IGA (IMMUNOGLOBULIN A)

TURBIDIMETRY

Intended use:

Immunoglobulin A in the sample precipitates in the presence of anti-human immunoglobulin A antibodies. The light scattering of the antigen-antibody complexes is proportional to the immunoglobulin A concentration and can be measured by turbidimetry[1,2].

Test principle:

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

Reagent concentration:

R1: Buffer pH 7.5, PEG > 2% ,stabilizers and preservatives.
R2: Anti -human IgA antibody >2 % stabilizers and preservatives.

Preparation and stability:

R1: Reagent is provided ready to use.

R2: Reagent is provide 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 at +2^0 C to +8^0 C

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

Specimen:

Serum, plasma. Keep specimens away form 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 1000 (approximate triglycerides concentration: 1290 mg/dl). There is poor correlation between turbidly and triglycerides concentration. Rheumatoid factors < 630 U/l do not interfere.

Testing procedure:

Applications for automated systems are available on request.

Materials provided

- Working solutions as described above *Additional materials required*
- Calibrators and controls as indicated below
- 0.9% NaCl

Manual procedure:		
Wavelength:	600 nm	
Temperature:	+37°C	
Cuvette:	1 cm	
Zero adjustment:	against reagent blank	
	Blank	Sample/ Calibrator
Sample/Calibrator	-- --	5 µl
R1	600 µl	600 µl
Mix, incubate at 37^{0}C for 5 minutes.Read against reagent blank the absorbances of calibrator and Sample		
R2	150 µl	150 µl
Mix ,incubate at 37^{0}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 IGA in patient sera has to be calculated from A using linear method For zero value is recommended to use saline solution (0.9%)		

Measuring/reportable range:

10 - 2000 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).

Expected values:

Adults: 70 - 400 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.

Imprecision:

Reproducibility was determined using

İntra -assay(n=10)	Mean (mg/dl)	S.D(mg/dl)	C.V%
Sample 1	146	2	1,04
Sample 2	238	2	0,94
İnter -assay(n=20)	Mean (mg/dl)	S.D(mg/dl)	C.V%
Sample 1	146	7	4,99
Sample 2	240	10	4,16

Methods comparison

A comparison between BIOANALYTIC and a commercially available product gave the following results: IgA competitor = x IgA BIOANALYTIC = y

n = 21

y = 0.97x + 4 mg/dL r2 = 0.99

Quality Control:

Human Control Serum:

Protein Control Serum L2 1 x 1 ml #B10844

Protein Control Serum L1 1 x 1 ml #B10845

Calibration:

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

S1:BIOANALYTIC PROTEIN CALIBRATOR

Literature:

1.Narayanan S. Method-comparison studies on immunoglobulins. *Clin Chem* 1982; 28: 1528-1531.

2.Price CP, Spencer K and Whicher J. Light-scattering immunoassay of specific proteins: a review. *Ann Clin Biochem* 1983; 20: 1-14.

3.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 standarization against the IFCC/CAP reference material (CRM 470). *Eur J Clin Chem Clin Biochem* 1996; 34: 517-520.

4.Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

5. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.

Order information (Cat No.) :

CR429	B24190	B27191	B30191	B33191	B37190
B21190	B25190	B28190	B31190	B34190	B80190
B21191	B25191	B28191	B32190	B35190	
B22190	B27190	B30190	B33190	B36190	

Manufacturer

Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti
Adress : İkitelli O.S.B Mutsan San.Sit. M4 Blok No:17-19 Başakşehir/İSTANBUL
Tel:+90(212) 549 33 88- Fax:+90 (212) 549 55 50
Web :www.diaclinica.com

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

ISO 9001:2015
ISO 13485:2016