IMMUNOGLOBULIN-M (IgM)

(Turbidimetry Method)

Intended Use

IgM is a reagent kit used for the quantitative determination of IgM level in human serum or plasma. The reagents are for *in-vitro* diagnostic use.

Principle

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.

Reagent provided

1. R1 – IgM Buffer
2. R2 – IgM Antibody
3. R3 – IgM Calibrator

Reagent storage and stability

The reagent and standard are stable till the expiry date stated on the container label.

Specimen collection and preservation

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 upto 3 days or at -20°C for up to 1 month. Avoid repeated freezing and thawing.

Plotting of Multipoint Curve

The IgM is based on Non-Linear Reactions, hence it is strongly recommended to rub Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial Dilution Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dilution	Neat	1/2	1/4	1/8	1/16

Assay guidelines for Analyzers

Reaction type	End point
Reaction slope	Increasing
Incubation time	5 mins + 5 mins at 37°C
Wavelength	340 nm
Blank with	Reagent Blank
Sample volume	10 µl (0.01 ml)
Reagent volume	1000 µl (1.0 ml)
Standard Concentration	Refer Calibrator Vial
Factor	-
Low Normal	40mg/dl
High Normal	230mg/dl
Linearity	Up to 500 mg/dl

Assay guidelines for Manual procedure

Reagents	Blank (B)	Calibrator (C)	Test (T)
R1 IgM Buffer	750 µl	750 µl	750 µl

Calibrator		10 µl	-
Sample	-		10 µl
Mix well and incubate for 5 mins at 37°C			
R2 IgM Antibody	250 µl	250 µl	250 µl

Mix well& incubate for 5 min at 37°C. Measure the absorbance of calibrator & sample against reagent Blank (B).

Calculation

$$\text{IgM. Con.} = \frac{\text{Abs. Test}}{\text{Abs. Cal.}} \times \text{Calibrator Con.}$$

Normal Range

40-230 mg/dl

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

- The Kit is for in vitra 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.

Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware and accuracy of pipetting.

References

1. S Fagarasan and T Honjo (2003). "Intestinal IgM Synthesis Regulation of Front-line Body Defenses". Nat. Rev. Immunology 3(1):52-72
2. Burtis C, Ashwood, ER (ed). Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, P; WB Saunders Co; 509; 1999
3. Junqueria, Luiz C.; Jose Carneiro (2003). Basic Histology. McGraw-Hill
4. Tietz NW, Pruden E, McPherson RA, Fuhrman. SA (Eds). Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA;WB Saunders Co; 355-357; 1995.

Symbols

IVD In Vitro Diagnostics. Caution. Keep away from sun light. Date of Manufacture.

LOT Batch No. Read Instructions. Fragile. Product Expiry Date.

CONT Content. Storage Temperature. Keep Dry. Manufactured By.

REF Catalogue No.

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