

Immunoglobulin G FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin G (IgG) in serum or plasma on DiaSys respons[®] 920

Order Information

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

Method

Immunoturbidimetric test

Principle

Determination of IgG concentration by photometric measurement of antigen-antibody-reaction of antibodies against 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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
- Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- 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.
- In very rare cases, samples of patients with gammopathy might give falsified results [8].
- 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.
- 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. Freeze only once.

Calibrators and Controls

DiaSys TruCal Protein calibrator set is recommended for calibration. 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** | 2 mg/dL IgG |
| No prozone effect up to 8000 mg/dL IgG | |
| On-board stability | 30 days |
| Calibration stability | 10 days |

| Interfering substance | Interferences < 10 % | IgG [mg/dL] |
|--|----------------------|-------------|
| Hemoglobin | up to 600 mg/dL | 384 |
| | up to 1200 mg/dL | 1741 |
| Bilirubin, conjugated | up to 60 mg/dL | 392 |
| | up to 60 mg/dL | 1843 |
| Bilirubin, unconjugated | up to 60 mg/dL | 391 |
| | up to 60 mg/dL | 1844 |
| Lipemia (triglycerides) | up to 2000 mg/dL | 382 |
| | up to 2000 mg/dL | 1541 |
| 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] | 373 | 1094 | 1923 |
| Coefficient of variation [%] | 1.30 | 2.29 | 2.38 |
| Between run (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [mg/dL] | 641 | 1127 | 1981 |
| Coefficient of variation [%] | 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 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

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- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.



Manufacturer

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Immunoglobulin G FS Application for serum and plasma

| Test Details | | Test Volumes | | Reference Ranges | |
|--------------------|--------------------|---------------------|----------------|--------------------------|----------------------------|
| Test | : IGG | | | Auto Rerun | : <input type="checkbox"/> |
| Report Name | : Immunoglobulin G | | | Online Calibration | : <input type="checkbox"/> |
| Unit | : mg/dL | Decimal Places | : 0 | Cuvette Wash | : <input type="checkbox"/> |
| 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 | | | | Sample Types | |
| Normal | : 2.00 μ L | Dilution Ratio | : 1 X | <input checked="" type="checkbox"/> Serum | |
| Increase | : 4.00 μ L | Dilution Ratio | : 1 X | <input type="checkbox"/> Urine | |
| Decrease | : 2.00 μ L | Dilution Ratio | : 6 X | <input type="checkbox"/> CSF | |
| Standard Volume | : 2.00 μ L | | | <input checked="" type="checkbox"/> Plasma | |
| | | | | <input type="checkbox"/> Whole Blood | |
| | | | | <input type="checkbox"/> Other | |
| Reagent Volumes and Stirrer Speed | | | | | |
| RGT-1 Volume | : 200 μ L | R1 Stirrer Speed | : Low | | |
| RGT-2 Volume | : 40 μ L | R2 Stirrer Speed | : Low | | |

| Test Details | | Test Volumes | | Reference Ranges | |
|------------------------|-------------|--------------|--|--|--|
| Test | : IGG | | | | |
| Sample Type | : Serum | | | | |
| Reference Range | : DEFAULT | | | | |
| Category | : Male | | | | |
| Reference Range | | | | Sample Types | |
| | Lower Limit | Upper Limit | | <input checked="" type="checkbox"/> Serum | |
| | (mg/dL) | (mg/dL) | | <input type="checkbox"/> Urine | |
| Normal | : 700.00 | : 1600.00 | | <input type="checkbox"/> CSF | |
| Panic | : 0.00 | : 0.00 | | <input checked="" type="checkbox"/> Plasma | |
| | | | | <input type="checkbox"/> Whole Blood | |
| | | | | <input type="checkbox"/> Other | |