Immunoglobulin M (IgM) Diagnostic Reagent Kit (Immunoturbidimetry Method)
Product Instruction

Product name
Generic Name: Immunoglobulin M (IgM) Diagnostic Reagent Kit (Immunoturbidimetry Method)
Abbreviation: IgM

Package Specifications

R1	R2
40ml×1	10ml×1
800ml×1	200ml×1
8000ml×1	2000ml×1

Calibrator (lyophilized):
Specification 1 (1.0mL×4; 4 levels);
Quality Control (lyophilized):
Specification 1 (1.0mL×1; 1 level).

Intended use
Immunoglobulin M (IgM) diagnostic reagent is used for the quantitative in vitro determination of IgM in human serum on photometric systems.

Clinical significance
IgM is the earliest antibody synthesized and secreted during individual development. Fetus at the late stage of embryonic development can produce IgM. IgM is also the earliest antibody that appears in the primary humoral immune response, and it first appears during infection. The detection of IgM in serum indicates recent infection and can be used for early diagnosis of infection.

Principle
When Immunoglobulin M in human serum and its corresponding antibody (goat anti-human immunoglobulin M antibody) meet in the liquid phase, an antigen-antibody complex immediately forms and a certain turbidity also forms. Compared with the calibrators treated in the same way, the content of immunoglobulin M in the sample can be calculated.

Main ingredient

Composition	Main ingredients
R1	Phosphate buffer 20mmol/L
	Lipid elimination agent 5g/L
	Sodium chloride 9g/L
R2	Goat anti-human IgM specific antiserum 33%
Calibrator	Tris 50mM
	Trehalose 5%
	BSA 5%
	human immunoglobulin M
Quality Control	Tris 50mM
	Trehalose 5%
	BSA 5%
	human immunoglobulin M

Storage and stability
This kit stays stable for 18 months when stored in a dark condition at 2-8℃(do not freeze). After being opened for the first time, the kit can be stored at 2-8℃ in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Fresh serum;
-20℃, stable for 7 days.

Assay procedure
1. Reagent preparation
This reagent is liquid and can be used directly.

Main wavelength	340nm	Sample(S)	3 μl
Subwavelength	700nm	Reagent 1	240 μl
Reation temperature	37℃	Reagent 2	60 μl
Cuvette light path	1cm	Reaction type	Two Point End

2. Operation steps

Add to the cuvette:	
Sample (S)	3 μl
R1	240 μl
Mix well, incubate at 37℃ for 5 minutes, 340nm, set zero with a blank tube, and measure the absorbance A1, then add	
R2	60 μl
Mix well, incubate at 37℃for 5 minutes, 340nm, set zero with a blank tube, and measure the absorbance A2, absorbance A2 △A= A2- A1	

Calculations
Calculate and plot ΔA = (A2 – A1) of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and read values in mg/dl on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

Reference interval
0.50 g/L-2.20g/L
It is recommended that each laboratory should establish its own reference interval.

Quality control
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics
1. Measuring range
0.1g/L-4g/L
Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.
2. Sensitivity
When a control serum (1.5g/L) is used as a sample, the range of absorbance change should not be smaller than 0.1400.

Interference
When Hemoglobin≤5g/L, ascorbic acid (vitamin C)≤1000mg/L, triglyceride≤10 mmol/L, heparin lithium≤200U/mL, heparin sodium≤200U/mL, rheumatoid factor≤800IU/mL, no effects on the experimental results are to be found. In order not to affect the test results, please pay special attention to the operation.

Automation
Special adaptations for automatic analyzers can be made on request.

Precautions and warnings
General precautions
For in vitro diagnostic use only.
Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement
Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
Reagents with different lot numbers should not be

interchanged or mixed.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
Material safety data sheet available for professional user on request.

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