BioMajesty

Immunoglobulin A FS*

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

Order Information

Cat. No. 1 7202 99 10 964
R1: 6 x 90 tests
R2: 6 x 90 tests

Method

Immunoturbidimetric test

Principle

Determination of the IgA concentration by photometric measurement of antigen-antibody-reaction of antibodies to human IgA with IgA 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		300 mmol/L
	Anti-human IgA 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 clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy 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]:

3 months	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, the DiaSys TruCal Protein calibrator set is recommended. The assigned values of the 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 set (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 900 mg/dL (56.3 µmol/L) IgA, 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**	5 mg/dL (0.3 µmol/L) IgA
No prozone effect up to 5000 mg/dL (313 µmol/L) IgA	
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 900 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
No cross reaction with IgM or 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]	122	244	319
Mean [µmol/L]	7.63	15.3	19.9
Coefficient of variation [%]	2.42	1.06	0.94
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	122	229	316
Mean [µmol/L]	7.63	14.3	19.8
Coefficient of variation [%]	1.96	2.22	2.19

Method comparison (n=100)	
Test x	Competitor Immunoglobulin A
Test y	DiaSys Immunoglobulin A FS
Slope	1.03
Intercept	–13.5 mg/dL (–0.84 µmol/L)
Coefficient of correlation	0.999

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

Conversion factor

IgA [mg/dL] x 0.0625 = IgA [µmol/L]

Reference Range

Adults [2]		70 – 400 mg/dL	4.38 – 25.0 µmol/L
Children [3]	< 1 month	7 – 94 mg/dL	0.44 – 5.88 µmol/L
	1 – 12 month(s)	10 – 131 mg/dL	0.63 – 8.19 µmol/L
	1 – 3 year(s)	19 – 220 mg/dL	1.19 – 13.8 µmol/L
	4 – 5 years	48 – 345 mg/dL	3.00 – 21.6 µmol/L
	6 – 7 years	41 – 297 mg/dL	2.56 – 18.6 µmol/L
	8 – 10 years	51 – 297 mg/dL	3.19 – 18.6 µmol/L
	11 – 13 years	44 – 395 mg/dL	2.75 – 24.7 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. 44 - 45.
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.
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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

IVD CE

DiaSys Diagnostic Systems GmbH
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Immunoglobulin A FS

Chemistry code 10 720

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	IGA
Digits	2
M-wave L.	571
S-wave.L	****
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 2	**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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