

**DIAGNOSTIC KIT  
FOR DETERMINATION OF  
IgE LEVEL**



**OS – TOTAL IgE**

**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 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) 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.

**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.

**APPLICATION**

Reagent ID: 200

Specific Test Parameters									
General		LIH	ISE	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:									
	Sex	Age L	Year	Month	Age H	Year	Month	L	H
1.	#	#	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#	#	#
7. None Selected								#	#
8. Out of Range								#	#
Panic Value:		L	#	H	#	Unit:	IU/ml	Decimal Places:	2

Calibration Specific								
General		ISE						
Test name:		IgE				Type:	Serum	
Calibration Type:		6AB	Formula:	Spline	Counts:	1	Process:	CONC
	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H			
Point 1:	#		**	-2.0000	2.5000			
Point 2:	#		*	-2.0000	2.5000			
Point 3:	#		*	-2.0000	2.5000			
Point 4:	#		*	-2.0000	2.5000			
Point 5:	#		*	-2.0000	2.5000			
Point 6:	#		*	-2.0000	2.5000			
Point 7:	#		*	-2.0000	2.5000			
1-Point Cal.Point:		<input type="checkbox"/>	with CONC-0	Slope Check:	None	Advanced Calibration:	#	
MB Type Factor:			Calibration Stability Period:					

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

**REFERENCE VALUES<sup>3</sup>**

serum, plasma	< 358 IU/ml
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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.

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) 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:

$$y = 1.01 x + 11.7 \text{ IU/ml};$$

$$R = 0.9967 \quad (R - \text{correlation coefficient})$$

## 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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