Immunoglobulin E Turbidimetric
IgE Turbidimetric

An IgE test system is a device intended for the quantitative in vitro determination of immunoglobulin E (IgE) concentration in human serum or plasma.

Liquid. Dual 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
TA200	5 x 50 mL	01R89-41	1818 Tests	BY9500	2144 Tests	MIGE20	1061 Tests
TA201	5 x 25 mL	01R89-31	545 Tests	BY9501	1608 Tests	MIGE21	707 Tests
TA202	5 x 10 mL	01R89-21	364 Tests	NIG200	400 Tests	KIGE20	4364 Tests
LIG20	3600 Tests	SIGE20	1246 Tests	DME20	1260 Tests		
LIG21	1800 Tests	SIGE21	692 Tests	RIGE21	923 Tests		

* 01R89-41 / 01R89-31 / 01R89-21 Ref Number Products are Produced Specifically for Abbott Architect Biochemistry Analyzer Series

INTENDED USE

The test is applied for quantitative determination of immunoglobulin E (IgE) concentration in human serum or plasma.

TEST PRINCIPLE

Based on antigen antibody reaction. IgE is an immunoglobulin with a molecular weight of approximately 190,000Da and is normally present in the blood in trace amounts. IgE antibodies are the chief immunoglobulin responsible for immediate hypersensitivity reactions in humans.

Quantitative determination of IgE is maybe done by an immunoturbidimetric method, by automatic analysers or in manual. Mixing a sample with a precise Antigen to a solution having the corresponding anti-serum (Antibody), in a well-defined ratio, it is possible to have turbidity.

Using our multipoint Calibrator, it is possible to prepare a Calibration Curve to refer, generally not rectilinear and not crossing the origin.

Plotting on the Calibration Curve absorbance values and concentration for each single sample, may be determined the concentration of each sample.

TEST PARAMETERS

Method : Two points, Immunoturbidimetric
Wavelength : Main 578 nm
Temperature: 37°C
Sample : Serum, plasma
Linearity : 14 - 1000 IU/mL

REAGENTS COMPOSITION

Reagent 1:

Buffer PBS modif	> 25 mmol/L
Sodium Azide	≤ 0.09% w/v

Reagent 2 Latex Particle

Anti-IgE (goat) Latex	
Buffer PBS modif	≤45 mmol/L
Sodium Azide	≤0.09% w/v

REAGENTS PREPARATION

All reagents are ready to use.
Working reagent: If reagents are mixed in reduced quantities, mix 2 parts of reagent 1 with 1 part of reagent 2. (2 mL R1+1 mL R2)

Working reagents are stable for 7 days at 2-8ºC when they are stored in closed vials and avoiding contamination after preparation.

Reagent 1: Buffer Solution
Reagent is ready to use.
Buffer is ready for use and is stable up to the expiry date when stored at +2 to +8°C protected from light.

Reagent 2: Latex Suspension
Reagent is ready to use.
Latex suspension is ready for use and stable up to the expiry date when stored at +2 to +8°C protected from light.

Before using invert several times and preventing from formation of foam.

For manual working procedures; if working reagent will be used; first shake Reagent 2 vial gently then pouring its contents to reagent 1 vial. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse

the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

On board stability of R1 and R2 are 30 days. Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. There is a strong relation between on board stability and auto analysers cooling specification and carry-over values.

SAMPLE

Collect Serum using standard sampling tubes and plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin, Citrate) using heparinised tubes. Analyse immediately or store at 2°C to 8°C for up to 72 hours or 6 months at -20°C.

For reagents which are related antigen antibody interaction, do not shake the sample, R2, control and calibrator; just gently mix.

TEST PROCEDURE

Sample Start
In case of request, ready application procedures dedicated to different kind of photometers and ready manual working procedures can be supplied.

In case of request, ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied.

Substrate Start
In case of request, ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied.

CALCULATION

The IgE concentration in the sample is calculated using the following general formula:

$$\frac{A2 - A1\ Sample}{A2 - A1\ Standard} \times C\ Standard = C\ Sample$$

Unit Conversion

IU/mL = KIU/L
IgE U/mL*0.715= IgE IU/mL
IgE µgr/L*0.298= IgE IU/mL

REFERENCE INTERVALS (NORMAL VALUES)

Upper Limit of Normal Range (95th percentile)

New Born:	1.5 IU/mL
Up to 1 year:	15.0 IU/mL
Children 1 to 5 year	60.0 IU/mL
Children 6 to 9 year	90.0 IU/mL
Children 10 to 15 year	200.0 IU/ML
Adults	**100.0 IU/ML**

*It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

QUALITY CONTROL AND CALIBRATION

Daily quality control is recommended.
Ref No: IGCN01 (01R98-01) IGE Control Level I
Ref No: IGCN02 (01R98-01) IGE Control Level II

Calibration:
Ref No: IGCL06 (01R99-01) IGE Calibrator Set
Calibration stability: 30 days, may differ from analyzers models.

*Calibration Stability is strongly depending of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days in general.

*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 (LOQ) (Based on CLSI EP17A2E document and ARCHITECT c Systems, Also LOQ values are based on CV% values lover %20): 14 IU/mL. Considerable variation may be seen in linearity depending on the analyzer model and application method.

Sensitivity (LOD) (Based on CLSI EP17A2E document): 5 IU/ML.

High Linearity: This method is linear between IgE concentrations of 14 and 1000 IU/ml (or 7-500 IU/mL). These values are dependent on the lot specific value of the calibrator in use.

Considerable variation may be seen in linearity depending on the analyzer model and application method.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run) (intra-assay): Intra assay precision is determined on 20 replications of 2 samples.

Mean concentration	S.D.	CV%	n
106.5 IU/ml	6.5	3.2	20
197.2 IU/ml	5.8	1.5	20

Reproducibility (run to run) (inter-assay): Determined for 5 days with 20 replications for each days, for two samples.

Mean concentration	S.D.	CV%	n
108.1 IU/ml	6.8	3.3	20
199.5 IU/ml	7.4	2	20

Correlation: Corr with a reference reagent is: r=0,99 (Between 30 IU/ML to 450 IU/ML)

Trueness: No systematic differences seen in results obtained with this reagent when compared with reference reagents. It's available to get details of comparison experiments in case of requirement.

Prozone effect: It was not observed up to a level of 22000 IU/ml.

Interferance: According to findings, the assay was not affected by the interference with the following analyte concentrations:

Triglycerides	1000 mg/dL,
Free Bilirubin	25 mg/dL,
Conjugated Bilirubin	25 mg/dL,
Hemoglobin	1000 mg/dl,
Intralipid®	800 mg/dL.

Methods comparison and a Correlation
A correlation coefficient of 0.98 was obtained with an alternate commercially available method.

Accuracy: A group of 20 sera has been tested using this procedure and using a similar reagent available on the market. The comparison gave these results:
Linear regression equation y = 1.0037x - 4
Correlation coefficient r = 0.9993 n = 20

An analyzer has been used to obtain these performance characteristics. Usage of different analyzer or a manual procedure may cause the variance in results.

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 capped and kept at 2-8°C. Caps of the reagents bottles can not 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 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

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IgE : Immunoglobulin E
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
R2	Reagent 2
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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