

# Immunoglobulin M FS\*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin M (IgM) in serum or plasma on DiaSys respons<sup>®</sup>910

## 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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
- Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [8].
- 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.
- 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

Discard contaminated specimens. Freeze only once.

### Calibrators and Controls

For calibration, DiaSys TruCal Protein calibrator set is recommended. TruCal Protein calibrator values have been made traceable to the reference material ERM<sup>®</sup>-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 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 8000 mg/dL IgM	
On-board stability	21 days
Calibration stability	7 days

Interfering substance	Interferences < 10 %	IgM [mg/dL]
Hemoglobin	up to 500 mg/dL	17.9
	up to 1100 mg/dL	206
Bilirubin, conjugated	up to 60 mg/dL	19.5
	up to 65 mg/dL	207
Bilirubin, unconjugated	up to 60 mg/dL	17.8
	up to 65 mg/dL	213
Lipemia (triglycerides)	up to 1000 mg/dL	15.2
	up to 2000 mg/dL	205

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]	74.0	233	426
Coefficient of variation [%]	3.62	2.57	3.26
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	69.8	235	404
Coefficient of variation [%]	3.85	3.73	5.08

Method comparison (n=107)	
Test x	Immunoglobulin M FS Hitachi 911
Test y	Immunoglobulin M FS respons <sup>®</sup> 910
Slope	0.958
Intercept	-0.124 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 [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

- Guder WG, Narayanan S et al. List of Analytes; Preanalytical Variables. 1<sup>st</sup> ed. Darmstadt: Git Verlag, 1996: 16-7.
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- 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.
- Heil R, Koberstein R, Zawta B. Referenzbereiche für Kinder und Erwachsene. Roche Diagnostics 2004. p. 48 - 49.
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- Johnson AM, Rohlfis EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER. editors. Tietz textbook of clinical chemistry. 3<sup>rd</sup> ed. Philadelphia: W. B. Saunders Company; 1999. p. 507-12.
- Bartl R, Hoehltlen-Vollmar W, Thomas L. Monoclonal immunoglobulins. In: Thomas L. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 742-58.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

### Manufacturer

  DiaSys Diagnostic Systems GmbH  
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## Immunoglobulin M FS

### 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	IGM
Shortcut:	
Reagent barcode reference:	716
Host reference:	716

Technic	
Type:	End point
First reagent:[ $\mu$ L]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[ $\mu$ L]	36
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	08:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [ $\mu$ L]	0 (no hemolysis)
Cleaner	
Sample [ $\mu$ L]	0
Technical limits	
Concentration technical limits-Lower	2.0000
Concentration technical limits-Upper	800.0000
SERUM	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=40.0 <=230.0
URINE	
PLASMA	>=40.0 <=230.0
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0150
Cal. 6	0.0250
Drift limit [%]	7.00

Calculations	
Model	Logit-Log 4P
Degree	

\* Enter calibrator value