respons®920

Immunoglobulin M FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin M (IgM) in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 7222 99 10 921
4 twin containers for 80 tests each

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. DiaSys respons containers provide protection from light. 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. In very rare cases, samples of patients with gammopathy might give falsified results [8].
5. 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.
6. 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 tray.

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. Freeze only once.

Calibrators and Controls

DiaSys TruCal Protein calibrator set is recommended for calibration. TruCal Protein calibrator values 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 Levels)	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 800 mg/dL 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**	2 mg/dL IgM
No prozone effect up to 5700 mg/dL IgM	
On-board stability	4 weeks
Calibration stability	2 weeks

Interfering substance	Interferences < 10 %	IgM [mg/dL]
Hemoglobin	up to 500 mg/dL	53.5
	up to 1000 mg/dL	206
Bilirubin, conjugated	up to 65 mg/dL	18.4
	up to 65 mg/dL	222
Bilirubin, unconjugated	up to 65 mg/dL	18.4
	up to 65 mg/dL	222
Lipemia (triglycerides)	up to 500 mg/dL	39.1
	up to 1500 mg/dL	220
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	69.9	228	440
Coefficient of variation [%]	2.84	1.64	2.41
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	77.5	224	376
Coefficient of variation [%]	2.33	2.80	2.95

Method comparison (n=107)	
Test x	Immunoglobulin M FS Hitachi 911
Test y	Immunoglobulin M FS respons®920
Slope	1.03
Intercept	1.39 mg/dL
Coefficient of correlation	0.999

****** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion Factor

IgM [mg/dL] x 0.0103 = IgM [µmol/L]

Reference Range

Adults [3]	40 – 230 mg/dL	0.41 – 2.37 µmol/L
Children [4]		
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. 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.
3. 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.
4. Heil R, Koberstein R, Zawta B. Referenzbereiche für Kinder und Erwachsene. Roche Diagnostics 2004. p. 48–49.
5. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 667-78.
6. 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.
7. Bartl R, Hoechtlen-Vollmar W, Thomas L. Monoclonal immunoglobulins. In: Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 742-58.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

DiaSys Diagnostic Systems GmbH
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* fluid stable

respons®920

Immunoglobulin M FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	IGM				Auto Rerun	☐	
Report Name	:	Immunoglobulin M				Online Calibration	☐	
Unit	:	mg/dL	Decimal Places	:	2	Cuvette Wash	☐	
Wavelength-Primary	:	340	Secondary	:	700	Total Reagents	:	2
Assay Type	:	2 - Point	Curve Type	:	4P Logit-Log	Reagent R1	:	IGM R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	IGM R2
M2 Start	:	29	M2 End	:	29			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.0000	Calibrator Level 1		**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator Level 2		**
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000	Calibrator Level 3		**
Technical Minimum	:	*	Technical Maximum	:	*	Calibrator Level 4		**
Y = aX + b a =	:	1.0000	b=	:	0.0000	Calibrator Level 5		**

*Technical limits are automatically defined by the software via the upper and lower calibrator level.
** Enter blank value/calibrator value.

Test Details			Test Volumes			Reference Ranges
Test	:	IGM				
Sample Type	:	Serum				

Sample Volumes

Normal	:	2.00 µL	Dilution Ratio	:	1 X	
Increase	:	6.00 µL	Dilution Ratio	:	1 X	
Decrease	:	2.00 µL	Dilution Ratio	:	6 X	
Standard Volume	:	2.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	Low
RGT-2 Volume	:	36 µL	R2 Stirrer Speed	:	Low

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	IGM		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	40.0	230
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other