration date. Store vials away from light. Upon reconstitution, Direct Bilirubin and Total Bilirubin will be stable for 24 hours when stored at 2-8°C. The remaining analytes will be stable for 7 days when stored at 2-8°C. Upon thawing, do not refreeze. Discard remaining calibrator material after use.

PROCEDURE

CONE Lyophilized Chemistry Calibrator should be treated in the same manner as patient samples in accordance with instructions for the testing determination method being used.

Reconstitute the calibrator using a volumetric pipette with exactly 3.0mL DI water. Replace the stopper, and allow the product to sit for 30 minutes after reconstitution. Gently swirl the vial occasionally, avoiding the formation of bubbles or foam in the material. 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 Calibrator 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 Calibrator is manufactured in accordance with industry guidelines and standards. To perform as intended, the calibrator 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 Lot #4672F001 (Representative Values)

Analyte - Instrument, Reagent	4672F001	
Albumin	UNITS	MEAN
Beckman AU 400, Pointe Reagent	g/dL	4.1
Alkaline Phosphatase (ALP)		
Beckman AU 400, Pointe Reagent	U/L	392
Alanine Aminotransferase (ALT)		
Beckman AU 400, Pointe Reagent	U/L	233
Amylase		
Beckman AU 400, Sekisui Reagent	U/L	291
Aspartate Transaminase (AST)		
Beckman AU 400, Pointe Reagent	U/L	294
Bilirubin – Direct		
Beckman AU 400, Sekisui Reagent	mg/dL	2.0
Bilirubin – Total		
Beckman AU 400, Sekisui Reagent	mg/dL	4.5
BUN (Urea Nitrogen)		
Beckman AU 400, Pointe Reagent	mg/dL	53
Calcium		
Beckman AU 400, Pointe Reagent	mg/dL	12.8
Chloride		
AVL, ISE	mmol/L	114
Creatine Kinase (CK)		
Beckman AU 400, Sekisui Reagent	U/L	766
Creatinine		
Beckman AU 400, Pointe Reagent	mg/dL	5.5
Gamma-Glutamyl Transferase (GGT)		
Beckman AU 400, Pointe Reagent	U/L	208
Glucose		
Beckman AU 400, Pointe Reagent	mg/dL	298
HDL Cholesterol		
Beckman AU 400, Sekisui Reagent	mg/dL	55
Iron		
Beckman AU 400, Sekisui Reagent	µg/dL	205
Total Cholesterol		
Beckman AU 400, Sekisui Reagent	mg/dL	262
Lactate		
Beckman AU 400, Pointe Reagent	mmol/L	2.64



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Analyte - Instrument	4672F001	
Lactate Dehydrogenase (LDH)		
Beckman AU 400, Pointe Reagent	U/L	465
Magnesium		
Mindray BS-200, Pointe Reagent	mg/dL	4.4
Sodium		
AVL, ISE	mmol/L	150
Phosphorus		
Beckman AU 400, Pointe Reagent	mg/dL	5.4
Potassium		
AVL, ISE	mmol/L	6.2
Total Protein		
Beckman AU 400, Pointe Reagent	g/dL	7.0
Triglyceride		
Beckman AU 400, Sekisui Reagent	mg/dL	259
Uric Acid		
Beckman AU 400, Pointe Reagent	mg/dL	10.0