respons®920

Immunoglobulin G FS*

Order Information

Cat. No.	Kit size
1 7212 99 10 921	Σ 320 (4 x 80)

Intended Use

Diagnostic reagent for quantitative in vitro determination of immunoglobulin G (IgG) in human serum or heparin plasma on automated respons®920.

Summary

The human immunoglobulin classes (IgG, IgA, IgM, IgE and IgD) are a group of functionally and structurally closely related glycoproteins. Human IgG has a molecular weight of about 150 000 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 IgG or IgG is produced by plasma cells (B-cells) and represents about 75% of all soluble immunoglobulin classes [2]. The main functions of IgG are binding of antigens, initiating complement activation and triggering further catabolism of the antigen [1]. Decreased IgG concentrations occur in primary as well as in secondary immunodeficiency syndromes. Increased loss of proteins due to nephrotic syndrome may result in a decreased IgG concentration [1]. A high increase of one immunoglobulin class deriving from multiple myeloma might lead to a decrease in other immunoglobulin classes like IgG. Increased IgG concentrations occur in severe infections and autoimmune diseases [1,2]. Many forms of myeloma produce high amounts of monoclonal or polyclonal IgG. Quantitative IgG determination is important for differential diagnosis of these diseases. All methods for IgG quantitation are calibrated for polyclonal IgG. The quantitation of monoclonal IgG is not standardized and values may differ for different reagents and methods. 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 IgG concentration by photometric measurement of antigen antibody reaction of antibodies to human IgG with 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 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. 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.
4. In very rare cases, samples of patients with gammopathy might give falsified results [3].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. 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.
7. 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.
8. 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]:

4 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

Performance Characteristics

Measuring range from 1.15 mg/dL up to 3200 mg/dL, depending on the concentration of the highest calibrator. Linearity is given within ± 10%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	1.15 mg/dL
Limit of quantitation**	1.15 mg/dL
No prozone effect up to 8000 mg/dL.	
Onboard stability	30 days
Calibration stability	10 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Bilirubin (conjugated)	60 mg/dL	392
	60 mg/dL	1843
Bilirubin (unconjugated)	60 mg/dL	391
	60 mg/dL	1844
Hemolysis	600 mg/dL	384
	1200 mg/dL	1741
Lipemia (triglycerides)	2000 mg/dL	382
	2000 mg/dL	1541
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]	373	1094	1923
CV [%]	1.30	2.29	2.38
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	641	1127	1981
CV [%]	2.42	3.71	2.81

Method comparison (n=128)	
Test x	DiaSys Immunoglobulin G FS (Hitachi 917)
Test y	DiaSys Immunoglobulin G FS (respons®920)
Slope	0.983
Intercept	20.9 mg/dL
Coefficient of correlation	0.997

** according to CLSI document EP17-A, Vol. 24, No. 34

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

Reference Range [1]

	[mg/dL]	[µmol/L]
Adults	700 – 1600	46.9 – 107
Children		
Newborns	660 – 1750	44.2 – 117
1 month	390 – 1050	26.1 – 70.4
2 months	250 – 680	16.8 – 46.6
3 months	200 – 550	13.4 – 36.9
4 months	200 – 540	13.4 – 36.2
5 months	220 – 600	14.7 – 40.2
6 months	260 – 490	17.4 – 32.8
7 months	290 – 770	19.4 – 51.6
8 months	320 – 840	21.4 – 56.3
9 months	330 – 880	22.1 – 59.0
10 months	350 – 910	23.5 – 61.0
11 months	350 – 930	23.5 – 62.3
12 months	360 – 950	24.1 – 63.7
2 years	470 – 1230	31.5 – 82.4
4 years	540 – 1340	36.2 – 89.8
6 years	590 – 1430	39.5 – 95.8
8 years	630 – 1500	42.2 – 101
10 years	670 – 1530	44.9 – 103
12 years	700 – 1550	46.9 – 104
14 years	710 – 1560	47.6 – 105
16 years	720 – 1560	48.2 – 105
18 years	730 – 1550	48.9 – 104

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; 2024 [cited 2024 March 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.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240-1243.
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

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable

respons®920

Immunoglobulin G FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	IGG				Auto Rerun	:	☐
Report Name	:	Immunoglobulin G				Online Calibration	:	☐
Unit	:	mg/dL	Decimal Places	:	0	Cuvette Wash	:	☐
Wavelength-Primary	:	578	Secondary	:	0	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	4P Logit-Log	Reagent R1:	:	IGG R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	IGG 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 %	:	0.00	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 software via upper and lower calibrator level.
** Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	IGG		
Sample Type	:	Serum		

Sample Volumes

Normal	:	2.00	µL	Dilution Ratio	:	1	X
Increase	:	4.00	µL	Dilution Ratio	:	1	X
Decrease	:	2.00	µL	Dilution Ratio	:	6	X
Standard Volume	:	2.00	µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	200	µL	R1 Stirrer Speed	:	Low
RGT-2 Volume	:	40	µL	R2 Stirrer Speed	:	Low

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	IGG		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	700.00	1600.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other