IMMUNOGLOBULIN-E(IgE)

(Turbidimetry Method)

CHEM *Count*

INTRODUCTION

IgE is an immunoglobulin with a molecular weight of approximately 190,000Da and is normally present in the blood in trace amounts. IgE antibodies are the chief immunoglobulin responsible for immediate hypersensitivity reactions in humans

METHOD PRINCIPLE

The Kit utilizes latex-enhanced immunoturbidimetry to measure the IgG level in human serum or plasma. During the test, IgE in the sample binds with the specific anti IgE antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry, analyzer. The change in absorbance is proportional to the level of IgG in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations

KIT CONTENTS

R1 - IgE Buffer	1 x 10 ml	1 x 20 ml
R2 - IgE Antibody	1 x 5 ml	1 x 10 ml
R3 - IgE Calibrator Sets	6 x 0.5 ml	6 x 0.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 7-10 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-IgE and R2-IgE reagents of 2 parts of R1-IgE with 1 part of R2-IgE. Avoid foaming.

CONCENTRATIONS IN THE TEST

R1 - Phosphate buffer, Polyethylene glycol, Sodium azide < 0.1%

R2 - Anti-IgE antibodies, Tris buffer, sodium azide < 0.1%

Warnings and notes

1. The Kit is for in vitro diagnostic use only. Not for use in humans \ or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 630 nm
- Thermostat at 37ºC
- General laboratory equipment

SPECIMEN

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 4° C for up to 3 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing

PLOTTING OF MULTIPOINT CURVE

The Turbichem IgE is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

PROCEDURE

These reagents may be used both for manual assay and in several automatic analyzers. **Programme Sheets** are available on request.

Wavelength	570 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette:

Reagent	Blank(B)	Calibrator (C)	Test (T)
R1 IgE Buffer	670 µl	670 µl	670 µl
Calibrator	-	15 µl	-
Sample	-	-	15 µl
Mix well and incubate for 5 mins at 37° C			
R2 IgE Antibody	330 µl	330 µl	330 µl

Mix well & incubate for 5 min. at 37℃. Measure the absorbance of calibrator & sample **against Reagent blank(B)**

CALCULATION

$$\text{IgE concentration} = \frac{\text{Abs.Test}}{\text{Abs.Calibrator}} \times \text{Calibrator Concentration}$$

REFERENCE VALUES

Less than 1 year old	1.35 - 19.5	IU/mL
1 -3 yrs	5.24 - 30.0	IU/mL
4 -6 yrs	5.20 - 112.0	IU/mL
6 - 9 yrs	13.12 - 142.0	IU/mL
10 - 12 yrs	11.20 - 172.0	IU/mL
13 - 18 yrs	25.00 - 126.00	IU/mL
> 19 yrs	28.00 - 140.0	IU/mL

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

PERFORMANCE CHARACTERISTICS

- **Linearity:** 3 to 1000 IU/mL
- **Precision:** within Run CV < 6 %
- **Specificity / Interferences**
  No interference detected for bilirubin upto 60 mg/dL and hemoglobin 10 g/L

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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SYSTEM PARAMETERS

Method	End Point
Wavelength	570 nm
Zero Setting	Reagent Blank
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	5 mins + 5 mins
Delay Time	----
Read Time	----
No. of Reading	2
Interval Time	----
Sample Volume	0.015 ml (15 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	Refer Calibrator vial
Units	IU/ml
Factor	----
Reaction Slope	Increasing
Linearity	1000 IU/ml

IVD