

CORMAY TOTAL IgE

DIAGNOSTIC KIT FOR DETERMINATION OF IgE LEVELS



Kit name	Kit size	Cat. No
CORMAY TOTAL IgE	1 x 75 ml	6-304

PROCEDURE

wavelength	572 nm
temperature	37°C

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 anti-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 known concentration.

REAGENTS

Package	
1-Reagent	1 x 50 ml
2-Reagent	1 x 25 ml

Reagent preparation and stability

The reagents are ready to use.
The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. Protect from light!

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.
- After measurements are taken, reagent bottles should be 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).

It is recommended to perform the assay with freshly collected samples. 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. Samples which contain an excessive amount of IgE should be diluted with physiological saline and re-tested.

These reagents may be used in automatic analysers according to their service manual. These reagents may be used directly in HITACHI 911/912 analysers. Applications for analysers are available on request.

REFERENCE VALUES

serum, plasma	< 358 U/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. Renewed calibration is recommended: after 1 month when using the reagent on the analyser, after lot change, as required. The standard solutions should be measured at least twice.

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 U/ml.
- Antigen excess:** up to 50000 U/ml.
- Specificity / Interferences**
Haemoglobin up to 500 mg/dl, bilirubin up to 30 mg/dl, triglycerides up to 1500 mg/dl, RF up to 500 U/ml do not interfere with the test.

Precision

Repeatability (within run) n = 10	Mean [U/ml]	SD [U/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 commercially available assay (x) using 55 samples gave following results:
 $y = 1.01x + 11.7$ U/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).

Date of issue: 10. 2004.

MANUFACTURER

P.Z. CORMAY

ul. Rapackiego 19, 20-150 Lublin, POLAND

P.O. Box 122, 20-954 Lublin 2

tel.: +48 (0) 81 749 44 00

fax: +48 (0) 81 749 44 34

<http://www.pzcormay.pl>

10/04/10/04