IMMUNOGLOBULIN G

Cat.No.	Pack name	Packing (Content)
BLT20027	IgG	5 x 25 ml IgG Buffer 1 x 10 ml IgG Antiserum 1 x 1 ml IgG Calibrator

EN

CE IVD

Intended Use
Quantitative determination of IgG in human serumby turbidimetric immunoassay.

Diagnostic Implications
IgG is a predominant serum immunoglobulin. The measurement of IgG is important for typing immunodeficiencies 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 defense against infection.

Method
Measurement of antigen-antibody reaction by the end-point method.

Reagents Provided

Buffer
Phosphate buffered saline (pH 7.43).
Polyethylene glycol (5 g/l)
Sodium azide (0.95 g/l).

Antiserum
Phosphate buffered saline (pH 7.43).
Polyclonal goat anti-human IgG (variable).
Sodium azide (0.95 g/l).

Calibrator
Pooled human serum, liquid and stabilized. Contains 0.09% sodium azide as preservative.
Concentration: See bottle label

Preparation and Stability of Reagents

Reagent Preparation
Liquid reagents, ready for use.

Stability and Storage
The reagents are 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.

Reagents required but not supplied
1. Sodium Chloride (9 g/l)
2. Calibrators and Controls

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Cat. No.:	Product name	Pack name	Content
BLT20024	IgG CALIBRATOR	IgG CAL H	1 x 1 ml
BLT20034	MULTICONTROL LEVEL 1	MULTICON L1	1 x 1 ml
BLT20035	MULTICONTROL LEVEL 2	MULTICON L1	1 x 1 ml

Sample collection
Use fresh serum. If the test can not 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.

Automation

Application procedures on clinical chemistry analyzers are available upon request.

Manual Procedure
Sample/Control: dilute 1:10 in saline 9 g/l
Reference curve : generate a reference curve by diluting the standard high level 1:10, 1:20, 1:40, 1:80, 1:160 in saline 9 g/l. Use saline 9 g/l as zero point.
Test : Mix 20 µl diluted standards, controls and samples with 900 µl buffer. Read optical density (OD1) of samples, controls and standards at 340 nm. Add 100 µl of IgG Antiserum. Mix and incubate for 5 minutes at room temperature. Read optical densities (OD2) of samples, controls and standards at 340 nm.

Calculate ΔOD's, plot a standardcurve and read the concentration of controls and samples.

Reference Values
680 - 1445 mg/dl (IFCC)
This range is given for orientation only. Each laboratory should establish its own reference values.

Performances
The performance characteristics for the IgG reagents were measured on a clinical chemistry analyzer.

Measuring Range : 0 - 2700 mg/dl

Detection Limit : 90 mg/dl

Hook effect : > 10000 mg/dl

Sensitivity : 0.00014 ABS units/concentration unit

Precision: [%CV]

	Low	Medium	High
Intra-Run	2.50	3.25	4.18
Inter-Run	4.08	1.83	

Accuracy: [mg/dl]

Control	Assigned	Measured
BIO-RAD 1	909(727-1091)	948
BIO-RAD 2	2695(2156-3234)	2732

Specificity : Monospecific
Interferences : No interference for : Hemoglobin (1000 mg/dl), Na-citrate (1000 mg/dl), Heparin (50 mg/dl), Bilirubin (20 mg/dl), Triglyceride (2500 mg/dl)
Limitations : None

Comparison with nephelometry: y = 0.987x – 0.2018
r = 0.9636

Stability at 4° C : at least 3 years after production

Precautions and warnings
1. 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. Polyethyleneglycol is not biohazardous
4. 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.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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References

Dati, F. et al., Lab. Med. 13, 87 (1989)

USED SYMBOLS:

REF Catalogue No

CE Mark - Device comply with the Directive 98/79/EC

LOT Batch Code

IVD In Vitro Diagnostics

Expiry Date.

Consult Instruction for Use

Manufactured by

Storage temperature

IMMUNOGLOBULIN G Product Name

CONT Content

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