Immunoglobulin M FS*

Order Information

Cat. No.	Kit size		
1 7222 99 10 930	R1 4 x 20 mL	+	R2 2 x 8 mL
1 7222 99 10 935	R1 2 x 20 mL	+	R2 1 x 8 mL

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of immunoglobulin M (IgM) in human serum or heparin plasma on automated photometric systems.

Summary

The human immunoglobulin classes (IgG, IgA, IgM, IgE and IgD) are a group of functionally and structurally closely related glycoproteins. Serum IgM has a molecular weight of about 970 000 dalton and consists of five monomers which are linked by five connection peptides (J-chains). Each of the five Y-shaped units consists of two identical heavy chains and two identical light chains connected by disulfide bonds [1]. IgM is produced by plasma cells (B-cells) and represents about 5 to 10% of all soluble immunoglobulin classes [2]. IgM plays a major role in immune homeostasis and protection against autoimmunity and inflammatory processes. During initial immune response to an exogenous antigen, IgM is the first antibody secreted by the adaptive immune system in response to a foreign antigen [1,2]. Decreased IgM concentrations occur in primary as well as in secondary immunodeficiency syndromes. Protein losing enteropathy (PLE) may result in a decreased IgM concentration. A high increase of one immunoglobulin class deriving from multiple myeloma might lead to a decrease in other immunoglobulin classes like IgM [1]. Increased IgM concentrations occur in pathogen infections (e.g. Hepatitis A, B and C), nephrotic syndrome, Hyper-IgM syndrome and various autoimmune diseases [1]. Many forms of myeloma, especially Waldenström's macroglobulinemia, produce high amounts of monoclonal or polyclonal IgM. Quantitative IgM determination is necessary for differential diagnosis of these diseases. All methods for IgM quantitation are calibrated for polyclonal IgM. The quantitation of monoclonal IgM is not standardized and values may differ for different reagents and methods. Values should only be used for follow up studies. Monoclonal immunoglobulinemia requires detailed differential diagnostic investigation in addition to the quantitative determination [1].

Method

Immunoturbidimetric test

Determination of IgM concentration by photometric measurement of antigen antibody reaction of antibodies to human IgM with IgM present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
	NaCl		150 mmol/L
R2:	TRIS	pH 8.0	100 mmol/L
	NaCl		1150 mmol/L
	Anti-human IgM antibody (goat)		< 1 %

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

2 months	at	20 – 25°C
4 months	at	4 – 8°C
6 months	at	-20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	410/694 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent 1	125 µL
Reagent 2	25 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 32/33 (464 s/478 s)
Calibration	Logit Log 3

Calculation

The concentration of IgM in unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log. The calibration curve is obtained with 5 calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

Conversion Factor
Immunoglobulin M [mg/dL] x 0.0103 = Immunoglobulin M [µmol/L]

Calibrators and Controls

DiaSys TruCal Protein is recommended for calibration. Calibrator values have been made traceable to the reference material ERM®-DA470k/IFCC. Use DiaSys TruLab Protein Level 1 and Level 2 for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Protein	5 9200 99 10 039	5 x 1 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range up to 750 mg/dL, depending on the concentration of the highest calibrator. Linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.	
Limit of detection**	1 mg/dL
No prozone effect up to 8000 mg/dL.	

Interference by	**Interferences ≤ 10% up to**	**Analyte concentration [mg/dL]**
Bilirubin (conjugated)	60 mg/dL	92.8
Bilirubin (unconjugated)	60 mg/dL	92.3
Hemolysis	800 mg/dL	93.0
Lipemia (triglycerides)	2000 mg/dL	92.5
No cross reaction with IgA or IgG was observed.		
For further information on interfering substances, refer to the literature [5-7].		

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	64.9	129	195
CV [%]	1.75	1.20	0.993
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	64.0	134	191
CV [%]	3.17	2.05	2.25

Method comparison (n=99)	
Test x	Competitor Immunoglobulin M (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Immunoglobulin M FS (BioMajesty® JCA-BM6010/C)
Slope	0.976
Intercept	-4.78 mg/dL
Coefficient of correlation	0.993

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Reference Range [1]

	Male		Female	
	[mg/dL]	[µmol/L]	[mg/dL]	[µmol/L]
Adults	40 – 230	0.41 – 2.37	40 – 280	0.41 – 2.88
Children				
Newborns	6 – 21	0.06 – 0.22	6 – 21	0.06 – 0.22
3 months	17 – 66	0.18 – 0.68	17 – 66	0.18 – 0.68
6 months	26 – 100	0.27 – 1.03	26 – 100	0.27 – 1.03
9 months	33 – 130	0.34 – 1.34	33 – 130	0.34 – 1.34
12 months	37 – 140	0.38 – 1.44	40 – 150	0.41 – 1.55
2 years	41 – 160	0.42 – 1.65	47 – 180	0.48 – 1.85
4 years	43 – 160	0.44 – 1.65	52 – 190	0.54 – 1.96
6 years	45 – 170	0.46 – 1.75	56 – 210	0.58 – 2.16
8 years	47 – 180	0.48 – 1.85	60 – 220	0.62 – 2.27
10 years	48 – 180	0.49 – 1.85	62 – 230	0.64 – 2.37
12 years	49 – 180	0.50 – 1.85	65 – 240	0.67 – 2.47
14 years	50 – 180	0.52 – 1.85	66 – 250	0.68 – 2.58
16 years	50 – 190	0.52 – 1.96	68 – 260	0.70 – 2.68
18 years	51 – 190	0.53 – 1.96	68 – 260	0.70 – 2.68

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 03 11]. Available from: https://www.clinical-laboratory-diagnostics.com/
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IVD CE

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* Fluid Stable