IgE

Immunoturbidimetric method for the determination of Immunoglobulin E

SUMMARY

Immunoglobulin E (IgE) is an immunoglobulin which is present in blood in trace amounts. Continuous production of IgE antibodies (reagins) in response to natural common allergens, causes high levels in serum and the development of allergic reactions such as asthma, hay fever, dermatitis and food allergies.
High IgE levels are also seen in parasitic diseases, IgE myeloma and hepatitis. The determination of serum IgE is thus useful for diagnosis, treatment and monitoring of such diseases.

PRINCIPLE

Immunoglobulin E present in the sample reacts with the latex particles coated with anti-human IgE antibodies producing agglutination. The turbidity caused by agglutination is proportional to the concentration of IgE in the sample and can be measured spectrophotometrically.

PROVIDED REAGENTS

A. Reagent A: 50 mmol/l glycine buffer, pH 8.3, containing 0.9 g/l sodium azide as preservative.
B. Reagent B: latex particles coated with anti-human IgE mouse antibodies in glycine buffer, pH 7.3, containing 0.9 g/l sodium azide as preservative.

NON-PROVIDED REAGENTS

- I**gE Calibrator Turbitest AA** from Wiener lab.
- Saline solution (9 g/l NaCl)

INSTRUCTIONS FOR USE

Provided Reagents: ready to use.

WARNINGS

The reagents are for "in vitro" diagnostic use.
Use the reagents keeping the usual work precautions in the clinical laboratory.
All reagents and samples should be discarded according to local regulations.

STABILITY AND STORAGE INSTRUCTIONS

Provided Reagents are stable at 2-10 ºC until the expiration date shown on the box. Do not freeze.

SAMPLE

Serum or plasma
a) Collection: obtain serum in the usual way.
b) Additives: if the sample used is plasma, the use of heparin, EDTA or citrate as anticoagulant is recommended.
c) Known interfering substances: no interference is observed by bilirubin up to 30 mg/dl, hemoglobin up to 500 mg/dl and triglycerides up to 500 mg/dl.
Refer to Young bibliography for the effects of drugs on the present method.
d) Stability and storage instructions: preferably use fresh samples. If the test cannot be performed immediately, it can be frozen (-20ºC). Avoid repeated freezing and thawing.

REQUIRED MATERIAL (non-provided)

- Volumetric material for measuring the stated volumes.
- Autoanalyzer.

CALIBRATION

Use **IgE Calibrator Turbitest AA** from Wiener lab for calibration. Calibrator concentrations differ batch to batch and are indicated on the label of the reagent.
Use saline solution (0.9% NaCl) for zero point calibration (blank solution).
It is recommended that each laboratory determine the calibration frequency depending on the automated analyzer in use, as well as the type and number of tests to be performed. A new calibration curve should be performed at least once a month or when a new batch of reagents is used.

ASSAY CONDITIONS

General parameters for automatic analyzers:

Reaction type	Endpoint
Primary Wavelength	570 nm
Temperature	37ºC
Sample volume	3.5 ul
Reagent volume	140 ul
Reagent B volume	70 ul
Reagent A Incubation	5 min
Reagent B Incubation	5 min
Calibration	6 points

QUALITY CONTROL METHOD

I**gE Control Turbitest AA** from Wiener lab.
The Controls are processed in the same way as the samples.

REFERENCE VALUES

Normal values are considered up to 358 IU/ml
It is recommended that each laboratory establish its own reference range for its population.

UNITS CONVERSION
IgE (IU/ml) = IgE (kIU/l)

PROCEDURE LIMITATIONS
See Known interfering substances under SAMPLE.
Turbidity and particles in the samples may interfere with the test. Therefore, the particles that may result from an incomplete coagulation or denaturation of proteins, must be removed by centrifugation prior to testing.
Samples containing IgE levels above the assay range, should be diluted using 9 g/l NaCl (e.g. 1 + 1) and retested. Correct the results according to the dilution factor (e.g. 2).

PERFORMANCE
a) Accuracy
It is evaluated according to protocol EP 15-A from CLSI. In this study two samples with different levels of IgE tested with 2 daily runs in duplicate for 5 days were used.

Mean	CV_{wr}	CV_{total}
62,36 IU/ml	0,56%	1,40%
393,40 IU/ml	0,47%	1,67%

b) Detection limit: 5 IU/ml.
c) Linearity: up to 1000 IU/ml.
d) Prozone effect: no prozone effect was observed up to 15,000 IU/ml IgE with a measuring range up to 1000 IU/ml.

PARAMETERS FOR AUTOANALYZERS
For programming instructions refer to the user manual of the analyzer in use.
For calibration use l**gE Calibrator Turbitest AA** from Wiener lab.

WIENER LAB PROVIDES
1 x 30 ml Reagent A
1 x 15 ml Reagent B
(Cat. Nº 1513267)

1 x 30 ml Reagent A
1 x 15 ml Reagent B
(Cat. Nº 1009704)

1 x 30 ml Reagent A
1 x 15 ml Reagent B
(Cat. Nº 1009971)

REFERENCES

- Ichihara, K. et al - J. Clin. Lab. Anal. 10:110 (1996).
- Itoh, Y. et al - J. Clin. Lab. Anal. 11:39 (1997).
- Maynard, Y. et al - Clin. Chem. 32/5:752 (1986).
- Dati, F - Journal of IFCC VIII/1:29 (1996).
- EP15-A - User Verification of Precision and Estimation of Bias; Approved Guideline - NCCLS.
- Tietz Textbook of Clinical Chemistry - Burtis, C.; Ashwood, E. (5º Edition) WB Saunders, 2001.
- Young, D.S. - "Effects of Drugs on Clinical Laboratory Tests", AACC Press, 5th ed., 2000.

SYMBOLS
The following symbols are used in the packaging for Wiener lab. diagnostic reagents kits.

CE	This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices
EC REP	Authorized representative in the European Community
IVD	"In vitro" diagnostic medical device
Σ	Contains sufficient for <n> tests
	Use by
	Temperature limitation (store at)
	Do not freeze
	Biological risks
→	Volume after reconstitution
Cont.	Contents
LOT	Batch code
	Manufactured by:
	Harmful
	Corrosive / Caustic
	Irritant
i	Consult instructions for use
Calibr.	Calibrator
CONTROL +	Control
CONTROL +	Positive Control
CONTROL −	Negative Control
REF	Catalog number

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