BioMajesty

Immunoglobulin M FS*

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

Order Information

Cat. No. 1 7222 99 10 964
R1: 6 x 90 tests
R2: 6 x 90 tests

Method

Immunoturbidimetric test

Principle

Determination of the IgM concentration by photometric measurement of antigen-antibody-reaction between antibodies to human IgM and 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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

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 animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammophathy might give falsified results [8].
4. Please refer to the safety data sheets 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.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:

7 days	at	20 – 25°C
3 months	at	4 – 8°C
6 months	at	–20°C

Only freeze once! Discard contaminated specimens!

Calibrators and Controls

For calibration, DiaSys TruCal Protein calibrator set is recommended. The assigned values of these calibrators have been made traceable to the reference material ERM®-DA470k/IFCC. For internal quality control DiaSys TruLab Protein controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Protein (5 Level)	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 (7.73 µmol/L) IgM, at least up to the concentration of the highest calibrator (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 (0.01 µmol/L) IgM
No prozone effect up to 8000 mg/dL (82.4 µmol/L) d'IgM	
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Conjugated Bilirubin up to 60 mg/dL
Unconjugated Bilirubin up to 60 mg/dL
Hemoglobin up to 800 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
No cross reaction with IgA and IgG was observed.
For further information on interfering substances refer to Young DS [7].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	64.9	129	195
Mean [µmol/L]	0.67	1.33	2.01
Coefficient of variation [%]	1.75	1.20	0.99
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	64.0	134	191
Mean [µmol/L]	0.66	1.38	1.97
Coefficient of variation [%]	3.17	2.05	2.25

Method comparison (n=99)	
Test x	Competitor Immunoglobulin M
Test y	DiaSys Immunoglobulin M FS
Slope	0.976
Intercept	–4.8 mg/dL (–0.05 µmol/L)
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

IgM [mg/dL] x 0.0103 = IgM [µmol/L]

Reference Range

Adults [2]		40 – 230 mg/dL	0.41 – 2.37 µmol/L
Children [3]	Newborns	10 – 30 mg/dL	0.10 – 0.31 µmol/L
	1 – 3 month(s)	10 – 70 mg/dL	0.10 – 0.72 µmol/L
	4 – 6 months	20 – 100 mg/dL	0.21 – 1.03 µmol/L
	7 – 12 months	30 – 100 mg/dL	0.31 – 1.03 µmol/L
	2 years	40 – 140 mg/dL	0.41 – 1.44 µmol/L
	3 – 5 years	40 – 180 mg/dL	0.41 – 1.85 µmol/L
	6 – 9 years	40 – 160 mg/dL	0.41 – 1.65 µmol/L
	10 – 13 years	40 – 150 mg/dL	0.41 – 1.55 µmol/L

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

Literature

1. Guder WG, Narayanan S et al. List of Analytes; Preanalytical Variables. 1st ed. Darmstadt: Git Verlag, 1996: 16-7.
2. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
3. Heil R, Koberstein R, Zawta B. Referenzbereiche für Kinder und Erwachsene. Roche Diagnostics 2004. p. 48 - 49.
4. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 667-78.
5. Johnson AM, Rohlfs 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.
6. Bartl R, Hoechtlen-Vollmar W, Thomas L. Monoclonal immunoglobulins. In: Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlags-gesellschaft; 1998. p. 742-58.
7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer
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IVD CE

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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.I	0
M-DET.P.m	32
M-DET.P.n	33
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	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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