CORMAY TOTAL IgE

DIAGNOSTIC KIT FOR DETERMINATION OF IgE LEVELS

Kit name	**Cat. No**
CORMAY TOTAL IgE 500	6-324
CORMAY TOTAL IgE „bulk”	2-106

INTRODUCTION

IgE is an immunoglobulin with a molecular weight of approximately 190 kD normally present in the blood 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 (helminth) 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.

METHOD PRINCIPLE

When an antigen-antibody reaction occurs between IgE in a sample and anty-IgE antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of IgE in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentration.

REAGENTS

Package

	CORMAY TOTAL IgE 500	CORMAY TOTAL IgE „bulk”
1-Reagent	1 x 500 ml	--*
2-Reagent	1 x 250 ml	--*

* reagent volume is printed on the label.

Reagent preparation and stability

The reagents are ready to use.

The reagents when stored at 2-10°C are stable up to expiry date printed on the package. On board stability of the reagents depends on type of analyser used for analysis. Protect from light and avoid contamination!

Concentrations in the test

suspension of latex particles sensitized with (mouse) anti-IgE antibodies (pH 7.3)	0.125 w/v%
glycine buffer solution (pH 8.3)	

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- After measurements are taken, reagent bottles should capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum or plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin, citric acid).

If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

wavelength	572 nm
temperature	37°C

These reagents may be used in automatic analysers according to their service manual. Applications for analysers are available on request.

REFERENCE VALUES [3]

serum, plasma	< 358 IU/ml

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL II (Cat. No 4-290) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY IgE CALIBRATORS kit (Cat. No 4-280) is recommended.

Calibration stability depends on type of analyser used for analysis. The calibration curve should be prepared with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser TBA-30R. Results may vary if a different instrument is used.

- **Analytical range:** 25 – 1000 IU/ml.

For higher concentration of IgE dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**

Haemoglobin up to 0.5 g/dl, bilirubin up to 60 mg/dl, triglycerides up to 1500 mg/dl, RF up to 560 IU/ml do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [IU/ml]	SD [IU/ml]	CV [%]
level 1	40.5	2.7	6.57
level 2	427.4	7.7	1.80

- **Method comparison**

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 55 samples gave following results:

y = 1.01 x + 11.7 IU/ml;

R = 0.9967 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Neumeister B., Besenthal I., Liebich H.: Diagnostyka laboratoryjna., Urban & Partner, 126-127, (2001).
2. Roitt I., Brostoff J., Male D.: Immunology., 22.2-22.5, MOSBY, (1996).
3. Koji I.: Immunoglobulin E, Medical Practice, 4, 585 (1987).

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