

Bioway Chemistry Reagent Series

Beta 2-Microglobulin Test Kit

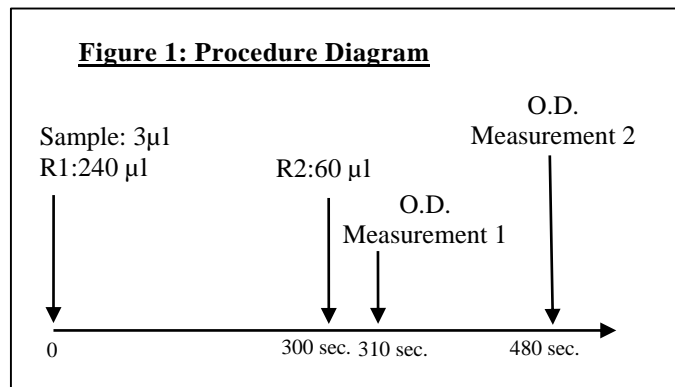
Detection of Beta 2-Microglobulin in Human Serum or urine on Chemistry Analyzers



Cat. No. R057K11

Beta 2-Microglobulin Test Kit

SUMMARY OF TEST PROCEDURE



*Refer to Figure 1 and the package insert for detail

Table 1: Instrument Parameters*

| | | | |
|----------------------|------------------------|-------------------|----------|
| Calibration method | 6 point non-linear | Slope of reaction | increase |
| Wavelength | Pr: 546nm Se: 700nm | Sample volume | 3 µl |
| Test method | 2 point end | R1 volume | 240 µl |
| Reaction temperature | 37°C | R2 volume | 60 µl |

INTENDED USE

Bioway Chemistry Reagent Series Beta 2-Microglobulin Reagent Kit (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of Beta 2-Microglobulin in human serum or urine on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Beta 2-microglobulin (B2M) is a component of MHC class 1 molecules that is filtered out of the body by the kidney's glomeruli and almost completely reabsorbed by proximal tubules. Measuring the B2M levels can be useful in the diagnosis of renal function. Increased B2M levels are found in systemic lupus erythematosus, rheumatoid arthritis, and Sjogren's syndrome. Decreased levels of B2M are seen in tubular kidney disease. B2M levels can also be used to monitor kidney transplant recovery, as B2M levels increase in renal allograft rejections.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the B2M level in human serum or urine. During the test, B2M in the sample binds with the anti-B2M that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of B2M in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

| | |
|-----------|---|
| R1 | Buffer solution, sodium azide < 0.1% |
| R2 | latex particles coated with anti-B2M, sodium azide < 0.1% |

MATERIALS NEEDED BUT NOT PROVIDED

- Automated chemistry analyzer.
- B2M 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 through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening.

PRECAUTIONS

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
- Reagents contain less than 0.1% sodium azide as 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 or urine samples.

For urine samples, centrifuge and stabilize the B2M in the sample by adjusting the pH to 7 – 8 with K₂HPO₄.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, serum sample can be stored at 2- 8° C for up to 7 days, and urine sample can be stored at 2- 8° C for 2 days when stabilized to pH 7-8.

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.

- Add 3 µl of sample and 240 µl of R1; mix well and incubate at 37°C for 300 seconds.
- Add 60 µl of R2, mix well and incubate at 37°C for 10 seconds.
- Take optical density measurement OD 1.
- Take optical density measurement OD 2 at 480 seconds.
- Calculate $\Delta OD = OD 2 - OD 1$

RESULT

The B2M value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

Serum sample: 1.01 – 2.97 mg/L

Urine sample: 0.10 – 0.30 mg/L

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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. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0.2 – 18 mg/L ($R \geq 0.990$)

Precision: Within Run: $CV \leq 6\%$;
Run-to-Run: $CV \leq 10\%$

Interference: no interference detected for: Bilirubin (60 mg/dL), triglyceride (1000 mg/dL), and hemoglobin (1000 mg/dL).

Reagent Blank Absorbance: at 546 nm wavelength and 10 mm optical diameter, O.D. ≤ 1.30 .

REFERENCES

1. Evrin P-E, Wibell L. The serum levels and urinary excretion of B-2-microglobulin in apparently healthy subjects. *Scand J Clin Lab Invest* 1972; 29: 69-74.
2. Güssow D, Rein R, Ginjaar I, Hochstenbach F, Seemann G, Kottman A, Ploegh HL (1 November 1987). "The human beta 2-microglobulin gene. Primary structure and definition of the transcriptional unit". *J. Immunol.* 139 (9): 3132–8.
3. Revillard JP, Vincent C. Structure and metabolism of beta-2-microglobulin (review). *Contrib Nephrol* 1988; 62: 44-53.
4. Schweizer RT, Moore R, Bartus SA, Bow L, Hayden J. Beta-2-microglobulin monitoring after renal transplantation. *Transplant Proc* 1981; 13: 1620-3.

Not Intended for Sale in the United States.

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