BioMajesty®

Immunoglobulin A FS*

Order Information

Cat. No.
1 7202 99 10 964

Kit size
Σ 540 (R1: 6 x 90, R2: 6 x 90)

Intended Use

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

Summary

The human immunoglobulin classes (IgG, IgA, IgM, IgE and IgD) are a group of functionally and structurally closely related glycoproteins. Human IgA has a molecular weight of about 160000 dalton and consists of two identical heavy chains and two identical light chains connected by disulfide bonds in a characteristic Y-shaped form [1]. Serum IgA is produced by plasma cells (B-cells) and represents approximately 15% of all soluble immunoglobulin classes [2]. About 90% of serum IgA is monomeric while the rest is polymeric. Moreover, most of IgA is not present in serum but is located on the surface of mucous membranes [1]. Serum IgA activates the complement system through the alternative pathway, and has specific antibody functions. However, the detailed functions of serum IgA are still unclear. In secretory IgA, the two Y-shaped pieces are bound together not only by a joining chain but also by a special peptide called secretory component. Furthermore, secretory IgA is synthesized independently from serum IgA and is primarily present in body secretions like saliva, tears, colostrum, nasal secretions, tracheobronchial mucus, gastrointestinal secretions and breast milk [1,2]. The most important functions of secretory IgA are binding of microorganisms on mucous membranes, activation of alternative complement pathway and activation of inflammatory cascades [1,2]. Decreased serum IgA concentrations occur in primary as well as in secondary immunodeficiency syndromes. A high increase of one immunoglobulin class deriving from multiple myeloma might lead to a decrease in other immunoglobulin classes like IgA [1]. Furthermore, severe intestinal diseases with chronic diarrhea are associated with IgA loss. On the other hand, increased IgA levels occur in severe infections and autoimmune diseases. Especially inflammatory processes of the liver may result in elevated serum IgA levels [1,2]. Like for other Ig-classes, many forms of myeloma produce high amounts of monoclonal or polyclonal IgA. Quantitative serum IgA determination is necessary for differential diagnosis of these diseases. All methods for IgA quantitation are calibrated for polyclonal serum IgA. The quantitation of monoclonal IgA is not standardized and values may differ for different reagents and methods. Therefore, these values should only be used for follow up studies. Monoclonal immunoglobulinemia requires detailed differential diagnostic investigation in addition to the quantitative determination [1].

Method

Immunoturbidimetric test

Determination of 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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) 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.
7. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

8 months	at	20 – 25°C
8 months	at	4 – 8°C
8 months	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal Protein is recommended for calibration. Calibrator values have been made traceable to the reference material ERM®-DA470k/IFCC. Use DiaSys TruLab Protein Level 1 and Level 2 for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Protein	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

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Performance Characteristics

Measuring range up to 900 mg/dL, depending on the concentration of the highest calibrator. Linearity is given within ± 5%. 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
No prozone effect up to 5000 mg/dL.	
Onboard stability	6 weeks
Calibration stability	6 weeks

Interference by	**Interferences ≤ 10% up to**	**Analyte concentration [mg/dL]**
Bilirubin (conjugated)	60 mg/dL	194
Bilirubin (unconjugated)	60 mg/dL	195
Hemolysis	900 mg/dL	195
Lipemia (triglycerides)	2000 mg/dL	199
No cross reaction with IgM or IgG was observed.		
For further information on interfering substances, refer to the literature [5-7].		

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	122	244	319
CV [%]	2.42	1.06	0.936
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	122	229	316
CV [%]	1.96	2.22	2.19

Method comparison (n=100)	
Test x	Competitor Immunoglobulin A (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Immunoglobulin A FS (BioMajesty® JCA-BM6010/C)
Slope	1.03
Intercept	-13.5 mg/dL
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
Immunoglobulin A [mg/dL] x 0.0625 = Immunoglobulin A [µmol/L]

Reference Range [1]

	[mg/dL]	[µmol/L]
Adults	70 – 500	4.38 – 31.3
Children		
Newborns	1 – 6	0.06 – 0.38
3 months	10 – 34	0.63 – 2.13
6 months	8 – 60	0.50 – 3.75
9 months	11 – 80	0.69 – 5.00
12 months	14 – 90	0.88 – 5.63
2 years	21 – 150	1.31 – 9.38
4 years	30 – 190	1.88 – 11.88
6 years	38 – 220	2.38 – 13.75
8 years	46 – 250	2.88 – 15.63
10 years	52 – 270	3.25 – 16.88
12 years	58 – 290	3.63 – 18.13
14 years	63 – 300	3.94 – 18.75
16 years	67 – 310	4.19 – 19.38
18 years	70 – 320	4.38 – 20.00

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 03 05]. Available from: https:// www.clinical-laboratory-diagnostics.com
2. 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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4. W.G. Guder, F. da Fonseca-Wollheim, W. Heil, et al. Quality of Diagnostic Samples. German Society for Clinical Chemistry and Laboratory Medicine. 3rd completely revised edition 2010.
5. 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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/ aaccweb/aacc/, accessed in March 2024. Published by AACC Press and John Wiley and Sons, Inc.
7. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001;38:376-85.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

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* Fluid Stable

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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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