Immunoglobulin G FS*

Order Information

Cat. No.	Kit size		
1 7212 99 10 930	R1 4 x 20 mL	+	R2 2 x 8 mL
1 7212 99 10 935	R1 2 x 20 mL	+	R2 1 x 8 mL

Kits for use in conjunction with DiaSys CE applications.

Intended Use

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

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. 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.

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.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	571 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent 1	175 µL
Reagent 2	35 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 32/33 (464 s/478 s)
Calibration	Logit Log 3

Calculation

The concentration of IgG in unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log. The calibration curve is obtained with 5 calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

Conversion Factor

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

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

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range up to 3200 mg/dL, depending on the concentration of the highest calibrator. Linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Limit of detection**	1 mg/dL

No prozone effect up to 8000 mg/dL.

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Bilirubin (conjugated)	60 mg/dL	1025
Bilirubin (unconjugated)	60 mg/dL	1025
Hemolysis	900 mg/dL	1022
Lipemia (triglycerides)	2000 mg/dL	1035
No cross reaction with IgA or IgM 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]	925	986	2366
CV [%]	2.01	1.54	1.20
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	906	1691	2327
CV [%]	2.75	2.58	2.37

Method comparison (n=51)	
Test x	Competitor Immunoglobulin G (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Immunoglobulin G FS (BioMajesty® JCA-BM6010/C)
Slope	1.02
Intercept	-16.6 mg/dL
Coefficient of correlation	0.998

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

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.
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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.
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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.

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IVD CE

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* Fluid Stable