IgE- turbilatex

Latex turbidimetry

Quantitative determination of immunoglobulin E (IgE)

CE

IVD

PACKAGING

Ref.: 101-0478	Cont.: 1 x 20 mL / 1 x 10 mL

Store 2 - 8º C.

CLINICAL SIGNIFICANCE

IgE is an immunoglobulin with a molecular weight of approximately 190,000 normally present in trace amounts. Continual production of IgE antibodies in response to common naturally occurring allergens, however, often results in elevated serum levels and in the development of such clinically important Type I allergic reactions as asthma, hay fever, dermatitis and food allergies. Elevated IgE levels are also seen in parasitic diseases, IgE myeloma, and in hepatitis. The measurement of IgE in human serum is thus considered to be useful in the diagnosis, treatment assessment of disease progression, or postoperative prognosis for such conditions.

PRINCIPLE OF THE METHOD

The IgE-Turbilatex is a quantitative turbidimetric test for the measurement of IgE in human serum or plasma.

Latex particles coated with mouse IgG anti-human IgE are agglutinated when mixed with samples containing IgE. The agglutination causes an absorbance change, dependent upon the IgE contents of the patient sample that can be quantified by comparison from a calibrator of known IgE concentration.

REAGENTS

Diluent (R1)	Glycine buffer, pH 8.3. Sodium azide 0.95 g/L.
Latex (R2)	Latex particles coated with mouse IgG anti-human IgE, pH 7.3. Sodium azide 0.95 g/L.
Optional	Ref: 101-0479 IgE Calibrator Ref: 101-0480 IgE Control

CALIBRATION

The sensitivity of the assay and the target value of the calibrator have been standardized against the International Reference Preparation of IgE 75/502 (2nd IRP 1981) from WHO. It is not recommended the use of other commercially available IgE calibrators.

PREPARATION

Reagents: Ready to use.

Calibration curve: Prepare the following IgE calibrator dilutions in NaCl 9 g/L. Multiply the concentration of the IgE calibrator by the corresponding factor stated in table bellow to obtain the IgE concentration of each dilution.

Calibrator dliution	1	2	3	4	5
IgE Calibrator (µL) NaCl 9 g/L (µL)	-- 100	12.5 87.5	25 75	50 50	100 --
Factor	0	0.125	0.25	0.5	1.0

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8º C and contaminations are prevented during their use. Do not use reagents over the expiration date.

Frozen Latex and Diluent could change the functionality of the test.

Reagent deterioration: Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37º C.
- Spectrophotometer or photometer thermostatable at 37º C with a 570 nm filter (560 – 580 nm).

SAMPLES

Fresh serum. Stable 7 days at 2-8º C or 3 months at –20º C.

The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolized or lipemic samples.

PROCEDURE

1. Bring the reagents and the photometer (cuvette holder) to 37º C.
2. Assay conditions:

   Wavelength : 570 nm (560-580 nm)
   Temperature : 37º C
   Cuvette ligth path : 1cm

3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

R1. Diluent (µL)	650
R2. Latex (µL)	350
Calibrator or Sample (µL)	15

5. Mix and read the absorbance immediately (A_1) after 5 minutes (A_2) of the sample addition.

Chronolab has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

CALCULATIONS

Calculate the absorbance difference (A_2-A_1) of each point of the calibration curve and plot the values obtained against the IgE concentration of each calibrator dilution. IgE concentration in the sample is calculated by interpolation of its (A_2-A_1) in the calibration curve.

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Chronolab Control Serum IgE is available (Ref.: 101-0480).

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Up to 350 IU/mL. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. **Measurement range:** Up to 1000 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit and measurement range depends on the sample to reagent / ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
2. **Limit detection:** Values less than 25 IU/mL give non-reproducible results.
3. **Prozone effect:** No prozone effect was detected upon 10,000 IU/mL.
4. **Sensitivity:** Δ 0.5 mA. IU/mL
5. **Precision (within run):** CV 6.57% (mean=40.5 IU/mL), CV 1.80% (mean=427.4 IU/mL).
6. **Accuracy:** Results obtained using this reagents (y) were compared to those obtained using a nephelometric method (x). 70 samples were assayed by both methods. The correlation coefficient (r) was 0.987 and the regression line equation y = 1.023x –10.360.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Hemoglobin (500 mg/dL), bilirubin-C (60 mg/dL), bilirubin-F (60 mg/dL), lipemia (15 g/L), and rheumatoid factors (560 IU/mL), do not interfere. Other susbstances may interfere[4].

NOTES

Clinical diagnosis should be not made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAFIA

1. Bergstrand, GC et al. Scand J Clin Invest 1956; 8: 174.
2. Singer J M et al. Amer J Med 1956; 21: 888.
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4. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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