NEO TURBI

IMMUNOGLOBULIN-G (IgG)

(Turbidimetry Method)

KIT NAME	KIT SIZE
NEO TURBI - IgG	1 x 20 ml

NEOGENIX
DIAGNOSTICS PVT LTD

INTRODUCTION

Immunoglobulin G (IgG) is intended for Invitro quantitative determination of IgG in human serum. Immunoglobulin G (IgG) is the principle immunoglobulin in all extracellular fluids and makes up about 75% of the plasma immunogloulins in adults. IgG provides one of the body's major defence against bacterial infection by eliminating small soluble proteins and enhance the clearance through the reticuloendothelial system. Measurement of IgG levels is used for diagnosis of infectious and inflammatory diseases, diagnosis of malignancies, and detection of soluble antigens and monitoring therapy in myeloma. Deficiency of IgG may be genetic or acquired

METHOD PRINCIPLE

The Kit utilizes latex-enhanced immunoturbidimetry to measure the IgG level in human serum or plasma. During the test, IgGin the sample binds with the specific anti IgG antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry, analyzer. The change in absorbance is proportional to the level of IgG in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations

KIT CONTENTS

R1 - IgG Buffer	1 x 15 ml
R2 - IgG Antibody	1 x 5 ml
R3 - IgG Calibrator	0.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 7-10 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-IgG and R2-IgG reagents of 3 parts of R1-IgG with 1 part of R2-IgG. Avoid foaming.

CONCENTRATIONS IN THE TEST

R1 - Phosphate buffer, Polyethylene glycol, Sodium azide < 0.1%
R2 - Anti-IgG antibodies, Tris buffer, sodium azide < 0.1%

Warnings and notes

1. The Kit is for in vitro diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 630 nm
- Thermostat at 37ºC
- General laboratory equipment

SPECIMEN

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 4° C for up to 3 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing

PLOTTING OF MULTIPOINT CURVE

The Turbichem IgG is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial Dilution Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE

These reagents may be used both for manual assay and in several automatic analyzers. Programme Sheets are available on request.

Wavelength 630 nm
Temperature 37°C
Cuvette 1 cm

Pipette into the cuvette:

Reagent	Blank	Calibrator (C)	Test (T)
R1 IgG Buffer	750 µl	750 µl	750 µl
Calibrator	-	10 µl	-
Sample	-	-	10 µl
Distilled Water	10 µl	-	-
Mix well and incubator for 5 mins. at 37° C			
R2 IgG Anitbody	250 µl	250 µl	250 µl

Mix well & incubate for 5 min. at 37 C. Measure the absorbance of calibrator & sample against reagent blank (B).

CALCULATION

$$\text{IgG concentration} = \frac{\text{Abs.Test}}{\text{Abs.Calibrator}} \times \text{Calibrator Concentration}$$

REFERENCE VALUES

800 to 1700 mg/dL

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

PERFORMANCE CHARACTERISTICS

- **Linearity:** 0 to 3500 mg/dL
- **Precision:** within Run CV $\leq$ 6 %
- **Specificity / Interferences**
  No interference detected for bilirubin upto 60 mg/dL and hemoglobin 10 g/L

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Burtis C, Ashwood, ER (ed). Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA; WB Saunders Co; 509; 1999.
2. Junqueira, Luiz C.; Jose Carneiro (2003). Basic Histology. McGraw-Hill. S Fagarasan and T Honjo (2003). "Intestinal IgA Synthesis: Regulation of Front-line Body Defenses". Nat. Rev Immunology 3(1): 63–72.
3. Tietz NW, Pruden E, McPherson RA, Fuhrman, SA (eds).Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Co; 355–357; 1995.

SYSTEM PARAMETERS

Method	End Point
Wavelength	630 nm
Zero Setting	Reagent Blank
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	5 mins + 5 mins
Delay Time	----
Read Time	----
No. of Reading	2
Interval Time	----
Sample Volume	0.010 ml (10 ul)
Reagent Volume	1.0 ml (1000 ul)
Calibrator Concentration	Refer Calibrator vial
Units	mg/dl
Factor	----
Reaction Slope	Increasing
Linearity	3500 mg/dl