Immunoglobulin G

CE REF C9100150A 1x60ml
Turbidimetry

Quantitative determination of human immunoglobulin G (IgG)
IVD

Store 2 - 8ºC.

INTENDED USE
The IgG is a quantitative turbidimetric test for the measurement of IgG in human serum or plasma.

PRINCIPLE OF THE METHOD
Anti-human IgG antibodies when mixed with samples containing IgG, form insoluble complexes. These complexes cause an absorbance change, dependent upon the IgG concentration of the patient sample, that can be quantified by comparison from a calibrator of know IgG concentration.

CLINICAL SIGNIFICANCE
IgG is the most important immunoglobulin produced by plasma cells, and represents about 75% of the total immunoglobulins. Its main function is to neutralize toxins in tisular spaces.
IgG deficit may be due to a congenital primary disturbance (immunodeficiency congenital and acquired) and is a special risk in children.
Polyclonal hyperimmunoglobulinemia is the normal response to infections, especially in hepatitis and cirrhosis as well as autoimmune diseases.
Increases of monoclonal IgG are found in multiple myeloma, lymphocytic leukemia, and Waldenström macroglobulinemia.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, PEG 8000, pH 8.3. Sodium azide 0.95 g/L.
Antibody (R2)	Goat serum, anti-human IgG, pH 7.5. Sodium azida 0.95 g/L.

CALIBRATION
The reagent (both monoreagent and bireagent) should be recalibrated every month, when the controls are out of specifications, and when changing the reagent lot or the instrument settings.

PREPARATION
Reagents: Ready to use.

Calibration Curve: Prepare the following SERUM PROTEINS CALIBRATOR (Cod.: 905CAL) Calibrator dilutions in NaCl 9 g/L as diluent. Multiply the concentration of the IgG calibrator by the corresponding factor stated in table bellow to obtain the IgG concentration of each dilution.

Calibrator dilution	1	2	3	4	5	6
Calibrator (µL)	--	10	25	50	75	100
NaCl 9 g/L (µL)	100	90	75	50	25	-
Factor	0	0.1	0.25	0.5	0.75	1.0

STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.
Reagent deterioration: The presence of particles and turbidity.
Do not freeze; frozen Antibody or Diluent could change the funcitionality of the test.

ADDITIONAL EQUIPMENT
- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 600 nm filter (580 - 620 nm).

SAMPLES
Fresh serum or plasma. EDTA or heparin should be used as anticoagulant. Stable 7 days at 2-8ºC or 3 months at –20ºC.
The samples with presence of fibrin should be centrifuged.
Do not use highly hemolized or lipemic samples.

PROCEDURE
1. Bring the reagents and the photometer (cuvette holder) to 37ºC.
2. Assay conditions:
   Wavelength : 600
   Temperature : 37 ºC
   Cuvette ligth path : 1cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

Reagent R1	1000 µL
Sample or Calibrator	5 µL

5. Mix and read the absorbance (A1) after the sample addition.
6. Immediately, pipette into de cuvette:

Reagent R2	200 µL

7. Mix and read the absorbance (A_2) of calibrators and sample exactly 5 minutes after the R2 addition.

Gesan has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

CALCULATIONS
Calculate the absorbance difference (A_2-A_1) of each point of the calibration curve and plot the values obtained against the IgG concentration of each calibrator dilution. IgG concentration in the sample is calculated by interpolation of its (A_2-A_1) in the calibration curve.

QUALITY CONTROL
Control sera are recommended to monitor the performance of manual and automated assay procedures.Gesan SERUM PROTEINS CONTROL (Cod.:905CTL). Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES[4]
Between 700 - 1600 mg/dL. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS
1. Measurement range: Up to 4000 mg/dL under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and re-tested again. The linearity limit and measurement range depends on the sample to reagent / ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
2. Detection Limit: Values less than 10.3 mg/dL give non-reproducible results.
3. Prozone effect: No prozone effect was detected upon 8000 mg/dL
4. Sensitivity: Δ 0.6 mA. mg/dL at 359 mg/dL:
5. Precision: The reagent has been tested for 20 days, using three levels of serum in a EP5-based study.
6. The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.
7.

EP5	CV (%)		
	340.3 mg/dl	801.96 mg/dl	1517.5 mg/dl
Total	2.1%	2.8%	4.8%
Within Run	0.9%	0.7%	1%
Between Run	1.5%	1.5%	1.8%
Between Day	1%	2.2%	4.4%

6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using the Elecsys method from Roche. 79 samples ranging from 450 to 2600 mg/dL of IgG were assayed. The correlation coefficient (r) was 0.94 and the regression equation y = 0.957x +105.67.

The results of the performance characteristics depend on the used analyzer.

INTERFERENCES[5-6]
Hemoglobin (10 g/L), bilirrubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Rheumatoid factors may interfere at 300 IU/mL. Other substances may interfere[6,7].

NOTES
1. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

1. Clinical Guide to Laboratory Tests, Edited by NW Tietz W B Saunders Co., Phipladelphia, 483, 1983.
2. Skoug Jonh W et al. Clin Chem 1988; 34/2: 309 – 315
3. Pesce AJ and Kaplan, LA. Methods in Clinical Chemistry. The CV Mosby Company, St. Louis MO, 1987.
4. Dati F et al. Eur J Clin Chem Clin Biochem 1966; 14: 401-406.
5. Young DS.Effects of disease on clinical laboratory tests, 3th ed. AACC Pres, 1997
6. Friedman and Young. Effects of disease on clinical laboratory tests, 3tn ed. AACC Pres, 1997.

PACKAGING

Ref.: C9100150A	Cont.	: 1 x 50 mL R1. Diluent : 1 x 10 mL R2. Antibody

Simbols

CE Mark (requirement of 98/79 regulation)

IVD in vitro medical device

LOT Batch Code

Use by

Storage temperature limits

Read instruction for use

Gesan Production srl

Gesan Production s.r.l.
Via Fiera dell'Eremita, 71 – Campobello di Mazara (TP) – Part. IVA 01928730819
Tel +39 0924 912396 – Fax +39 0924 912534 // Web: www.gesanproduction.it - e-mail: overseas@gesanproduction.it