

Immunoglobulin G FS*

Order Information

Cat. No.

1 7212 99 10 964

Kit size



540 (R1: 6 x 90, R2: 6 x 90)

Intended Use

Diagnostic reagent for quantitative in vitro determination of immunoglobulin G (IgG) 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 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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- 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.
- 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.

- 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 up to 3200 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** | 1 mg/dL | |
| No prozone effect up to 8000 mg/dL. | | |
| Onboard stability | 6 weeks | |
| Calibration stability | 4 weeks | |
| 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.

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/>
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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.
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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.

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.



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* Fluid Stable

Immunoglobulin G FS

Chemistry code 10 721

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 | 175 |
| R2e volume | 0 |
| R2 volume | 35 |
| 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.l | 0 |
| M-DET.P.m | 32 |
| M-DET.P.n | 33 |
| S-DET.P.p | 17 |
| S-DET.P.r | 18 |
| Check D.P.l. | 0 |
| Limit value | 0.003 |
| Variance | 10 |
| Reac.type | Inc |

| Sub-analy. Conditions | |
|-----------------------|------|
| Name | IGG |
| 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 3 | 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 |

entered by user