

IGG (IMMUNOGLOBULIN G)

TURBIDIMETRY

Intended use:

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^{1,2}.

Test principle:

Immunoglobulins G (IgG) selectively react with an anti-IgG antibody and form an immunocomplex. The produced turbidity is proportional to the concentration of IgG in the sample, and can be measured at the wavelength of 600 nm

Reagent concentration:

R1: Buffer pH 7.50, PEG ≥ 2%, stabilizers and preservative.

R2: Anti-human IgG antibody ≥ 2%, stabilizers and preservatives.

Preparation and stability:

R1: Reagent is provided ready to use.

R2: Reagent is provided ready to use.

The Reagent is stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during its use. Up to the expiration date 2° to 8°C

On board stability: R1: 28 days
R2: 28 days

Specimen:

Serum, plasma. Keep specimens away from direct light sources. Samples are stable 7 days when stored at 2-8°C and 1 month at -20°C.

Limitations - interference:

Criterion: Recovery within ±10% of initial value.

Icterus: No significant interference up to an index I of 26 (approximate conjugated and unconjugated bilirubin concentration: 26 mg/dl).

Hemolysis: No significant interference up to an index H of 1000 (approximate haemoglobin concentration: 1000 mg/dl).

Lipemia (Intralipid): No significant interference up to an index L of 950 (approximate triglycerides concentration: 2000 mg/dl). There is poor correlation between turbidly and triglycerides concentration. Rheumatoid factors < 630 IU/l do not interfere.

Expected values:

Adults: 700 - 1600 mg/dL

Newborns 700 - 1480 mg/dL

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range.

For diagnostic purposes the test results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

Measuring/reportable range:

20 - 3500 mg/dL

At higher concentrations, dilute the sample with 0.9% NaCl (e.g. 1 +4). Multiply the result by the appropriate factor (e.g.5).

Testing procedure:

Applications for automated systems are available on request.

Materials provided

· Working solutions as described above *Additional materials required*

0.9% NaCl

Manual procedure:		
Wavelength:	600 nm	
Temperature:	+37°C	
Cuvette:	1 cm	
Zero adjustment:	against reagent blank	
	Blank	Sample/ Calibrator
Sample/Calibrator	-- --	7.5 µl
R1	600 µl	600 µl
Mix, incubate at 37°C for 5 minutes. Read against reagent blank the absorbances of calibrator and Sample		
R2	150 µl	150 µl
Mix, incubate at 37°C for 5 minutes. Read against reagent blank the absorbances of calibrator and Sample		
Calculation:		
A = [(A) sample or Calibrator] - [(A) blank]		
The concentration of IgG in patient sera has to be calculated from A using linear method For zero value is recommended to use saline solution (0.9%)		

Imprecision:

intra -assay(n=10)	Mean (mg/dl)	S.D(mg/dl)	C.V%
Sample 1	1245	20	1,58
Sample 2	1601	19	1,16
inter -assay(n=20)	Mean (mg/dl)	S.D(mg/dl)	C.V%
Sample 1	1239	28	2,28
Sample 2	1598	28	1,77

Methods comparison:

A comparison between BIOANALYTIC and a commercially available product gave the following results:

IgG competitor = x IgG BIOANALYTIC = y

n = 72

y = 0.985x - 48 mg/dl

r2 = 0.99

Quality Control:

Human Control Serum:

BIOANALYTIC Protein Control Serum L2 1 x 1 ml #B10844

BIOANALYTIC Protein Control Serum L1 1 x 1 ml #B10845

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration:

BIOANALYTIC Protein Calibrators. 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.

S1: BIOANALYTIC PROTEIN CALIBRATOR

Calibration frequency:

Calibration is recommended

· After lot change

· As required following quality control procedures

· A calibration is recommended at least every 2 months, after reagent lot change or as required by quality control procedures.

Literature:

- Narayanan S. Method-comparison studies on immunoglobulins. *Clin Chem* 1982; 28: 1528-1531.
- Price CP, Spencer K and Whicher J. Light-scattering immunoassay of specific proteins: a review. *Ann Clin Biochem* 1983; 20: 1-14.
- Dati F et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference range for 14 proteins in serum based on the standardization against the IFCC/CAP reference material (CRM 470). *Eur J Clin Chem Clin Biochem* 1996; 34: 517-520.
- Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
- Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.

Order information (Cat No.):

CR434	B24200	B27201	B30201	B33201	B37200
B21200	B25200	B28200	B31200	B34200	B80200
B21201	B25201	B28201	B32200	B35200	
B22200	B27200	B30200	B33200	B36200	

Manufacturer








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SYMBOLS

-  IVD for in vitro diagnostic use only
-  LOT lot of manufacturing
-  REF code number
-  storage at temperature interval
-  expiration date (year/month)
-  warning, read enclosed documents
-  Read the directions

