Immunoglobulin G Assay Kit (IgG)

Method: immunoturbidimetric

Cat . No.	Size	Instrument
GB650M	R1: 2×50 ml R2: 2×10 ml	For Hitachi 7060/7150 &ShimadzuCL7200/8000
GS651M	R1: 2×50 ml R2: 2×10 ml	For Hitachi 7170/7080 &OlympusAU640/400/600

INTENDED USE
The immunoglobulin G assay kit is used for the quantitative determination of IgG in serum .

CLINICAL SIGNIFICANCE
IgG is the major Immunoglobulin produced by the plasma cells. It accounts for 70 to 75% of the total immunoglobulins. Its' major function is of neutralisation of toxins and destruction or removal of infectious agents that is accomplished by initiating either phagocytosis or to compliment cascade. IgG antibodies are produced in response to most bacteria and viruses. IgG has 4 main sub classes (IgG 1, IgG2, IgG3 and IgG4). Polyclonal IgG increases may be present in systemac lupus rythematosis, chronic liver disease, infectious disease and cystic fibrosis. Monoclonal IgG increases are present in IgG myeloma. Decreased levels of IgG are found in congenital and acquired immunodeficiency diseases of selective IgG subclass deficiencies. Decreased IgG concentrations are also seen in protein losing enteropathies, nephorotic syndrome and through the skin form burns.

ASSAY PRINCIPLES
This assay is based on the reaction between IgG antigen and anti-IgG antibody. This reaction forms an insoluble complex producing a turbidity, which is measured spectrophotometrically. The amount of complex formed is directly proportional to the amount of IgG in the sample.

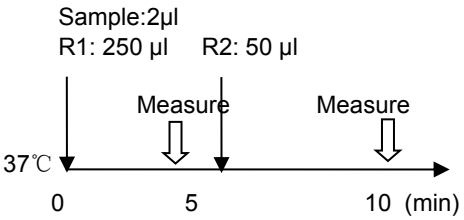
REAGENT COMPOSITION

Contents	Concentration of solutions
Reagent 1 (R1)	
TRIS Buffer pH 7.6 with PEG	18.16 mmol/l
Sodium Chloride	123.20 mmol/l
Preservative & Detergent	---
Reagent 2 (R2)	
TRIS Buffer pH 7.6	18.16 mmol/l
Anti IgG antibody	---
Preservative	---

SAMPLE COLLECTION AND PREPARATION
Use fresh patient serum , serum should be separated from cells within 2 hours after collection.
Stability: up to 3 months at 2-8℃.

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
Once opened avoiding contamination.

ASSAY PROCEDURE
Test Procedure for Analyzers (Hitachi 7080)
Assay Mode: 2 POINT END 16-31
Wave Length (sub/ main): None/ 700nm



CALIBRATION
Recommend that this assay should be calibrated using special protein calibrator GC-IgG.

CALCULATION OF RESULTS
The analyser automatically calculates the IgG concentration in the sample according to the calibration curve.

QUALITY CONTROL
Randox liquid assayed special protein controls, Level 1 Level 2 and Level 3 are recommended for daily quality control. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE
Serum or plasma: 700 to 1600 mg/dl (7 to 16 g/l)
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear between IgG concentrations of 30-3500 mg/dl (0.3-35.0 g/l). If the Sample above this concentration should be diluted it with 0.9% NaCl and repeat assay.

PRECISION
The CV of the test should be CV ≤5%

Intar assay precision			
N=20	level 1	level 2	level 3
Mean(mg/dl)	701.34	1415.77	2257.54
SD	22.27	21.87	31.15
CV(%)	3.18	1.55	1.38

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/dl)	709.3	713.7	711.1

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$\bar{x}$	711.4
(Xmax-Xmin)/$\bar{x}$	(713.7-709.3)/711.4*100=0.37%

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin up to 500 mg/dl
Intralipid up to 500 mg/dl
Direct bilirubin up to 40 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Gitlin D, Edelhoch HJ. Immunol. 1951, 66, 76-78.
2. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54 and 462-494.
3. Guder WG, Narayanan S, Wisser H, Zawta B. List of Analytes; Pre-analytical Variables. Brochure in: Samples: From the Patient to the Laboratory. Darmstadt: GIT Verlag, 1996.

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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