SPECTRUM

The Creative Approach to Bioscience

IMMUNOGLOBULIN E (IgE)

REF: 548 001 50 test

R1 Buffer 1 x16 ml
R2 Latex 1 x 6 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

Intended Use

In vitro diagnostic reagents for the quantitative determination of Immunoglobulin E (IgE) in human serum by the Immunoturbidimetric procedure.

Background

The Immunoglobulin E (IgE) has a molecular weight of aprox. 190000 g/mol and is produced by the organism in small quantities. Allergic diseases are a sign of hypersensitivity of the body. The type I hypersensitivity reaction, also called immediate hypersensitivity, is IgE mediated and is characterised by an immediate reaction following contact with the antigen. Antigens facilitating an IgE response include components of grass pollen, components of food, parasites and secretions from insects. This antigen induces the mucosal-B-cells, in conjunction with T-helper cells, to produce specific IgE. The IgE molecules bind via Fc receptors to mast cells, which thus becomes sensitized. The next time when the antigen comes into contact with the sensitised mast cells, the bound IgE antibodies become cross-linked, leading to degranulation of the mast cells and release of mediators (as Histamine). The mediators bring about clinical signs typical for allergy, such as rhinitis, urtecaria, asthma and eczema. IgE is formed mainly in the lymph nodes and mucous membranes of the respiratory and gastrointestinal tracts. IgE molecules cannot pass through the placental barrier and do not activate complement. IgE determinations are indicated in the diagnosis and monitoring of allergic diseases.
Elevated IgE levels also occur in parasitosis and immunodeficiency syndromes, such as acquired T-cell deficiency or the Wiskott-Aldrich syndrome. In infants and small children with recurrent respiratory tract diseases (bronchitis, pseudocroup attacks), the determination of IgE is of prognostic relevance, also in some mielomas of IgE type.

Test Principle

The Spectrum IgE test is used for the quantitative in vitro determination of total immunoglobulin IgE in serum and plasma samples. Anti-IgE antibodies covalently bound to latex particles react with the antigen (IgE) in the sample to form an antigen-antibody reaction complex, which can be measured turbidimetrically after particle aggregation.

Reagents

Buffer R1
Phosphate buffer, pH:7,0 , containing protein stabilizers and < 0.1 % sodium azide as preservative. Free of polyethyleneglicol.
Latex reagent R2
Suspension of latex microparticules covalently bound anti-IgE antibodies suspended in a neutral aqueous solution, with < 0.1 % sodium azide as preservative.
Calibrator
Human - based reference fluid. Preservative: sodium azide, 0.075%
Ready to use ; stablity 4 weeks after opening.
Actual value is printed on the vial label.

Precautions and Warnings

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices. Disposal of all waste material should be in accordance with local guidelines. As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Material Required but not provided

Automatic analyzer.
Saline solution.
Controls.

Storage and Stability

The IgE reagents should be stored tightly capped at (2 - 8 ºC) when not in use. Do not freeze. Reagents in the original vials are stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).

Immediately following the completion of an assay run, the reagent vials should be capped until next use in order to maximize curve stability. Once opened the reagent can be used within 1 month if stored tightly closed at (2 - 8 ºC) after use. The IgE buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarted.

The IgE latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarted.

Specimen Collection and Preparation

Serum specimens should be collected by venipuncture following good laboratory practices.
Suitable assay specimens are human serum samples, as fresh as possible (stored up to 2 days at 2 - 8 ºC) or deep-frozen. Any additional clotting or precipitation which occurs due to the freeze/thaw cycle should be removed by centrifugation prior to assay.
Very Lipemic specimens, or turbid frozen specimens after thawing, must be clarified before the assay by high-speed centrifugation (15 min at approx. 15.000 rpm).
Heat inactivation of serum samples results in loss of IgE antigenicity and therefore must be avoided.

Calibration curve

Calibrator 1	100 µl of Spectrum IgE Calibrator*
Calibrator 2	100 µl of Calibrator 1 + 100 µl of Saline Solution
Calibrator 3	100 µl of Calibrator 2 + 100 µl of Saline Solution
Calibrator 4	100 µl of Calibrator 3 + 100 µl of Saline Solution
Calibrator 5	100 µl of Saline Solution

(*) See values on the label . Multiply by the appropriate factor.

For quality control use Spectrum Control or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Procedure

Wavelength	600 nm
Optical path	1 cm
Assay type	Turbidimetric
Temperature	37 °C
Incubation time	4 min.
Measurement	against reagent blank.

Bring the reagents at 37ºC and pipette:

	Blank	Calibrator	Sample
Buffer R1	300 µl	300 µl	300 µl
Latex reagent R2	110 µl	110 µl	110 µl
Mtix, Incubate one minute.			
Distilled Water	20 µl	----	----
Calibrator	----	20 µl	----
Sample	----	----	20 µl

For Blank, Calibrator and Sample, Mix and measure First absorbance after 2 seconds (A1), then incubate 4 min, after incubation read Second absorbance (A2).

Calibration and Quality Control

Standardization: use Spectrum Calibrators. The method was standardized against to IRP 75/502. For quality control use Spectrum Control or other suitable control material. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Calculation

$$\frac{(A_2\text{-}A_1)_{sample} - (A_2\text{-}A_1)_{blank}}{(A_2\text{-}A_1)_{calibrator} - (A_2\text{-}A_1)_{blank}} \times \text{Calibrator concentration}$$

Expected Values

The serum IgE concentration in healthy, nonatopic test subjects is very age dependent.

Age	IU/ml
New-borns	< 1.5
Infants<1 year	< 15
Children (1-5 years of age)	< 60
Children (6-9 years of age)	< 90
Children (10-15 years of age)	< 200
Adults	< 100

These data are to be interpreted as a guide. Each laboratory should establish its own reference intervals.

References

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Debelic,M. Clinical Significance of total and specific IgE in bronchial asthma. Allergol Immunopathol 1976;4: 361-70.

Grundbacher, F,J, Causes of variation in serum IgE levels, in normal population. J All Clin Immunol. 1975;56:104-11.

Dati, F. Ringel, K. Refernce values for serum IgE in healthy non atopic children and adults. Clin Chem. 1982; 28:1556.

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ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
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