

# TURBICHEM IMMUNOGLOBULIN-E

## IgE (Turbimetry Method)



KIT NAME	KIT SIZE	CAT. NO
Turbichem - IgE	1 x 30 ml	TIGE00030D

### 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 20 ml
R2 - IgE Antibody	1 x 10 ml
R3 - IgE Calibrator	1 vial

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

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

### ADDITIONALEQUIPMENT

- Automatic analyzer or photometer able to read at 630 nm
- Thermostat at 37°C
- 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.

### Serial Dilution Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dilution	Neat	1/2	1/4	1/8	1/16

### PROCEDURE

These reagents may be used both for manual assay and in several automatic analyzers. Applications for them are available on request.

Wavelength 570 nm  
 Temperature 37°C  
 Cuvette 1 cm

### Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)
R1 IgE Buffer	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

Mix well & incubate for 5 min. at 37°C. Measure the absorbance of calibrator & sample.

### CALCULATION

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

1. Berry, M. N. et al., (1988) Clin. Chem. 34,2295.
2. Tietz, N. W. (1983) Clinical guide to Laboratory Tests, p384 W.B. Saunders Co., Philadelphia.
3. Imagawa M. et al., Clin. Chim. Acta, 117, 199 (1981).
4. Neumeister B., Besenthal I., Liebich H.: Diagnostyka
5. Young D.S., Effect of drugs on Clinical Lab. Test, 5th Ed. AACC Press (2000).
6. CLSI(NCCLS) C49-A/H56-laboratoryjna., Urban & Partner, 126-127, (2001).
7. Roitt I., Brostoff J., Male D.: Immunology., 22.2 - 22.5, MOSBY, (1996).
8. CLSI(NCCLS) C49-A/H56-A: Collection, Handling, Transport and Storage for Body Fluids. Quick Guide.
9. Friedman RB, Young DS. Effects of Disease on Clinical Laboratory Tests 2nd Edition, AACC Press, 1989.
10. Ringel KP, Dati F, Buchholz, E. IgE Normalwerte bei Kindern. Laboratoriumsblätter 32, 26-34, 1982.
11. Biosafety in Microbiological and Biomedical Laboratories, Richmond JY, McKinney RW, eds. US Department of Health and Human Services, 4th Edition, 1999.
12. Guaita S, Simó JM, Ferré N, Joven J, Camps J. Evaluation of a particle-enhanced turbidimetric immunoassay for the measurement of immunoglobulin E in an iLab 900 analyzer. Clin Chem 45, 1557-1561, .
13. Renz H. Atopy and allergy. In: Thomas L. Immunochemical techniques. In: Thomas L, ed. Clinical Laboratory Diagnostics. Use and Assessment of Clinical Laboratory Results. 1st Edition. TH-Books, Frankfurt/Main, Germany, 1998.

## 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



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