Bioway Chemistry Reagent Series

Alpha1-Microglobulin Reagent Kit

Detection of Alpha1-Microglobulin in Human Serum on Chemistry Analyzers

Cat. No. R056K11 ***Alpha1-Microglobulin Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

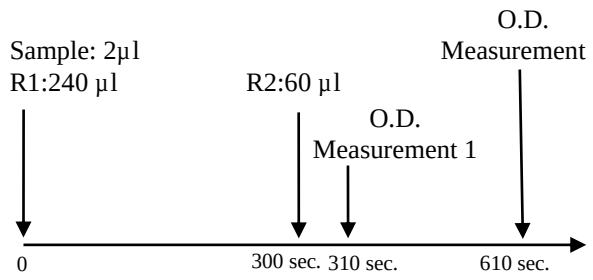

Table 1: Instrument Parameters*

Calibration method	6 point non-linear	Slope of reaction	increase
Wavelength	600nm	Sample volume	2 µl
Test method	2 point end	R1 volume	240 µl
Reaction temperature	37℃	R2 volume	60 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Alpha1-Microglobulin Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of Alpha1-Microglobulin in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Alpha1-Microglobulin (A1-MG), also known as Protein HC, is a tubular plasma and issue protein that is mainly synthesized in the liver. The main function of A1-MG is to remove heme from the issues and transport to the kidney to be broken down. Due to increased excretion shortly after tubular injury, detection of A1-MG can provide information for clinical diagnoses of tubular injury, primary glomerulonephritis, interstitial nephritis and diabetic nephropathy. Reduced level of A1-MG can also be found in patients with severe hepatic impairment.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the A1-MG level in human serum. During the test, A1-MG in the sample binds with the antibody that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer at wavelength of 600 nm. The change in absorbance is proportional to the level of A1-MG in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Tris buffer, NaCl, PEG
R2	latex particles coated with A1-MG antibody

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. A1-MG calibrator set (available for purchase) and control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable for 12 month when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening. Do not freeze the reagents.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Reagents contain preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum samples.
It is recommended to perform test immediately after sample collection to avoid hemolysis. If the test cannot be done immediately, store sample at 2- 8° C for 1 day or at -80° C for up to 1 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 6 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 2 µl of sample and 240 µl of R1; mix well and incubate at 37°C for 300 seconds.
2. Add 60 µl of R2, mix well and incubate at 37°C for 10 seconds.
3. Take optical density measurement OD 1.
4. Take optical density measurement OD 2 at 610 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The A1-MG value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

10 ～30 ng/mL

It is recommended for each laboratory to establish its own expected values.

QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Dilute sample with saline if measured value exceeds the linearity range. Calculate value by dilution factor.
3. Hemolysis samples may cause inconsistent results.
4. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 90 mg/L (R^2≥0.990)

Accuracy: relative deviation ≤ 10%

Precision: Within Run: CV≤6%;

Run-to-Run: CV≤15%

Reagent Blank Absorbance: at 600nm wavelength and 10 mm optical diameter, O.D. ≤ 1.70.

Sensitivity: when measuring sample with 27.5 mg/L A1-MG, ΔOD should be between 0.02 and 0.25.

REFERENCES

1. Berggard B,Ekstrom B and Akeratrom B.α1-micro globulin. Scard .J.Clin Lab. Invest. 1980: 40; Suppl.154.

Not Intended for Sale in the United States.

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