respons®910

Immunoglobulin G FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin G (IgG) in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 7212 99 10 921
4 twin containers for 80 tests each

Method

Immunoturbidimetric test

Principle

Determination of the concentration IgG by photometric measurement of antigen-antibody-reaction between antibodies to human IgG and IgG 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 IgG 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

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 laboratory practice.
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 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. Only freeze once!

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 3200 mg/dL IgG, 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 rerun function).	
Limit of detection**	6 mg/dL IgG
No prozone effect up to 8000 mg/dL IgG	
On-board stability	28 days
Calibration stability	10 days

Interfering substance	**Interferences < 10 %**	**IgG [mg/dL]**
Hemoglobin	up to 600 mg/dL	372
	up to 1200 mg/dL	2040
Bilirubin, conjugated	up to 60 mg/dL	409
	up to 60 mg/dL	2056
Bilirubin, unconjugated	up to 60 mg/dL	415
	up to 60 mg/dL	2156
Lipemia (triglycerides)	up to 2000 mg/dL	392
	up to 2000 mg/dL	1974
No cross reaction with IgA and IgM was observed.		
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]	580	1111	1923
Coefficient of variation [%]	2.10	2.32	2.90
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	454	1237	2093
Coefficient of variation [%]	2.23	5.74	5.46

Method comparison (n=128)	
Test x	DiaSys Immunoglobulin G FS Hitachi 917
Test y	DiaSys Immunoglobulin G FS respons®910
Slope	1.053
Intercept	–24.1 mg/dL
Coefficient of correlation	0.994

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

Conversion factor

Immunoglobulin G [mg/dL] x 0.067 = Immunoglobulin G [µmol/L]

Reference Range

Adults [3]		700 – 1600 mg/dL	46.9 – 107 µmol/L
Children [4]	Newborns	700 – 1600 mg/dL	46.9 – 107 µmol/L
	1 – 3 month(s)	250 – 750 mg/dL	16.8 – 50.3 µmol/L
	4 – 6 months	180 – 800 mg/dL	12.3 – 53.6 µmol/L
	7 – 12 months	300 – 1000 mg/dL	20.1 – 67.0 µmol/L
	2 years	350 – 1000 mg/dL	23.5 – 67.0 µmol/L
	3 – 5 years	500 – 1300 mg/dL	33.5 – 87.1 µmol/L
	6 – 9 years	600 – 1300 mg/dL	40.2 – 87.1 µmol/L
	10 – 13 years	700 – 1400 mg/dL	46.9 – 93.8 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. 46 - 47.
5. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 667-78.
6. 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.
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: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer

DiaSys Diagnostic Systems GmbH
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respons®910

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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:	IGG
Shortcut:	
Reagent barcode reference:	715
Host reference:	715

Technic	
Type:	End point
First reagent:[µL]	200
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
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]	06:00
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 [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	6.0000
Concentration technical limits-Upper	3282.0000
SERUM	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	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	>=700.0 <=1600.0
URINE	
PLASMA	>=700.0 <=1600.0
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	0.0150
Cal. 4	0.0200
Cal. 5	0.0300
Cal. 6	0.0500
Drift limit [%]	2.00

Calculations	
Model	Akima Spline
Degree	

* Enter calibrator value