Microalbumin

En

REF 08V6025

Alinity c

Diagnostic reagent for the determination of Microalbumin concentration.
Liquid. Dual reagent (Ratio: R1/R2: 4/1). Store at +2/+8°C. For In Vitro Diagnostic use. **Do not freeze.**
The products with 08V6025 reference numbers provided are compatible for use with Abbott Alinity biochemistry autoanalyzer series.

Changes made in the instructions for use are marked as gray.

The instructions must be followed carefully. The reliability of the test results cannot be guaranteed unless these instructions are followed.

NAME
Microalbumin

INTENDED USE
The Microalbumin assay is used for the quantitative determination of Microalbumin concentration in human urine on Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST
Microalbuminuria indicates slightly elevated urinary albumin excretion. In most cases, microalbuminuria is of glomerular origin and indicates initial glomerulosclerosis. Microalbuminuria has a high predictive value for nephropathy in insulin-dependent diabetes subjects and for premature mortality due to cardiovascular disease in non-insulin-dependent diabetes subjects and in the general population. All cardiovascular risk factors can be determinants for microalbuminuria constitution, especially the genetic determinants of these risk factors. Thus, microalbuminuria can be an indicator to summarize renal or cardiovascular risk, or both, in various populations.[1]

Early detection of glomerular damage, while it is minimal and reversible, is extremely important. For both Type I and Type II diabetes mellitus, monitoring urinary microalbumin is an important component of treatment.[2]

PRINCIPLES OF THE PROCEDURE
The test has turbidimetric measurement method. Albumin in the urine sample causes agglutination of the latex particles coated with anti-human albumin. The agglutination of the particles is proportional to the albumin concentration and can be measured turbidimetrically.

REAGENTS

Kit Contents

R1 Borate buffer (≤ 0.12 mol/L). Sodium azide (≤ 0,1%).
R2 Latex particles coated with anti-human albumin antibodies. Sodium azide (≤ 0,1%).

Warnings and Precautions
IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger
EUH032 : Releases a very toxic gas if contacts with acid.
H317 : May cause allergic skin reaction.

Precaution
P280 :Use protective gloves / clothes / glasses / mask.
P264 :Wash your hands properly after using.
P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.
Intervention
P302+P352 :Wash with plenty of water and soap if it contacts with skin.
P333+P313 :Seek medical help if it irritates your skin or develops rash.
P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal
P501 :Dispose the vials and contents according to the local regulations.

Reagent Handling
- Reagent cartridges should be kept in an upright position for at least 1 hours after receipt and before use to eliminate any air bubbles that may have formed inside.
- If the cartridge is dropped, it should be kept upright for 8 hours before use to allow the air bubbles to dissipate.
- Foam and air bubbles may form in the reagents; this may prevent accurate detection of the reagent level inside the cartridge, leading to insufficient reagent aspiration and potentially affecting the analysis results.

Reagent Storage [3]

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	+2/+8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	

Reagents should not be frozen.

Indications of Reagent Deterioration
When a calibration error occurs or the control value falls outside the accepted range, the reagents may be considered to have deteriorated. In this case, the test results are not valid and the samples should be reanalyzed. Recalibration may be required.

Alternative Result Units
Use the unit conversion table provided below for alternative result units.

Default Unit	Conversion Factor	Result Unit
µg/mL	1	mg/L

SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

Sample Types
The recommended sample types for this test are listed below.

Sample Type	Collection Tube
Urine	Urinal containers

Follow the instructions provided with your sample collection tubes for use and handling.

Sample Conditions
- Fresh samples should be used. After collection, the samples should be analyzed as promptly as possible.
- To reduce the risk of contamination between samples, a new pipette or pipette tip should be used for each procedure.
- To calculate the microalbumin-to-creatinine ratio in a spot urine sample, a urine creatinine measurement must first be performed.
- Non-hemolytic samples should be used. Hemolyzed samples may cause interference.
- The preservatives accepted for this analysis are 6N hydrochloric acid, acetic acid, chloroform, formalin, toluene, and xylene.

Sample Storage [4]

Temperature	Maximum Storage Time
+2/+8°C	14 days
-20°C	5 months

The information provided applies to urine samples. Repeated freeze–thaw

cycles of samples should be avoided.

PROCEDURE

Materials Provided
Microalbumin Reagent Kit
Materials Required but Not Provided

- Microalbumin Calibrator
- Microalbumin Control Set or commercially available controls
- Saline solution (0.85%–0.90% NaCl) for sample dilution

Assay Procedure

- If primary or aliquot tubes are used, ensure that a sufficient amount of sample is available.
- To prevent evaporation of the specimen, make sure that the tube volume is adequate before each test.
- Minimum Sample Volume Requirements:
  - Sample volume for a single test: 6 µL
  - This volume does not include dead space or the additional aspiration volume.

Sample Dilution Procedures

This method shows measurement linearity up to 300 mg/L. For samples with results above this value, the automatic dilution procedure of the autoanalyzer should be applied or manual dilution may be performed.

Automatic Dilution Protocol

The system dilutes the sample at a 1:10 ratio and automatically calculates the concentration by multiplying the result by the dilution factor.

Manual Dilution Procedures

Dilute the sample with a 0.85%–0.90% NaCl solution. Enter the dilution factor on the relevant screen of the device. If the user does not enter the dilution factor, the result must be manually multiplied by the correct factor before it is reported. If the result of the diluted sample is below 2 mg/L, which is the lower limit of the measurement range, the result is not reported, and the procedure is repeated with an appropriate dilution.

Calibration

The use of a Microalbumin Calibrator is required for this test.

Microalbumin Calibrator
Ref.No: A301M

Calibration stability is 30 days. Changes in the reagent lot number require recalibration. Calibration is necessary if quality control results are not within acceptable limits.

Quality Control Procedures

Commercially available control materials with values assigned by this method may be used. Recommended:

Microalbumin Control Level I
Ref.No: A302M

Microalbumin Control Level II
Ref.No: A303M

At least two levels of control should be run every 24 hours. Each laboratory should establish its own quality control procedures. If more stringent control monitoring is required, refer to the quality control procedures established for your laboratory.

LIMITATIONS OF THE PROCEDURE

- Since the microalbumin test uses polyclonal antibodies against human albumin, it may exhibit cross-reactivity with similar proteins; therefore, controls containing non-human proteins should not be used, and only microalbumin controls containing human albumin should be preferred.

EXPECTED VALUES

Each laboratory should investigate the transferability of expected values for its own patient population and, if necessary, establish its own reference range.

Reference Range [7]

	Spot collection[a] Microalbumin:Creatinine (µg/mg) or (mg/g)	24 hour collection[b] (mg/24 hr)	Timed collection[c] (µg/min)
Normal	< 30	< 30	< 20
Microalbuminuria	30-299	30-299	20-199
Macroalbuminuria	≥ 300	≥ 300	≥ 200

a. Spot collection = (microalbumin (µg/mL) ÷ creatinine urine (mg/dL)) × $\frac{100\ mL}{dL}$ or
Spot collection = microalbumin (mg/L) ÷ creatinine urin e (mmol/L)

b. 24 hour collection = (microalbumin (µg/mL) × Volume mL) ÷ $\frac{1000\ \mu g}{mg}$

c. Timed collection = (microalbumin (µg/mL) × Volume mL) ÷ Time (min)

According to the American Diabetes Association (ADA), microalbumin levels can be measured from 24-hour, timed, or spot urine samples. Normal albumin levels, as well as microalbuminuria and macroalbuminuria levels, are listed above for each type of sample.[5,6]

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

Sample	n	Mean (mg/L)	Within-Run (Repeatability)[14,15] SD	Within-Run (Repeatability)[14,15] %CV	Within-Laboratory (Total)*[14,15] SD	Within-Laboratory (Total)*[14,15] %CV
Level 1	80	24	0.6	2.5	1.2	5.0
Level 2	80	97	2.4	2.5	3.3	3.4

*: Includes within-run, between-run, and between-day variability.

Lower Measurement Limits

The lower measurement limits refer to the range between the lower limit of quantitation (LLoQ) and the upper limit of quantitation (ULoQ), within which the analyte concentration can be measured with the required medical and laboratory accuracy without dilution, concentration, or any pre-treatment.[8] The LoD and LoQ values have been verified using the CLSI EP17-A2:2012 protocol.[9]

	mg/L
LoD**	1.3
LoQ***	2.0

**: The LoD represents the lowest concentration at which the analyte can be detected with 95% probability, based on ≥ 60 replicates of samples with low analyte levels.

***: When determining the LoQ value, a coefficient of variation (%CV) of ≤20% is used as the basis.

Measuring Interval

This method shows measurement linearity up to 2- 300 mg L. For samples with results above this value, the automatic dilution procedure should be applied. For additional information, please refer to the instrument's user manual. Linearity studies data have been verified by using CLSI EP06-A:2003 protocol.[10]

Interference

Endogenous interferant and analyte concentrations that have been used in the Microalbumin scanning tests has been determined according to "CLSI EP37-ED1:2018" and "CLSI EP07-ED3:2018" manuals.[11,12]

The total acceptable error rate, which is going to be used to detect whether the observed differential value obtained from Microlbumin interference scanning test is appropriate, is determined as ±10%.[13]

In Microalbumin test results, no significant interaction has been observed in the determined endogenous interferant and analyte concentrations or between interferants and analyte.

Interferant-Concentration	Microalbumin Target (mg/L)	N	Observed Recovery %
Bilirubin Total 20 mg/dL	33.5	3	92

It should be noted that, in addition to endogenous interferents, various drugs and metabolites; anticoagulants (e.g., heparin, EDTA, citrate, oxalate) and preservatives (e.g., sodium fluoride, iodoacetate, hydrochloric acid); substances that may come into contact with samples during collection and handling (such as serum separation devices, sample collection containers and their contents, catheters, catheter flushing solutions, skin disinfectants, hand sanitizers and lotions, glassware detergents, powdered gloves, etc.); dietary substances known to affect certain tests (e.g., caffeine, beta-carotene, poppy seeds); or certain

substances present in a sample that may cause interference due to foreign proteins (e.g., heterophilic antibodies), autoimmune responses (e.g., autoantibodies), or malignancy (e.g., paraproteins causing interference in phosphate tests and indirect ion-selective electrode methods) may lead to various interferences and erroneous evaluations for many different reasons.[12]

These performance characteristics were obtained using an autoanalyzer. Results may vary when different equipment or manual procedures are used.

Method Comparison

As a result of the statistical evaluation of method comparison data, the table was constructed according to the Passing–Bablok regression method as follows:

Archem Microalbumin – Roche Cobas Integra 400 Plus

	Units	n	Correlation Coefficient	Intercept	Slpoe	Concentration Range
Urine	mg/L	100	0.9993	0.2448	1.0058	4,3-298,4

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests

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