DIAGNOSTIC KIT FOR DETERMINATION OF IgE LEVEL

OS – TOTAL IgE



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

1-Reagent 1 x 44.5 ml 2-Reagent 1 x 23.5 ml

The reagents when stored at 2-10°C are stable up to expiry date printed on the package. The reagents are stable for 5 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

suspension of latex particles sensitized with (mouse) anti-IgE antibodies (pH 7.3) glycine buffer solution (pH 8.3)

0.125 w/v%

Warnings and notes

- Product for in vitro diagnostic use only.
- 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.

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

These reagents may be used in automatic analysers Olympus AU400/AU640.

1-Reagent and 2-Reagent are ready to use.

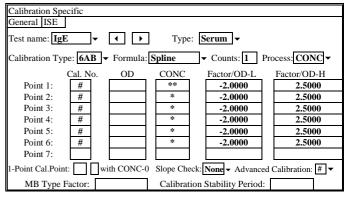
For reagent blank 0.9% NaCl is recommended.

CECORMAN

APPLICATION

Reagent ID: 200							
Specific Test Parameters							
General LIH ISE F	Range						
Test name: IgE ▼	Type: Serum • Operation: Yes •						
Sample: Volume 5	μL Dilution 0 μL Pre-Dilution Rate: 1						
Reagents: R1 Volume 200	μL Dilution 0 μL Min OD Max OD						
R2 Volume 100	μL Dilution 0 μL L -2.0000 H 2.5000						
Reagent OD Limit:							
Wavelength: Pri. 570	▼ Sec. None ▼ First L -2.0000 First H 2.5000						
Method: FIXED	Last L -2.0000 Last H 2.5000						
Reaction Slope: +	▼ Dynamic Range:						
Measuring Point 1: First 13	Last 19 L H						
Measuring Point 2: First	Last Correlation Factor:						
Linearity:	% A 1.000 B 0.000						
No-Lag-Time:	▼ On-board Stability Period:						

Specific Test Parameters								
General LIH ISE Range								
Test name: IgE ▼ ▼ Type: Serum ▼								
Value/Flag: # ▼ Level L: # Level H: #								
Normal Ranges:								
	Age L	Age H						
Sex	Year Month	n Year Mont	h <u>L</u>	H				
1. # ▼	# #	# #	#	#				
2. # ▼	# #	# #	#	#				
3. # ▼	# #	# #	#	#				
4. # ▼	# #	# #	#	#				
5. # ▼	# #	# #	#	#				
6. # ▼	# #	# #	#	#				
7. None Select	ed		#	#				
8 Out of Range # #								
L H								
Panic Value:	#	#	Unit: IU/ml Dec	cimal Places: 2				



- # User defined
- * Calibrator value
- ** Saline should be used as calibrator 1

REFERENCE VALUES³

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.

OUALITY 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.

The calibration curve should be prepared every 5 weeks, 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 30 mg/dl, triglycerides up to 1500 mg/dl, RF up to 500 IU/ml do not interfere with the test.

Precision

Repeatability (run to run)	Mean	SD	CV
n = 10	[IU/ml]	[IU/ml]	[%]
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

- Neumeister B., Besenthal I., Liebich H.: Diagnostyka laboratoryjna., Urban & Partner, 126-127, (2001).
- 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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