TURBICHEM IMMUNOGLOBULIN-M

IgM (Turbidimetry method)

KIT NAME	KIT SIZE	CAT. NO
Turbichem - IgM	1 x 40 ml	TIGM00040D

GENUINE BIOSYSTEM

INTRODUCTION

Immunoglobulin M (IgM) is intended for Invitro quantitative determination of IgM in human serum. 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 particular effective in combating bacterial infectionsbecause 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.

METHOD PRINCIPLE

The Kit utilizes latex-enhanced immunoturbidimetry to measure the IgM level in human serum or plasma. 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.

KIT CONTENTS

R1 - IgM Buffer	1 x 30 ml
R2 - IgM Antibody	1 x 10 ml
R3 - IgM Calibrator	1 vial

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 7-10 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-IgM and R2-IgM reagents of 3 parts of R1-IgM with 1 part of R2-IgM. Avoid foaming.

CONCENTRATIONS IN THE TEST

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

Warnings and notes

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

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 340 nm
- Thermostat at 37ºC
- General laboratory equipment

SPECIMEN

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

PLOTTING OF MULTIPOINT CURVE

The Turbichem IgM is based on Non-Linear Reactions, hence it is strongly recommended to run 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 Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE

These reagents may be used both for manual assay and in several automatic analyzers. Applications for them are available on request.

Wavelength	340 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)
R1 IgM Buffer	750 µl	750 µl
Caibrator	10 µl	-
Sample	-	10 µl
Mix well and incubate for 5 mins at 37° C		
R2 IgMAntibody	250 µl	250 µl

Mix well & incubate for 5 min. at 37°C. Measure the absorbance of calibrator & sample.

CALCULATION

$$\text{IgM concentration} = \frac{\text{Abs.Test}}{\text{Abs.Calibrator}} \times \text{Calibrator Concentration}$$

REFERENCE VALUES

40 to 230 mg/dL

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

PERFORMANCE CHARACTERISTICS

- **Linearity:** 0 to 500 mg/dL
- **Precision:** within Run CV ≤ 6 %
- **Specificity / Interferences**
  No interference detected for bilirubin upto 60 mg/dL and hemoglobin 500 mg/dL

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Consensus of a Group of Professional Societies and Diagnostic Companies on Guidelines for Interim Reference Rangesfor 14 Proteins in Serum Based on the Standardization against the IFCC/BDR/CAP Reference Material (CRM 470). EurJ Clin Chem Biochem 1996:34;517-520.
2. Houghton Mifflin Company, 2004. "Immunoglobulin M." The american Heritage Dictionary of the English Language, Fourth Edition. Accessed on 12 Oct. 2007.
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

SYSTEM PARAMETERS

Method	End Point
Wavelength	340 nm
Zero Setting	Reagent Blank
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	5 mins + 5 mins
Delay Time	----
Read Time	----
No. of Reading	2
Interval Time	----
Sample Volume	0.01 ml (10 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	Refer Calibrator vial
Units	mg/dl
Factor	----
Reaction Slope	Increasing
Linearity	500 mg/dl

IVD CE

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