Immunoglobulin M Assay Kit (IgM)

Method: immunoturbidimetric

Cat . No.	Size	Instrument
GB660M	R1: 2×50 ml R2: 2×10 ml	For Hitachi 7060/7150 &ShimadzuCL7200/8000
GS661M	R1: 2×50 ml R2: 2×10 ml	For Hitachi 7170/7080 &OlympusAU640/400/600

INTENDED USE
The immunoglobulin M assay kit is used for the quantitative determination of IgM in serum .

CLINICAL SIGNIFICANCE
IgM is the most primitive and least specialised immunoglobulin. In adult serum it is the third must abundant immunoglobulin accounting for 5 to 10% of the circulating immunoglobulins. IgM is the first specific antibody to appear in serum after infection and it is capable of activating compliment thus helping to kill bacteria. Increased polyclonal IgM levels are found in viral, bacterial and parasitic infections, liver disease, rheumatoid arthritis and cystic fibrosis. Monoclonal IgM is increased in Waldenstroms Macroglobulinemia. Decreased levels of IgM are found in protein losing enteropathies and in burns.

ASSAY PRINCIPLE
This assay is based on the reaction between IgM antigen and anti-IgM antibody. This reaction forms an insoluble complex producing a turbidity, which is measured spectrophotometrically. The amount of complex formed is directly proportional to the amount of IgM in the sample.

IgM Antigen + Anti-IgM Antibodies ⟶ Antigen/Antibody complex

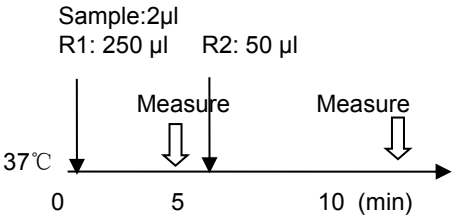
REAGENT COMPOSITION

Contents	Concentration of solutions
Reagent 1 (R1)	
TRIS Buffer pH 7.6 with PEG	18.16 mmol/l
Sodium Chloride	123.20 mmol/l
Preservative & Detergent	---
Reagent 2 (R2)	
TRIS Buffer pH 7.6	18.16 mmol/l
Anti IgM antibody	---
Preservative	---

SAMPLE COLLECTION AND PREPARATION
Use fresh patient serum samples, serum should be separated from cells within 2 hours after collection.
Stability: up to 3 months at 2-8℃.

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
Once opened avoiding contamination.

ASSAY PROCEDURE
Test Procedure for Analyzers (Hitachi 7080)
Assay Mode: 2 POINT END 16-31
Wave Length (sub / main): None /340nm



CALIBRATION
Recommend that this assay should be calibrated using special protein calibrator GC-IgM.

CALCULATION OF RESULTS
The analyser automatically calculates the IgM concentration in the sample according to the calibration curve.

QUALITY CONTROL
Randox liquid assayed special protein controls, Level 1 Level 2 and Level 3 are recommended for daily quality control. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE
Serum or plasma: 10 to230 mg/dl(0.4 to 2.3 g/l)
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS
LINEARITY
The method is linear between IgM concentrations of 15-350 mg/dl (0.15-3.5 g/l). If the concentration in sample is above this concentration,please dilute it with 0.9% NaCl and repeat assay.

PRECISION
The CV of the test should be CV ≤5%

Intar assay precision			
N=20	level 1	level 2	level 3
Mean(mg/dl)	84.45	166.25	245.50
SD	1.41	1.55	2.22
CV(%)	1.67	0.93	0.91

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/dl)	83.1	80.4	80.3
$\bar{x}$	81.3		
(Xmax-Xmin)/$\bar{x}$	(83.1-80.3)/81.3*100=2.59%		

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CE version 2014

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin	up to 1000 mg/dl
Direct bilirubin	up to 70 mg/dl
Intralipid	up to 1000 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Becker, W.: Laboratoriumblatter 1980; 30: 25.
2. Geiger, H. & Hoffman, P.: Z. Kinderheilk 1970; 109: 22.
3. Whicher, J.J., Price, C.P., Spencer, K., Critical 01/11/96 Reviews in Clinical Laboratory Sciences, 1983; 18: 213-216.

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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