ACCUCARE® IgE Turbilatex Kit is intended to determine the content of IgE in Human Serum Samples. Only for In Vitro Diagnostic use

ORDER INFORMATION

REF	Cont.
TIE 21	1 X 21 mL
TIE 45	1 X 45 mL
TIE 60	1 X 60 mL

CLINICAL SIGNIFICANCE

IgE is secretory immunoglobulin with a molecular weight of 196000. It consists of two light chains and two heavy chains. It is produced by plasma cells in the lamina propria of nasopharynx, tonsil, bronchus, gastrointestinal mucosa, etc. it is the main antibody causing type I allergy. The most obvious basic biological characteristics is homologous cytoplasm. Human IgE can only sensitize human and monkey cells, but cannot make them allergic. Other animals are allergic. IgE is the most unstable to heat in immunoglobulin. Among the five kinds of immunoglobulins, the half – life of IgE is the shortest, and it has the highest decomposition rate and the lowest synthesis rate. Therefore, the content of IgE in serum is the lowest the value of IgE in serum of normal people is about 10-340IU/ml, which is generally slightly higher in males than in females. In allergic constitution or hypersensitive patients, the IgE in the serum is too high, often suggesting the existence of genetic allergy, or type I allergy

Method

Latex Enhanced Turbidimetric Method

PRINCIPLE

When the latex particles coated with IgE antibody are mixed with the samples containing IgE antigen, agglutination reaction occurs, which results in the change of absorbance. The size of latex particles is proportional to the content of IgE antigen in the samples. The content of IgE in the samples can be quantitatively determined by comparing the change of absorbance with the calibration product of known concentration.

REAGENT

Reagent I : PBS Buffer Solution, PEG, NaN_3, Surface Active agent
Reagent II : IgE Antibody, PBS Buffer Solution, NaN_3 Stabilizer

REAGENT PREPARATION

The Reagent is ready to use.

REAGENT STORAGE AND STABILITY

The kit was stable for 18 months at 2-8°C Pay attention to refrigeration during transportation.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

SAMPLE COLLECTION AND PRESERVATION

It is suitable for fresh serum or plasma samples. If the samples collected on the same day cannot be determined in time, please keep them at -20˚ C and thaw them quickly at 37°C before use. When bilirubin was less than 60 mg/dL, fat emulsion was less than 50 mg/dL and hemoglobin was less than 750 mg/dL, no interference was found.

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	570 nm
Reaction Temperature	37°C
Reaction Type	Fixed Time
Reaction Direction	Increasing
Cuvette	1 cm light path
Measurement	Against Distilled water
Sample Volume	5 µl
Reagent Volume1	200 µl
Reagent Volume2	100 µl
Incubation	5 minutes
Delay	10 Sec
Read Time	300 Sec
Linearity	25-1000 IU/ml

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	REAGENT BLANK	CALIBRATOR	SAMPLE
REAGENT I	200 µl	200 µl	200 µl
Cali.(C0,C1,C2, C3,C4,C5,C6)	-	5 µl	-
SAMPLE	-	-	5 µl
Mix well and incubate for 5 mins at 37°C & Immediately Add			
REAGENT II	100 µl	100 µl	100 µl
Mix well, and read the absorbance immediately A1 and after 5 minutes A2 of the sample addition.			

LINEARITY

Linearity Range: 25-1000IU/ml

REFERENCE VALUES

Serum / Plasma	≤340IU/ml

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- When the concentration of the samples ≥1000 IU/ml, more than the detection limit, it should be diluted by saline for many times.
- Only when using this kit, the matching calibration product is used in the applicable inspection system.

INTERFERENCE

- The linearity of this kit depends on the ratio of samples and reagents, reducing the amount of specimens can increase linearity, but decrease the reagent sensitivity. Excessive samples size will affect the standard curve.
- The first material should be performed 40 seconds after the addition of R2, and the second material is performed 300 seconds after the addition of R2.
- When used for diagnostics and therapeutic purposes, the results of this test should always be combined with history, symptoms and other clinical outcomes for patients explained.

BIBLIOGRAPHY

1. Mori, Others: Testing and Technology, 16,641-644 (1988)
2. Ercnna, The Immunoturbidimetric Measurement of Immunoglobulins, Clin, CHEM1990, 71 (3): 1410-1458
3. Guiding Principles for the Compilation of National Practice Rules for Clinical Laboratory (Third Edition) and Instructions for Diagnostic Reagents.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

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