

## Immunoglobulin M FS\*

### Order Information

**Cat. No.**

1 7222 99 10 964

**Kit size**

540 (R1: 6 x 90, R2: 6 x 90)

### Intended Use

Diagnostic reagent for quantitative in vitro determination of immunoglobulin M (IgM) in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

### 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**

<b>R1:</b> TRIS	pH 7.5	100 mmol/L
NaCl		150 mmol/L
<b>R2:</b> 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. The bottles are placed directly into the reagent rotor.

### 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.

### 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

Measuring range up to 750 mg/dL, depending on the concentration of the highest calibrator. Linearity is given within $\pm 5\%$ . In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	1 mg/dL
No prozone effect up to 8000 mg/dL.	
Onboard stability	6 weeks
Calibration stability	6 weeks

Interference by	Interferences $\leq 10\%$ up to	Analyte concentration [mg/dL]
<b>Bilirubin</b> (conjugated)	60 mg/dL	92.8
<b>Bilirubin</b> (unconjugated)	60 mg/dL	92.3
<b>Hemolysis</b>	800 mg/dL	93.0
<b>Lipemia</b> (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.

## Conversion Factor

Immunoglobulin M [mg/dL] x 0.0103 = Immunoglobulin M [ $\mu$ mol/L]

## Reference Range [1]

	Male		Female	
	[mg/dL]	[ $\mu$ mol/L]	[mg/dL]	[ $\mu$ mol/L]
<b>Adults</b>	40 – 230	0.41 – 2.37	40 – 280	0.41 – 2.88
<b>Children</b>				
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/>
2. Johnson AM, Rohlfis EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER. editors. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: W. B. Saunders Company;1999. p. 507-12.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240-1243.
4. W.G. Guder, F. da Fonseca-Wollheim, W. Heil, et al. Quality of Diagnostic Samples. German Society for Clinical Chemistry and Laboratory Medicine. 3rd completely revised edition 2010.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinf.wiley.com/aaccweb/aacc/>, accessed in April 2022. Published by AACC Press and John Wiley and Sons, Inc.
7. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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\* Fluid Stable

## Immunoglobulin M FS

Chemistry code 10 722

### Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	125
R2e volume	0
R2 volume	25
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.0
Sample vol (U)	1.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	32
M-DET.P.n	33
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	IGM
Digits	2
M-wave L.	410
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	1.0	1.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting								
Formula	Logit Log 3	Axis Conv	No conv					
Blank	Blank is 0	Points	6					
	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	1.0	No dil	0	0	0	9.999	-9.999
1	#	1.0	No dil	0	0	0	9.999	-9.999
2	#	1.0	No dil	0	0	0	9.999	-9.999
3	#	1.0	No dil	0	0	0	9.999	-9.999
4	#	1.0	No dil	0	0	0	9.999	-9.999
5	#	1.0	No dil	0	0	0	9.999	-9.999

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