Microalbumin Control Set

Intended Use
The Urine Microalbumin Controls are intended as a means of monitoring various microalbumin assay methods to validate quantitation of patient samples.

Control materials having known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method.

Product Description
These Urine Microalbumin Controls are supplied in two levels, 3 x 7 ml each level per box. They are ready to use, liquid, requiring no reconstitution or dilution. They are prepared from human urine, fortified to target levels with human albumin and creatinine. Preservatives including sodium azide have been added to inhibit microbial growth.

FOR *IN VITRO* DIAGNOSTIC USE ONLY.

Warnings and Precautions
POTENTIAL BIOHAZARDOUS MATERIAL.
All blood donor units comprising the source plasma used in the manufacture of the albumin have been tested and found non-reactive for Hepatitis B Surface Antigen and HIV antibody when tested by FDA accepted methods. No known test method can assure that a product derived from human blood does not contain Hepatitis or HIV virus. It is recommended that such samples be handled according to the Center for Disease Control's Bio-Safety Level 2 recommendations.

Dispose of Carefully. Sodium azide may accumulate in plumbing traps and pose a threat of explosion.

Storage and Stability
1. The controls should be stored at 2-8°C. When stored at 2-8°C, the controls are stable until the expiration date stated on the label.
2. When stored at 2-8°C between each use, the controls are stable for six months after opening.
3. When using the control with the Microalbumin Test Strips, the control will remain stable for six months after opening, until after 10 uses, or until the expiration date, whichever occurs first.
4. Discard the controls if turbid or if there is any evidence of microbial contamination. Discard controls in the same manner as other biological specimens, according to local guidelines.

Procedure
1. Remove the controls from the refrigerator and allow to come to room temperature (20-25°C), about 15-30 minutes.
2. Invert gently to assure homogeneity of the contents. Avoid foaming. Treat the control as you would a patient sample in accordance with the manufacturer's requirements of the test method.
3. Immediately recap the controls and return to 2-8°C when not in use.

Expected Values
The expected values have been established in the manufacturer's laboratory and from interlaboratory data using the listed manufacturer's reagents. Individual laboratory means should fall within the ranges listed. These values should be used as a guide in evaluating the performance of the test methods. Each laboratory should establish its own precision parameters for the methods used to measure each analyte.

Mean values and expected ranges apply to all models of the instrument listed unless otherwise noted.

Limitations
The expected mean and ranges were established using instrument manufacturer's reagents available at the time of the assay. Any future changes made by the manufacturer of a test method may give different values from those previously recovered. Use of methods other than the ones used to establish the expected values may give different values from the ones indicated. Limitations of the test method are included in the package insert for the reagent or instrument being used.

Depending on the instrument and the reagents used to measure creatinine, the mean creatinine values listed may decrease up to 10% over the entire shelf life of the control.

NOTE: When using Dimension and Vitros Slides for creatinine, dilute the level 2 control with an equal volume of diluent (1 part control to 1 part diluent). Run as usual and correct for the dilution.

REF M7562-CTL

LOT 515501

2017-12-31

2°C - 8°C

IVD

Manufactured for
Pointe Scientific, Inc.

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Analytes Instruments	Method	Unit	Level 1 Mean	Lot: 515501 Expected Range	Level 2 Mean	Lot: 515501 Expected Range
Microalbumin						
Abbott ARCHITECT	Turbidimetric Immunoassay	mg/L	9.8	7.8-11.7	66.1	52.8 – 79.3
Beckman Coulter® AU Instruments*	Turbidimetric Immunoassay	mg/L	9.1	7.3-10.9	61.9	49.5 – 74.3
Beckman Coulter® Synchron®*	Turbidimetric Immunoassay	mg/L	10.1	8.0 – 12.1	66.6	53.3 – 79.9
Roche Chemstrip Micral™*	Dipstick Immunoassay	mg/L	N/A	negative	N/A	20.0 – 100.0
Roche Cobas®6000 (cobas c 702)*	Turbidimetric Immunoassay	mg/L	11.3	9.1-13.6	69.3	55.4-83.2
Siemens BN™ II System*	Nephelometry	mg/L	10.7	8.6-12.9	68.1	54.5-81.7
Siemens Clinitek®	Clinitek Microalbumin Rgt Strips	mg/L	N/A	0.0 – ≤ 10	N/A	30.0 – 80.0
Siemens Dimension®*1	Turbidimetric Immunoassay	mg/L	9.8	7.8-11.7	67.6	54.1-81.1
Siemens Dimension Vista®	Turbidimetric Immunoassay	mg/L	12.3	9.2-15.4	75.4	60.3-90.5
Siemens DCA 2000/Vantage	Turbidimetric Immunoassay	mg/L	10.2	7.1-13.4	64.8	49.3-80.2
Pointe Scientific, Inc. **	Turbidimetric Immunoassay	mg/dL	1.0	0.7 – 1.3	6.1	4.3-7.9
Creatinine						
Abbott ARCHITECT	Turbidimetric Immunoassay	mg/dL	29.3	23.4-35.1	235.1	188.1-282.1
Beckman Coulter® AU Instruments*	Turbidimetric Immunoassay	mg/dL	33.7	27.0-40.4	240.8	192.6-288.9
Beckman Coulter® Synchron®*	Turbidimetric Immunoassay	mg/dL	31.7	25.4-38.0	240.2	192.2-288.3
Roche Cobas®6000 (cobas c 702)*	Turbidimetric Immunoassay	mg/dL	30.9	24.7-37.1	238.0	190.4-285.6
Siemens Clinitek	Clinitek Microalbumin Rgt Strips	mg/dL	N/A	10.0 – 50.0	N/A	200.0 – 300.0
Siemens Dimension®*1	Turbidimetric Immunoassay	mg/dL	30.4	21.3-39.5	231.2	185.0-277.4
Siemens Dimension Vista®	Turbidimetric Immunoassay	mg/dL	29.3	23.4-35.2	243.0	194.4-291.6
Siemens DCA 2000/Vantage*	Benedict/Behre	mg/dL	32.0	25.6-38.4	246.8	197.4-296.1

* Mean and range based on limited data.
** Mean and range calculated using data from Roche Hitachi, Roche Cobas Mira and Mindray BS200 analyzers.
1. Dimension RxL, ExL