INSTRUCTION OF IMMUNOGLOBULIN M

ASSAY KIT BY Immunoturbidimetry METHOD

Szybio
LIFE ORIGIN BIOTECH

[Product Name]

Immunoglobulin M (IgM) Assay Kit by Immunoturbidimetry Method

[Packing Specifications]

Basing on the bottle type, product model can be classified into 7170, 7060, 7020, Beckman, Toshiba,Mindray, Dupont, Innova, Siemens, KHB, Abbott, General type, etc.

R1：60ml×3	R2：45ml×1	R1：60ml×1	R2：15ml×1
R1：32ml×1	R2：8ml×1	R1：90ml×2	R2：45ml×1
R1：40ml×1	R2：10ml×1	R1：40ml×4	R2：40ml×1
R1：60ml×3	R2：15ml×3	R1：60ml×4	R2：60ml×1
R1：60ml×4	R2：15ml×4	R1：60ml×8	R2：60ml×2
R1：60ml×8	R2：15ml×8	R1：6×60T	R2：6×60T
R1：12×60T	R2：12×60T	R1：1×460T	R2：1×460T
R1：3×460T	R2: 3×460T	R1：4×460T	R2：4×460T
R1：8×460T	R2: 8×460T		

[Intended Use]

This product is used to determine IgM content in human serum.

[PRINCIPLE]

The Immunoglobulin M in human serum meets with its corresponding antibody (Goat anti-human IgM antibodies) in a liquid buffer to form antigen-antibody complex. And the turbidity formed is proportional to the IgM concentration in the linear range. IgM concentration in the sample can be calculated by comparing the calibrator result with same processing.

[Composition]

R1： Detection Reagent 1

Phosphate Buffer	60mmol/L
PEG, Fat-removing agent	Appropriate

R2： Detection Reagent 2

Goat anti-human IgM antibodies	Appropriate
Calibrator & Control	Optional

Calibrator：0.5ml×4；Control：0.5ml×1

[Storage And Stability]

Stored for up to 12 months at 2-8°C, protect from light. After opening, the reagent remains stable for 30 days at 2-8°C, protect from light.

[Applicable Instrument]

This assay kit is suitable for automatic or semi-automatic biochemical analyzer with 340nm and 700nm wavelength.

[Sample Requirements]

Use fasting serum. Samples testing should be completed at the same day after collected. Otherwise, the samples should be cryopreserved and avoid repeated freeze-thaw cycles. IgM in the samples remain stable for 7 days at 2-8°C and for 3 months at cryopreservation condition.

[Test Method]

1. BASIC PARAMETERS：

Method：End assay　　Temperature：37℃

Primary wavelength：340nm　　Secondary wavelength：700nm

Sample：3μl　　R1：240μl

R2：60μl　　Response direction: Positive

Reaction time：10min　　Calibration mode: Multi-point calibration

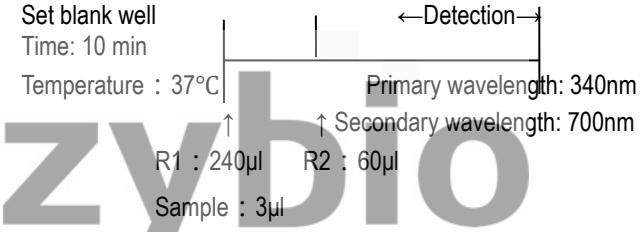
2. Assay Procedure

	Blank (B)	Sample (U)	Calibration (Ci)
ddH2O(μl)	3	-	-
Sample(μl)	-	3	-
Calibration (μl)	-	-	3
Reagent R1 (μl)	240	240	240
Mix well, incubate at 37℃ for 5 min. Take blank well as zero, measure the absorbance value A1 at 340nm.			
Reagent R2(μl)	60	60	60

Mix well ,incubate at 37℃ for 5 minutes. Take blank well as zero, measure the absorbance value A2 at 340nm.

Calculate ΔA＝A2-A1

ASSAY PROCEDURE SUMMARY



3. CALCULATIONS

Based on multi-point calibrator concentration and the corresponding absorbance change rate ΔA/min, the multi- point non-linear calibration model is used to define the working curve, sample absorbance change rate on the working curve with the corresponding concentration is concentration of sample..

[Reference Range]

0.50g/L-2.20g/L;

Recommendations: Each laboratory should establish its own reference range.

[Interpretation of Test Results]

1. The test results reflect only the status at the sampling time. Clinicians need to be combined with clinical data and other relevant test results to make judgment.

2. There is no significant effect on the test result when the sample contains ascorbate≤0.5g/L; bilirubin≤0.5g/L hemoglobin≤5.0g/L; triglyceride≤10.0g/L.

[Test Method Limitations]

Dilute with physiological saline and multiply the result by the dilution factor when the concentration of IgM is over 4.00g/L.

[Product Performance]

1. Detection Range：0.03 g/L -4.00g/L, r≥0.99。

2. Precision: Intra-assay CV≤3.0%, Inter-assay CV≤7.0%

3. Accuracy：Inaccuracy≤10％

4. Blank absorbance: the absorbance values ≤0.100 at 340nm wavelength and optical path 10mm.

【Precautions】

1. For in vitro diagnostic use only。
2. Reagents become cloudy or blank absorbance values>0.100, should be discarded.
3. The reagent and sample amount can be changed with same ratio according to needs.
4. The test equipment must be clean to avoid contamination.
5. Reagents and components of different batches are not interchangeable.
6. The waste solution generated by the test and decomposition difficultly packaging materials should be collected and sent to local waste treatment station.
7. Reagent in this kit contains chemical composition, should avoid eat or contact with skin and mucous membrane. If accidentally splashed on the skin or eyes, rinse, immediately wash with plenty of water and timely seek medical treatment if there is any discomfort.

[Reference]

Yingwu Ye et al. National Guide to Clinical Laboratory Procedures (Third Edition). Southeast University Press, 2006: 595-596.

[MANUFACTURER]

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[Product standards]

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[Specification approval date]

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