

Immunoglobulin A FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin A (IgA) in serum or plasma on DiaSys respons[®]920

Order Information

Cat. No. 1 7202 99 10 921

4 twin containers for 80 tests each

Method

Immunturbidimetric 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%
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)		

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 clinical laboratory practices.
- 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.
- 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 rotor.

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys TruCal Protein calibrator set is recommended for calibration. 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 (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 from 30 up to 900 mg/dL 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**	3 mg/dL IgA
No prozone effect up to 5000 mg/dL IgA	
On-board stability	4 weeks
Calibration stability	1 week

Interfering substance	Interferences < 10%	IgA [mg/dL]
Hemoglobin	up to 600 mg/dL	67.1
	up to 1200 mg/dL	287
Bilirubin, conjugated	up to 60 mg/dL	81.9
	up to 60 mg/dL	322
Bilirubin, unconjugated	up to 65 mg/dL	78.3
	up to 65 mg/dL	311
Lipemia (triglycerides)	up to 1800 mg/dL	100
	up to 2000 mg/dL	304
Rheumatoid factor	No interference up to 1700 IU/mL	
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]	77.1	96.3	284
Coefficient of variation [%]	2.10	2.02	2.24
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	79.3	94.7	276
Coefficient of variation [%]	4.41	4.07	3.62

Method comparison (n=140)	
Test x	DiaSys Immunoglobulin A FS Hitachi 917
Test y	DiaSys Immunoglobulin A FS respons [®] 920
Slope	1.03
Intercept	-4.93 mg/dL
Coefficient of correlation	0.999

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

Conversion factor

Immunoglobulin A [mg/dL] x 0.0625 = Immunoglobulin A [µmol/L]

Reference Range

Adults [3]		70 – 400 mg/dL	4.38 – 25.0 µmol/L
Children [4]	< 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. 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. 44-45.
5. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 667-78.
6. Johnson AM, Rohlf's 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
Alte Strasse 9 65558 Holzheim Germany

Immunoglobulin A FS Application for serum and plasma

Test Details	Test Volumes	Reference Ranges
Test : IGA		Auto Rerun : <input type="checkbox"/>
Report Name : Immunoglobulin A		Online Calibration : <input type="checkbox"/>
Unit : mg/dL	Decimal Places : 2	Cuvette Wash : <input type="checkbox"/>
Wavelength-Primary : 578	Secondary : 0	Total Reagents : 2
Assay Type : 2-Point	Curve Type : 4P Logit-Log	Reagent R1 : IGA R1
M1 Start : 15	M1 End : 15	Reagent R2 : IGA R2
M2 Start : 33	M2 End : 33	
Sample Replicates : 1	Standard Replicates : 3	Consumables/Calibrators:
Control Replicates : 1	Control Interval : 0	Blank/Level 0 : 0
Reaction Direction : Increasing	React. Abs. Limit : *	Calibrator Level 1 : **
Prozone Limit % : 97	Prozone Check : Lower	Calibrator Level 2 : **
Linearity Limit % : 0	Delta Abs. / Min. : 0.00	Calibrator Level 3 : **
Technical Minimum : *	Technical Maximum : *	Calibrator Level 4 : **
Y = aX + b a= : 1.00	b= : 0.00	Calibrator Level 5 : **

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

** Enter calibrator value.

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