Immunoglobulin G FS*

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

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
5 9200 99 10 037		3 x	1 mL	TruCal Protein high		
5 9200 99 10 039		5 x	1 mL	TruCal Protein:		
	Calibrator set with 5 different levels					

Summary [1-3]

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 which are bound together by disulfide bonds in a characteristic Y-shaped form. IgG is produced by plasma cells (B-cells) and represents about 75% of all soluble immmunoglobulin classes. The main function of IgG is to bind to antigens, initiating complement activation and trigger further catabolism of the antigen.
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. A high increase of one immunoglobulin class due to multiple myeloma may result in a decrease in other immunoglobulin classes like IgG. Increased IgG concentrations can be observed in severe infections and autoimmune diseases. 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.

Method

Immunoturbidimetric test

Principle

Determination of the IgG concentration 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 and contamination is avoided. Do not freeze the reagents and store them protected from light!

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.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma

Stability [4]:	3 months	at	20 – 25°C
	3 months	at	4 – 8°C
	6 months	at	–20°C

Only freeze once!
Discard contaminated specimens.

Assay Procedure for Analyzers

Application sheets for automated systems are available on request.

Wavelength	570 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	2 µL
Dist. water	2 µL	-
Reagent 1	350 µL	350 µL
Mix, incubate for 3 – 5 min., read absorbance (A1), then add:		
Reagent 2	70 µL	70 µL
Mix, incubate for 3 min., read absorbance (A2).		

$\Delta A = (A2 - A1)$ sample or calibrator

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.
Stability of calibration: 4 weeks

Conversion factor

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

Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal Protein calibrator set or TruCal Protein high calibrator are recommended. The assigned values of the calibrators have been made traceable to the reference material ERM®-DA470k/IFCC. For internal quality control a DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
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

The test has been developed to determine IgG concentrations within a measuring range from 175 - 3500 mg/dL, at least up to the concentration of the highest calibrator. When values exceed the upper samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.
If results are below the lower range, repeat measurement with double sample volume. If results are still below the range, check for prozone effect by diluting the sample.

Prozone Limit

No prozone effect was observed up to an IgG value of 8000 mg/dL.

Specificity/Interferences

Due to its antibodies, DiaSys Immunoglobulin G FS is a specific immunoassay for human IgG. No interference was observed by conjugated and unconjugated bilirubin up to 60 mg/dL, hemoglobin up to 1000 mg/dL, lipemia up to 2000 mg/dL triglycerides and RF up to 1700 IU/mL.
No cross reaction with IgA or IgM was observed under test conditions. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection

The lower limit of detection (the minimum concentration which can be measured and distinguished from zero) is 8 mg/dL.

Imprecision

According to protocol EP-5 of the NCCLS (National Committee of Clinical Laboratory Standards)

Within-run precision n = 40	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	1173	14.1	1.20
Sample 2	1854	29.1	1.57
Sample 3	2217	36.0	1.62

Between day precision n = 40	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	1173	9.49	0.81
Sample 2	1854	21.4	1.15
Sample 3	2217	34.1	1.54

Method Comparison

A comparison of DiaSys Immunoglobulin G FS to an immunoturbidimetric test (x) using 81 samples gave following results: y = 1.10 x – 52.9 mg/dL; r = 0.997.

A comparison of DiaSys Immunoglobulin G FS (y) to a nephelometric test (x) using 79 samples gave following results: y = 1.08 x – 51.6 mg/dL; r = 0.992.

Reference values

Adults [6]		700 – 1600 mg/dL	46.9 – 107 µmol/L
Children [7]	Newborns	700 – 1600 mg/dL	46.9 – 107 µmol/L
	1 – 3 months	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

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Manufacturer

IVD CE

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