

Intended Use

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

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 (18-25°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.

REF M7562-CTL

LOT 132801

2024-05-31



IVD



Manufactured for HORIBA Instruments Incorporated-Pointe Brand

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Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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Analytes			Level 1	Lot: 132801	Level 2	Lot: 132801
Instruments	Method	Unit	Mean	Expected Range	Mean	Expected Range
Microalbumin						
77 Elektronika (Visual / Analyzers)	Reagent Strip	mg/L	≤10.0	N/A	N/A	30 - 150
Analyticon (CombiScreen Strips Visual)	Reagent Strip	mg/L	10	N/A	N/A	30 - 150
Analyticon (Urilyzer® 100 Pro and CombiScreen Strips Visual)	Reagent Strip	mg/L	10	N/A	N/A	30 - 150
Abbott ARCHITECT	Turbidimetric Immunoassay	mg/L	9.1	7.1 – 11.2	69.6	55.7 – 83.5
Beckman Coulter® AU Instruments	Turbidimetric Immunoassay	mg/L	10.5	7.4 – 13.7	68.8	48.2 – 89.5
Roche Chemstrip Micral™	Dipstick Immunoassay	mg/L	N/A	0.0 - 20.0	N/A	50.0 - 100.0
Roche Hitachi/Modular®	Turbidimetric Immunoassay	mg/L	11.0	8.8 – 13.2	64.0	51.2 – 76.8
Roche Hitachi® (Sekisui Rgt)	Turbidimetric Immunoassay	mg/L	8.6	6.7 – 10.5	58.5	45.6 – 71.4
Siemens ADVIA® 1800	Turbidimetric Immunoassay	mg/L	---	Data Not Available	---	Data Not Available
Siemens CLINITEK	Clinitek Microalbumin Rgt Strips	mg/L	N/A	0.0 – ≤ 10.0	N/A	30.0 - 80.0
Siemens Dimension®	Turbidimetric Immunoassay	mg/L	10.1	7.0 – 13.1	70.1	56.1 – 84.1
Siemens DCA 2000/Vantage	Turbidimetric Immunoassay	mg/L	12.4	9.9 – 14.9	76.1	60.9 – 91.3
Pointe Scientific *	Turbidimetric Immunoassay	mg/dL	1.0	0.7 - 1.3	6.0	4.2 - 7.8
Creatinine						
77 Elektronika (Visual / Analyzers)	Reagent Strip	mg/dL	N/A	10.0 – 100.0	N/A	100.0 – 300.0
Analyticon (CombiScreen Strips Visual)	Reagent Strip	mg/dL	N/A	10.0 – 50.0	N/A	100.0 – 200.0
Analyticon (Urilyzer® 100 Pro and CombiScreen Strips Visual)	Reagent Strip	mg/dL	N/A	10.0 – 50.0	N/A	50.0 – 200.0
Abbott ARCHITECT	Turbidimetric Immunoassay	mg/dL	31.9	25.6 – 38.3	239.2	191.4 – 287.1
Beckman Coulter® AU Instruments	Turbidimetric Immunoassay	mg/dL	32.0	22.4 – 41.6	203.0	142.1 – 263.9
Roche Hitachi/Modular®	Turbidimetric Immunoassay	mg/dL	34.2	27.3 – 41.0	236.5	189.2 – 283.8
Roche Hitachi® (Sekisui Rgt.)	Picrate	mg/dL	33.5	26.8 – 40.2	230.9	184.7 – 277.1
Roche Hitachi® (Sekisui Rgt.)	Enzymatic	mg/dL	36.7	29.3 – 44.0	253.3	202.6 – 303.9
Siemens CLINITEK	Clinitek Microalbumin Rgt Strips	mg/dL	N/A	10.0 - 50.0	N/A	200.0 - 300.0
Siemens Dimension®	Turbidimetric Immunoassay	mg/dL	30.4	24.3 – 36.5	241.7	193.3 – 290.0
Siemens DCA 2000/Vantage	Benedict/Behre	mg/dL	38.9	31.2 – 46.7	261.9	209.5 – 314.3

* Mean and range calculated using data from Roche Hitachi, Cobas and Mindray BS200 analyzers.

Symbol Key

Use by (YYYY-MM-DD)	LOT Lot and batch code
REF Catalog number	Manufacturer
IVD In vitro diagnostic medical device	Temperature limitation
Consult instructions for use	Rx Only: Prescription Use Only
CE CE mark	EC REP Authorized representative in the European Community