Pariksha Biotech
A game changer in IVD

IgG Estimation Kit

High-Q Immunoglobulin IgG

Turbidimetric Immuno Assay (TIA)

HIGH®
Command on Quality

Intended Use:

Diagnostic reagent for quantitative in vitro determination of immunoglobulin G (IgG) in serum on photometric systems

Summary

The human immunoglobulin classes (IgG, IgA, IgM, IgE and IgD) are a group of functionally and structurally closely related glycoproteins. Human IgG has a molecular weight of about 150 000 dalton and consists of two identical heavy chains and two identical light chains which are bound together by disulfide bonds in a characteristic Y-shaped form. IgG is produced by plasma cells (B-cells) and represents about 75% of all soluble immmunoglobulin classes. The main function of IgG is to bind to antigens, initiating complement activation and trigger further catabolism of the antigen.

Decreased IgG concentrations occur in primary as well as in secondary immunodeficiency syndromes. Increased loss of proteins due to nephrotic syndrome may result in a decreased IgG concentration. A high increase of one immunoglobulin class due to multiple myeloma may result in a decrease in other immunoglobulin classes like IgG. Increased IgG concentrations can be observed in severe infections and autoimmune diseases. Many forms of myeloma produce high amounts of monoclonal or polyclonal IgG. Quantitative IgG determination is important for differential diagnosis of these diseases. All methods for IgG quantitation are calibrated for polyclonal IgG. The quantitation of monoclonal IgG is not standardized and values may differ for different reagents and methods. Values should only be used for follow up studies. Monoclonal immunoglobulinemia requires detailed differential diagnostic investigation in addition to the quantitative determination.

Specimen:

Serum, is the specimen.

Stability : 7 Days at 2-8°C and1 month at –20°C when frozen as aliquots

Avoid Freeze Thaw cycles

Components and the active ingredients of the reagents

Reagent 1 (R1) : 4-hydroxyethyl piperazine ethanesulfonic acid 50mmol/L

Reagent 2 (R2): Goat anti-human IgG antibody 1-3 mg/mL

All the reagents are liquids and are stable till the expiry date mentioned on the labels when stored properly at 2-8°C

Calibration:

IgG Calibrator is available as ready to use Liquid Calibrator and is stable till the expiry date mentioned on the labels when stored properly at 2-8°C

IgG Controls: Concentration lot specific and available as Lyophilized Controls and are available optionally. Controls are stable till the expiry date mentioned on the labels when stored properly at 2-8°C

Assay Procedure for Analyzers:

TEST PROCEDURE:

System Parameters:

Calibration Method	**Endpoint**
Reaction Direction	**Increasing**
Primary Wave Length	**630 (600-630)**
Flow Cell Temp.	**37°C**
Blank	**Distilled Water Blank**
Reagent Volume	**500 µl (R1 +R2)**
Sample Volume)	**5 µl**
Calibrator Conc	**Lot Specific (Check the labels))**
Units	**mg/dL**
Linearity	**3500**

PROCEDURE:

Reagent	**Cal**	**Sample**
IgG R1 Reagent	**400µL**	**400µL**
Calibrator	**5 µL**	**------**
Sample	**------**	**5µL**
Incubate for 5 Minutes at 37°C		
IgG R2 Reagent	**100µL**	**100µL**

Mix well and incubate for 5 minutes at 37°C Read the absorbance of Calibrator (C) Sample (S) against Distilled Water at 600 nms (600-630)

Calculations:

$$\text{IgG (in mg/dl)} = \frac{\text{Abs. of Sample}}{\text{Abs. of Calibrator}} \times \text{Calibrator Concentration}$$

Performance Characteristics:

Measuring Range (Linearity)

The test has been developed to determine IgG concentrations within a measuring range from 175 - 3500 mg/dL, at least up to the concentration of the highest calibrator. When values exceed the upper samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Specificity/Interferences:

Due to its antibodies, High-Q Immunoglobulin G is a specific immunoassay for human IgG. No interference was observed by conjugated and unconjugated bilirubin up to 60 mg/dL, hemoglobin up to 1000 mg/dL, lipemia up to 2000 mg/dL triglycerides and RF up to 1700 IU/mL.

No cross reaction with IgA or IgM was observed under test conditions.

Sensitivity/Limit of Detection:

The lower limit of detection (the minimum concentration which can be measured and distinguished from zero) is 8 mg/dL.

Imprecision:

According to protocol EP-5 of the NCCLS (National Committee of Clinical Laboratory Standards)

Within-run precision	Mean	SD	CV
n = 40	[mg/dL]	[mg/dL]	[%]
Sample 1	1173	14.1	1.20
Sample 2	1854	29.1	1.57
Sample 3	2217	36.0	1.62
Between day precision	Mean	SD	CV
n = 40	[mg/dL]	[mg/dL]	[%]
Sample 1	1173	9.49	0.81
Sample 2	1854	21.4	1.15
Sample 3	2217	34.1	1.54

Method Comparison:

A comparison of High-Q Immunoglobulin G to an immunoturbidimetric test (x) using 81 samples gave following results: y = 1.10 x – 52.9 mg/dL; r = 0.997.

A comparison of High-Q Immunoglobulin G (y) to a nephelometric test (x) using 79 samples gave following results: y = 1.08 x – 51.6 mg/dL; r = 0.992.

Reference values

Adults		**700 – 1600 mg/dL**
Children	**Newborns**	**700 – 1600 mg/dL**
	1 – 3 months	**250 – 750 mg/dL**
	4 – 6 months	**180 – 800 mg/dL**
	7 – 12 months	**300 – 1000 mg/dL**
	2 years	**350 – 1000 mg/dL**
	3 – 5 years	**500 – 1300 mg/dL**
	6 – 9 years	**600 – 1300 mg/dL**
	10 – 13 years	**700 – 1400 mg/dL**

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

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Literature

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7. Heil R, Koberstein R, Zawta B. Referenzbereiche für Kinder und Erwachsene. Roche Diagnostics 2004. p. 46–47.
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Ordering Information

Ref./Cat. No.	Pack Size	Presentation
P-IgG-25	25 ml	Liquid Stable two Reagents and Liquid Calibartor

Product Features

- Liquid Stable, Ready to use two reagents
- 10 Minutes Endpoint Assay
- Liquid Stable Calibrator Provided
- Linearity: 175-3500 mg/dL
- Measuring Wavelength 630nm (600 – 630 nm)
- Serum is the Specimen
- Available as multipurpose eagents and dedicated system packs

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Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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