

IgG (2nd generation)

Turbidimetric Immunoassay

REF: 522 001 (2 X 10 ml) + 0.5 ml High calibrator (40 test)

REF: 522 002 (2 X 25 ml) + 0.5 ml High calibrator (100 test)

Intended Use

For the quantitative determination of IgG in human serum by turbidimetric immunoassay for manual and automated chemistry analyzers.

Background

IgG is a predominant serum immunoglobulin. The measurement of IgG is important for typing immuno-deficiencies and myelomas. Increased levels are found in chronic infections and chronic inflammation. IgG is the only immunoglobulin which crosses the placenta and is therefore of special importance in the infants defence against infection.

Method

Antigen-antibody reaction using endpoint method.

Reagent (R)

Polyclonal goat anti-human IgG stabilised in saline supplemented with accelerator.

Sodium azide (0.95 g/L).

Reagents required but not supplied

1. Saline (9 g/L NaCl)
2. Calibrators and Controls

Reagent Preparation, Storage and Stability

The reagent is stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Specimen Collection and Preservation

Use fresh serum. If the test cannot be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

Procedure

Sample/Control: dilute 1:10 in saline (9 g/L NaCl).

Reference curve: generate a reference curve by diluting the standard high level 1:10, 1:20, 1:40, 1:80 and 1:160 using saline (9 g/L NaCl). Use saline (9 g/L NaCl) as zero point.

Test:

	Diluted Samples	Diluted Standards	Diluted Controls
Samples	5 µl
Standards	5 µl
Controls	5 µl
Reagent	500 µl	500 µl	500 µl

Mix and incubate for 5 minutes at room temperature.

Read optical density (OD) of samples, standards and control(s) at 340 nm. Plot a standard curve and read the concentration of controls and samples.



Reference Values

680 - 1445 mg/dL

These values are for reference only. Each laboratory should establish its own reference values.

Performance Characteristics

1-Dynamic Range

0 - 2615 mg/dL

2-Detection Limit

80 mg/dL

3-Hook effect

> 52320 mg/dL

4-Sensitivity:

0.00020 ABS units/concentration unit

5-Specificity

Mono-specific

6-Interferences:

-No interference for: Haemoglobin (1000 mg/dL), Na-citrate (1000 mg/dL), Heparin (50 mg/dL), Triglyceride (2500 mg/dL), EDTA (5mg/dL) and Turbidity (5%).

-Bilirubin (20 mg/dL) interferes with the test.

7-Precision (CV%)

	Low	Medium	High
Intra run	0.80	1.8	1.15
Inter run	1.7	2.1	2.3

8- Methods Comparison

A comparison between Spectrum Diagnostics IgG reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.998 was obtained.

Precautions and warnings

1. For In vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

References

1. Dati, F. et al., Lab. Med. 13, 87 (1989)
2. Ichihara, K. et al - J. Clin. Lab. Anal. 10:110, 1996

