Reactivos GPL

Barcelona, España

CE

- IgG -

IMMUNOGLOBULIN G
Turbidimetry

Store at: +2+8ºC.

Presentation:
Cod. IT130 CONT: R1 1 x 40 mL. + R2 1 x 10 mL .

Procedure

Diagnostic reagent for quantitative determination of human immunoglobulin G (IgG).

Only for *in vitro use in clinical laboratory* (IVD)

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

REAGENT COMPOSITION

Diluent (R1)	Tris buffer 20 mmol/L, PEG 8000, pH 8.2 Sodium azide 0.95 g/L.
Antibody (R2)	Goat serum, anti-human IgG, pH 7.5. Sodium azida 0.95 g/L.
Optional	PROT-CAL. Cod: IT210

REAGENT PREPARATION AND STABILITY
Antibody and diluent are ready to use.
CALIBRATION CURVE:
Prepare the following General Protein Calibrator dilutions in ClNa 9 g/L as diluent. Multiply the concentration of the IgG calibrator by the corresponding factor stated in table below to obtain the IgG concentration of each dilution.

Calibrator dilution	1	2	3	4	5	6
Calibrator (µL)	--	6.25	12.5	25	50	100
ClNa 9 g/L (µL)	100	93.75	87.5	75	50	--
Factor	0	0.0625	0.125	0.25	0.5	1.0

Signs of reagent deterioration:
- Particles and turbidity indicate contamination or reagents deterioration.

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.
Do not freeze; frozen Antibody or Diluent could change the functionality of the test.

CALIBRATION
The assay is calibrated to the Reference Material ERM-DA470k/IFCC. It must be used the PROT CAL Calibrator to calibrate the reagent. 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.

SPECIMEN
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.

Discard contaminated specimen

MATERIAL REQUIRED BUT NOT PROVIDED
- Thermostatic bath at 37º C.
- Spectrophotometer capable of accurate absorbance readings at 600 nm (580-620)

General laboratory equipment

PROCEDURE
MANUAL PROCEDURE
1. Bring the reagents and the photometer to 37º C.
2. Assay conditions:
   - Wavelength: ..... 600 nm.
   - Temperature: ..... 37º C
   - Cuvette light path: ..... 1 cm.
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

R_1: Diluent (µL)	800
Sample or Calibrator (µL)	10

5. Mix and read the absorbance (A_1) of the sample addition.
6. Immediately pipette into the cuvette:

R_2: Antibody (µL)	200

7. Mix and read the absorbance (A_2) of calibrators and samples exactly 2 minutes after the R_2 addition.

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 dilution. IgG concentration in the sample is calculated by interpolation of its (A_2-A_1) in the calibration curve.

QUALITY CONTROL
GENERAL PROTEIN CONTROLS Ref.: IT220.

Serum Controls are recommended for internal quality control. 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.

It is suggested that each laboratory establish its own reference range.

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 myoloma, lymphocytic leukemia, and Waldenström macroglobulinemia.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE
- *Measurement range* Up to 3000 mg/dL (Note 1) under the described assay conditions.
- *Limit detection*: Values less than 10.3 mg/dL give non-reproducible results.
- *Prozone effect*: No prozone effect was detected upon 8000 mg/dL.
- *Sensitivity*: Δ 0.6 mA.mg/dL. at 359 mg/dL.
- *Precision:* The reagent has been tested for 20 days, using two levels of serum in an EP5-based study.

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 %

- *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

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

NOTES
1. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and re-tested again. The linearity limit and measurement range depend 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. Clinical diagnosis should not be made on findings of a single test results, but should integrate both clinical and laboratory data.
3. GPL have instructions for many automatic instruments, available on request.

BIBLIOGRAPHY

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