

Bioway Chemistry Reagent Series

Immunoglobulin M Test Kit

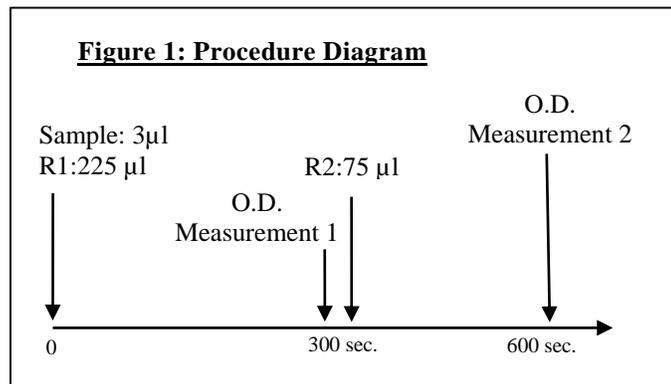
Detection of Immunoglobulin M in Human Serum on Chemistry Analyzers



Cat. No. R038k11

IgM 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	340 nm	Sample volume	3 µl
Test method	2 point end	R1 volume	225 µl
Reaction temperature	37°C	R2 volume	75 µl

INTENDED USE

Bioway Chemistry Reagent Series IgM Reagent Kit (the Kit) is an immunoturbidimetric assay intended for *in vitro* quantitative detection of immunoglobulin M in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Immunoglobulin M is the first immunoglobulin to appear in response to antigenic challenge and makes up about 5 to 10% of the total circulating immunoglobulins. IgM is particularly effective in combating bacterial infections because of its high binding affinity for proteins responsible for destroying bacterial cells. IgM levels increase due to viral infections, rheumatoid arthritis, chronic hepatocellular disease, active sarcoidosis, Waldenstrom's macroglobulinemia, and malignant lymphoma. Decreased levels of IgM are associated with recurrent, chronic, or severe infections, multiple myeloma, and protein-losing enteropathy.

TEST PRINCIPLES

The Kit utilizes immunoturbidimetry to measure the IgM level in human serum. During the test, IgM in the sample binds with the specific anti-IgM antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of IgM in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Phosphate buffer, Polyethylene glycol, Sodium azide < 0.1%
R2	anti-IgG antibodies, Tris buffer, sodium azide < 0.1%

MATERIALS NEEDED BUT NOT PROVIDED

- Automated chemistry analyzer.
- IgM 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 samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 4°C for up to 3 days or at -20°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.

- Add 3 µl of sample and 225 µl of R1; mix well and incubate at 37°C for 300 seconds.
- Take optical density measurement OD 1 just before addition of R2.
- Add 75 µl of R2, mix well and incubate at 37°C.
- Take optical density measurement OD 2 at 600 seconds.
- Calculate $\Delta OD = OD 2 - OD 1$

RESULT

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

EXPECTED VALUES

40 - 230 mg/dL.

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

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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 – 500 mg/dL ($R \geq 0.995$)

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

Interference: no interference detected for: Bilirubin (60 mg/dL), and hemoglobin (500 mg/dL).

Reagent Blank Absorbance: at 340 nm wavelength and 10 mm optical diameter, O.D. ≤ 0.30

REFERENCES

1. Consensus of a Group of Professional Societies and Diagnostic Companies on Guidelines for Interim Reference Ranges for 14 Proteins in Serum Based on the Standardization against the IFCC/BDR/CAP Reference Material (CRM 470). *Eur J Clin Chem Biochem* 1996;34:517-520.
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3. Ritchie, RF (ed). *Serum Proteins in Clinical Medicine*, Volume 1, Laboratory Section. Scarborough, ME: Foundation for Blood Research; 11.01-7; 1996.
4. Tietz NW, Pruden E, McPherson RA, Fuhrman, SA (eds). *Clinical Guide to Laboratory Tests*. 3rd ed. Philadelphia, PA: WB Saunders Co; 361-363; 1995.

Not Intended for Sale in the United States.

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