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	5x50 ML	RIGE21	923 Tests	BY9500	2144 Tests	MIGE20	1061 Tests
TA201	5x25 ML	TIGE20	2206 Tests	BY9501	1608 Tests	MIGE21	707 Tests
TA202	5x10 ML	TIGE21	1324 Tests	NIG200	400 Tests	KIGE20	4364 Tests
LIG20	3600 Tests	SIGE20	1246 Tests	DME20	528 Tests		
LIG21	1800 Tests	SIGE21	692 Tests				

INTENDED USE

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

TEST PRINCIPLE

Based on antigen anti body 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 : Endpoint, Turbidimetric
Wavelength : 600 nm
Temperature: 37°C
Sample : Serum, plasma
Linearity : 14 IU/mL - 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 4 parts of reagent 1 with 1 part of reagent 2. (4 MLR1+1 MLR2)
Working reagents are stable 7 days at 2-8ºC in case of closed vials and avoiding contamination after preparation.

Reagent 1: Buffer Solution
All reagents are ready to use.
On Board Stability: 30 days
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
All reagents are ready to use.
On Board Stability: 30 days
Latex suspension is ready for use and stable up to the expiry date when stored at +2 to +8°C protected from light. Invert several times before use, avoiding the formation of foam.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. 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 all reagents are 30 days. Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to 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, 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.

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

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) (Based on rules CLSI C28-P Document)*

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 IGE Control Level I
Ref No: IGCN03 IGE Control Level II

Calibration:
Ref No: IGCL06 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: 14 IU/mL

High Linearity: This method is linear between IgE concentrations of 14 and 1000 IU/ml. In the event of a rerun the upper limit of the assay range is extended to 1500 IU/mL. These values are dependent on the lot specific value of the calibrator in use.
Linearity may considerably vary depending on the instrument used.

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

Sensitivity (LOD) (Based on CLSI EP17 document): 3 IU/mL

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: It was not observed up to a level of 22240 IU/ml.

Interferance: Interference with the following analyte concentrations was not found to affect the assay. Triglycerides 1000 mg/dL, Free Bilirubin 25 mg/dL, Conjugated Bilirubin 25 mg/dL, Haemoglobin 1000 mg/dl, Intralipid® 800 mg/dL.

Methods comparison and a Correlation
A correlation coefficient of 1.00 was obtained with an alternate commercially available method. Two levels of controls should be assayed at least once a day.

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

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 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 "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

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

REFERENCES

1. Berry, M. N. et al., (1988) Clin. Chem. 34,2295.
2. Tietz, N. W. (1983) Clinical guide to Laboratory Tests, p384 W.B. Saunders Co., Philadelphia.
3. Imagawa M. et al., Clin. Chim. Acta, 117, 199 (1981).
4. Neumeister B., Besenthal I., Liebich H.: Diagnostyka
5. Young D.S., Effect of drugs on Clinical Lab. Test, 5th Ed. AACC Press (2000).
6. CLSI(NCCLS) C49-A/H56-laboratoryjna., Urban & Partner, 126-127, (2001).
7. Roitt I., Brostoff J., Male D.: Immunology., 22.2 – 22.5, MOSBY, (1996).

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

CE

Archem Diagnostics Industry LTD. ŞTİ.
Organize Sanayi Bölgesi, Mutsan Sanayi Sitesi
M8 Blok No: 48 Başakşehir / ISTANBUL TURKEY
Tlf: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr
www.archem.com.tr