IMMUNOGLOBULIN G

(IgG Turbidimetric)

Diagnostic reagent for determination of IgG concentration.

Liquid. Mono Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
TA150	5 X 25 mL	DMT150	990 Tests	BY151	2652 Tests	MAB150	909 Tests
TA151	5 x 10 mL	RAB150	370 Tests	KAB150	2439 Tests	MAB151	455 Tests
TAB150	1167 Tests	SAB151	545 Tests	KAB151	1220 Tests	LAB150	2667 Tests
NAB150	848 Tests						

INTENDED USE

The test is applied for the quantitative determination of IgG (Immunoglobulin G) in human serum or plasma.

The major immunoglobulin produced by plasma cells is IgG, which makes up to 75% of the total immunoglobulins.

Plasma IgG concentration is decreased in inherited or acquired deficiencies of immunoglobulin production.

Diffuse (polyclonal) hyperimmunoglobulinemia is the normal response to infections. IgG tends to predominate in autoimmune responses as well as in chronic active hepatitis. Increases in serum monoclonal IgG (paraprotein) are found in multiple myeloma and other proliferative disorders of plasma cells.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

TEST PRINCIPLE

Immunoglobulin G in the sample precipitates in the presence of anti-human immunoglobulin G antibodies. The light scattering of the antigen-antibody complexes is proportional to the immunoglobulin G concentration and can be measured by turbidimetry.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 540 nm
Temperature : 37°C
Sample : Serum / Plasma
Linearity : 0.2 mg/dL - 3500 mg/dL

REAGENT COMPOSITION

Reagent 1:
Imidazole buffer ≤ 0.2 mol/L,
Goat anti-human IgG antibodies,
Sodium azide ≤ 1.00 g/L, pH 7.5.

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE

Store at 2-8ºC.

The Reagent is stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during its use.

Indications of deterioration: Presence of particulate material, turbidity, absorbance of the blank over 0.300 at 540 nm.

Once opened vials (reagent 1) are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum or plasma collected by standard procedures. Use heparin or EDTA as anticoagulants. Lipemic samples are not suitable for testing.

IgG in serum or plasma IgG is stable for 7 days at 2-8°C, 15 days at 20 - 25°C and 3 years at -20°C.

For reagents which are related antigen antibody interaction, do not shake the sample, just gently mix.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Calibration curve: Plot the absorbance values of each calibrator against its IgG concentration. Use the Blank as the calibrator of 0 concentration. IgG concentration in the sample is calculated by interpolation of its absorbance on the calibration curve.

REFERENCE INTERVAL (NORMAL VALUES)*

Serum, adults: 700 - 1600 mg/dL

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

It is recommended to use the Protein Control Serum level I (PCN01) and II (PCN05) to verify the performance of the measurement procedure.

Protein Calibrators (ARCHEM). The set contains 5 different levels of IgG concentration and it should be used to prepare the calibration curve. The calibrators are supplied ready to use.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 0.2 mg/dL IgG

High Linearity: 3500 mg/dL. For higher values dilute sample 1/5 with distilled water and repeat measurement.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean concentration	CV	n
713 mg/dL	4.1%	20
1712 mg/dL	4.8%	20

Reproducibility (run to run) (Inter-assay)

Mean concentration	CV	n
713 mg/dL	4.8%	25
1712 mg/dL	4.1%	25

Sensitivity (LOD): 0.580 mA dL/mg at 1600 mg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Prozone effect: Falsely low values are obtained when IgG is present in the sample at a concentration higher than 6000 mg/dL.

Interferences: Bilirubin (20 mg/dL), hemoglobin (10 g/L) and rheumatoid factors (300 IU/mL) do not interfere. Lipemia (triglycerides > 15 g/L) may affect the results. Other drugs and substances may interfere.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.
8. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.

S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage
GLP : Good Laboratory Practice
IgG : Immunoglobulin G
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

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