

Immunoglobulin A FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin A (IgA) in serum or plasma on DiaSys respons[®]910

Order Information

Cat. No. 1 7202 99 10 921
4 twin containers for 80 tests each

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. 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.
- 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

Only freeze once!

Discard contaminated specimens.

Calibrators and Controls

For the calibration 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 (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 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	21 days
Calibration stability	10 days

Interfering substance	Interferences < 10%	IgA [mg/dL]
Hemoglobin	up to 1200 mg/dL	74.8
	up to 1200 mg/dL	279
Bilirubin, conjugated	up to 60 mg/dL	85.2
	up to 60 mg/dL	382
Bilirubin, unconjugated	up to 60 mg/dL	83.5
	up to 60 mg/dL	366
Lipemia (triglycerides)	up to 2000 mg/dL	111
	up to 2000 mg/dL	352

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]	83.3	107	328
Coefficient of variation [%]	3.39	3.86	3.18
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	84.5	102	317
Coefficient of variation [%]	3.26	3.32	3.84

Method comparison (n=140)	
Test x	DiaSys Immunoglobulin A FS Hitachi 917
Test y	DiaSys Immunoglobulin A FS respons [®] 910
Slope	0.963
Intercept	1.032 mg/dL
Coefficient of correlation	0.995

** 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

- Guder WG, Narayanan S et al. List of Analytes; Preanalytical Variables. 1st ed. Darmstadt: Git Verlag, 1996: 16-7.
- 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.
- 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. 44 - 45.
- Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 667-78.
- Johnson AM, Rohlfes 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.
- Bartl R, Hoechtl-Vollmar W, Thomas L. Monoclonal immunoglobulins. In: Thomas L. Clinical Laboratory Diagnostics. 1st 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 A 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:	IGA
Shortcut:	
Reagent barcode reference:	714
Host reference:	714

Technic	
Type:	End point
First reagent:[μ L]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	36
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	570
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
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 [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	3.0000
Concentration technical limits-Upper	900.0000
SERUM	
Normal volume [μ L]	3.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	1
URINE	
Normal volume [μ L]	3.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [μ L]	3.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	1
CSF	
Normal volume [μ L]	3.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [μ L]	3.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	1

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

Range	
Gender	All
Age	
SERUM	>=70.0 <=400.0
URINE	
PLASMA	>=70.0 <=400.0
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	0.1000
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0200
Cal. 5	0.0300
Cal. 6	0.0500
Drift limit [%]	5.00

Calculations	
Model	Akima Spline
Degree	

* Enter calibrator value