



CONE URINE CHEMISTRY CONTROL, LIQUID – 2 LEVEL KIT

Product	Lot Number	Contents	Expiration Date
CONE Urine Chemistry Control, 2 Level Kit	4987E001	2 Levels x 12 Vials	1 year from DOM
CONE Urine Chemistry Control, Level 1	5680E001	12 Vials x 3 mL	1 year from DOM
CONE Urine Chemistry Control, Level 2	5681E001	12 Vials x 3 mL	1 year from DOM

INTENDED USE

CONE Urine Chemistry Control is intended for use as quality control urine 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 Urine Chemistry Control is prepared from human urine 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 Urine Chemistry Control, store unopened at 2-8°C until the expiration date. Store vials away from the light. Upon opening, the control is stable for up to 30 days when stored tightly capped at 2-8°C.

PROCEDURE

CONE Urine Chemistry Control 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 Urine 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 Urine 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 donors whose material was 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 urine 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.



CONE URINE CHEMISTRY CONTROL, LIQUID – 2 LEVEL KIT

For In Vitro Diagnostic Use Only
Assigned Values and Ranges Lot #4987E001 (Representative Values)
Containing Vial Lots L1 #5680E001 & L2 #5681E001

Analyte - Instrument		LEVEL 1 – 5680E001			LEVEL 2 – 5681E001		
Amylase	UNITS	MEAN	Expected Range		MEAN	Expected Range	
Beckman AU 400	U/L	157	103	191	292	197	367
Calcium							
Beckman AU 400	mg/dL	7.2	6.2	8.2	12.3	11.0	13.7
Chloride							
AVL, Smartlyte ISE	mmol/L	121	76	140	274	191	355
Creatinine							
Beckman AU 400	mg/dL	70.6	53	98	154	122	226
Glucose							
Beckman AU 400	mg/dL	27	20	36	286	193	358
Magnesium							
Beckman AU 400	mg/dL	4.0	2.8	5.2	8.5	6.0	11.2
Phosphorus							
Beckman AU 400	mg/dL	25	18	34	49	36	66
Potassium							
AVL, Smartlyte ISE	mmol/L	21.5	18	33	78	64	118
Protein, Total							
Beckman AU 400	mg/dL	34.6	23	43	112.8	67	125
Sodium							
AVL, Smartlyte ISE	mmol/L	76	62	118	166	133	247
Microalbumin							
Beckman AU 400	mg/dL	1.5	0.8	1.8	9.6	7	13
Urea Nitrogen							
Beckman AU 400	mg/dL	490	299	555	760	484	862
Uric Acid							
Beckman AU 400	mg/dL	6.1	4.3	7.9	14	10.2	19
Osmolality							
Calculation	mOsm/kg	370	294	440	779	640	960
pH							
Accumet AR20	N/A	3.4	2.9	3.8	10.7	9.2	12.2
hCG							
Qualitative Icon 20 hCG	-	Neg	Neg	Neg	Pos	Pos	Pos