OBio...
Supporting Care to Cure
A Division of Orchard Medical

Immunoglobulin E (IgE)

IVD

Order Information

Cat. No.	Kit Configuration
OAR1109	Reagent 1: 2 x 20 mL Reagent 2: 2 x 10 mL
OMR1109	Reagent 1: 1 x 40 mL Reagent 2: 1 x 20 mL

Summary

Immunoglobulin E is responsible for protecting against allergens. Its concentration increases are common during allergic diseases (allergic rhinitis, exogenous asthma, hay fever, allergic dermatitis, chronic urticaria, drug and food allergies), parasitic infections and patients with IgE-type myeloma, ADIS, and non-Hodgkin's lymphoma.

Method

Latex Immunoturbidimetric test

Principle

IgE in the sample and specific IgE-antibody in the reagent react to form antigen-antibody complex and generate turbidity, which is proportional to the amount of IgE in the sample. Measuring the absorbance at a specific wavelength and compare with the calibration curve to calculate IgE concentration in the sample.

Reagent Storage Instruction And Stability

The reagent is stable until the expiration date on the label when stored tightly closed at 2°-8°C.
If found Particles and Turbidity means Reagent deterioration.
Do not freeze; frozen Latex or Buffer could change the functionality

of the test.
All the components of the kit are stable until the expiration date on the label when stored tightly.
Reagent 1: Buffer
Solution Reagent 2:
Latex Solution
Calibrator: Buffered Calibrator (Liq.)

Composition

Reagent contained: Buffer Solution, Latex particle coated Anti-IgE antibody & Preservative.
Calibrator: IgE Calibrator (Liq.) (IgE Value on Label)

Warnings and Precautions

1. **Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.**
2. **Take off immediately all contaminated clothing.**
3. **The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.**
4. **For professional use only!**

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent 1 & 2 and Calibrators are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.
7days at 2° – 8°C
60 days at –20°C
Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength	**578 nm (570 – 600 nm)**
Temperature	**37 °C**
Light path	**10 mm**

	Sample/ Calibrator
Reagent 1	**200 µL**
Sample /Calibrator	**5 µL**
Mix and incubate for 5 min. at 37°C, the Add Reagent 2,	
Reagent 2	**100 µL**
Mix, incubate for 90 sec. at 37°C and read the absorbance (A1) and incubate again for 210 sec. and read absorbance (A2).	

CALCULATIONS:

$$\text{IgE (IU/mL)} = \frac{\text{(A2-A1) sample}}{\text{(A2-A1) calibrator}} \times \text{Calibrator concentration}$$

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics Measuring Range

The test has been developed determine IgE concentration within a measuring range from 25 - 1000 IU/mL. If such value is exceeded the sample should be diluted 1 + 1 with double distilled water and results multiplied by 2.

Interferences

No interference was observed by, Bilirubin up to 20 mg/dL and Triglycerides up to 1000 mg/dL.

Sensitivity/Limit of Detection
The lower limit of detection is 25 IU/mL.

Linearity
The higher limit of detection is 1000 IU/mL.

Precision

Intra-assay n = 20	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	128.11	1.06	0.83
Sample 2	89.20	1.69	1.90

Inter-assay n = 20	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	83.87	1.19	1.42
Sample 2	183.03	1.35	0.74

Method Comparison
A comparison of Nucleus Diagnosys IgE (y) with a commercially available test (x) using 20 samples gave following results:
$y = 1.011 + 0.070$; $r^2 = 0.999$

Reference Range
Normal value upto < 198 IU/mL.

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. **Linlin Zhao. Assay method and clinical meaning for serum IgE test [J]. Medical examination, 2013,13 (36):316.**
2. **Corinne Rancinan,MDM, IgE serum level: A prognostic marker for AIDS in HIV-infected adults?[J] J Allergy Clin Immunol 1998,102:329-30.**

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