Immunoglobulin E
Turbilatex
Quantitative determination

Cat. No. 101-0478 *Size 1x20 ml/1x10 ml*

PRINCIPLE:
Latex particles coated with 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 calibartor of known IgE concentration.

CLINICAL SIGNIFICANCE:
IgE is an immunoglobulin with a molecular weight of 190,000 present in small traces in the human blood. Continuous production of IgE is a natural response to common occurring allergens, however, it increases considerably as a consequence of Type I allergic reactions as asthma, hay fever, dermatitis and food allergies. Elevated IgE levels are also seen in parasitic diseases, mieloma, and hepatitis. The measurement of IgE in human serum is useful in the diagnosis, treatment and prognosis of such diseases.

REAGENTS:

1. **Reagent 1 (1x20 ml)**
Buffer solution pH 8.3
2. **Reagent 2 (1x10 ml)**
IgE Latex

Optional: 101-0479 IgE Calibrator * 1x1 ml
101-0480 IgE Control 1x2 ml

****IgE concentration of the calibrator is stated on the vial label.***

PREPARATION AND STABILITY:

R.1: Ready to use.
R.2: Ready to use: It should be gently mixed before to use.

All the components of the kit are stable until the expiration date on the label when stored at 2-8ºC. Do not freeze.

SAMPLES:

Fresh serum. Stable 8 days at 2-8ºC o 3 months at -20ºC.
The samples with particles or fibrin should be centrifuged to eliminate them.
Do not use haemolized or lipemic samples.

PROCEDURE:

Wavelength:	570 nm (550-600)
Cuvette:	1 cm light path
Temperature:	37 °C
Zero:	distilled water

Pipette into a cuvette:	Calibrator	Sample
Calibrator	15 µl	--
Sample	--	15 µl
R1 Buffer	650 µl	650 µl
R2 LAtex	350 µl	350 µl
Mix and read the absorbance against blank after 10 seconds (A_1) and 5 minutes (A_2) of the latex addition.		

CALCULATION:

Calculate the absorbance differences A_2 - A_1 for the blank, calibrator and samples.

$$\frac{(A_2-A_1)_{sample}}{(A_2-A_1)_{calibrator}} \times \text{Calibrator concentration} = \mu g/L$$

Chronolab has instructions sheets available for several automatic analyzers.

REFERENCE VALUES:

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

PERFORMANCE CHARACTERISTICS:

1. *Measurement interval*: 50-1000 IU/mL, under the described assay conditions. The measurement range depends on the sample to reagent ratio. The upper limit of the range will be higher by decreasing sample volume, although the sensitivity will be reduced.
2. *Prozone effect*: No prozone effect was detected upon 50000 IU/mL.
3. *Sensitivity:* Values less than 50 IU/mL give non reproducible results.
4. *Precision*: < 3.82 % for 61.7 IU/mL samples and <3.26% for 463.3 IU/mL samples .

INTERFERENCES:

Bilirubin: up to 30 mg/dL do not interfere.
Hemoglobin: up to 5 g/L do not interfere.
Ascorbic acid: up to 500 mg/L do not interfere.

REFRENCES:

Ishizaka K et al. J. Immunol 1966; 97: 75
Johansson SGO et al Immunology 1967; 13: 381
Bennich H et al. Bull WHO 1968; 36: 151