IMMUNOGLOBULIN E (IGE) TEST KIT

Latex-Enhanced Immunoturbidimetric Method (LETIA)

SAWIN BIOMEDICALS PVT LTD.

Product Codes: 10033, 11033, 12033	**Reaction Type:** Fixed Time / Multi-Point Non-Linear Spline
Pack Sizes: 10 ml, 20 ml, 40 ml	**Matrix Target:** Human Serum & Plasma
Storage Temp: 2–8°C (Do Not Freeze)	**Wavelength:** 570 nm (550–600 nm) Flow Cell: 37°C

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This diagnostic reagent kit is intended for the quantitative in vitro determination of Immunoglobulin E (IgE) levels across human serum or plasma matrices using automated or semi-automated photometric chemistry platforms.

Clinical Significance: Immunoglobulin E (IgE) is a specialized class of antibodies primarily involved in defense mechanisms against parasitic infections (particularly helminths) and serves as the central mediator in immediate type-1 hypersensitivity allergic responses. IgE is synthesized by differentiated B lymphocytes in the respiratory and gastrointestinal tract submucosa. Elevated concentrations are highly diagnostic for atopic allergic disorders such as asthma, allergic rhinitis, atopic dermatitis, and hyper-IgE states.

METHOD PRINCIPLE

The IgE test kit relies on latex-enhanced immunoturbidimetry. Polystyrene latex particles are coated with specific mouse monoclonal anti-human IgE antibodies. When mixed with a patient sample containing IgE, these particles agglutinate, inducing an increase in optical turbidity:

> Serum IgE + Latex-Coated Monoclonal Anti-IgE → Immune Lattice Cross-Linking (Turbidity)

The rate of turbidity development is recorded photometrically by checking the increase in absorbance at 570 nm. The optical shift scales proportionally with the absolute concentration of IgE in the specimen matrix.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Reagent / Component Line	Calibrator Track	Patient Test Track
R1 - Buffer Reagent	400 µl	400 µl
Patient Serum / Calibrator	20 µl	20 µl
Mix carefully and adjust instrumentation parameters. Then add:		

Reagent / Component Line	Calibrator Track	Patient Test Track
R2 - Latex Suspension	100 µl	100 µl

Operational Directive: Mix carefully and record initial optical density 10 seconds post-addition of R2 (A_1). Read secondary optical absorbance exactly 120 seconds later (A_2). Calculate the delta value ($\Delta A = A_2 - A_1$).

STEP 2: CALCULATIONS & DATA TRACKING

> IgE Concentration (IU/mL) = ***[ΔA of Sample / ΔA of Calibrator] × Calibrator Concentration***

TECHNICAL PARAMETERS & DIAGNOSTIC SUPPORT LIMITS

Expected Reference	**Healthy Adults Baseline:** ≤ 100 IU/mL. Values exceeding this cut-off strongly suggest allergic sensitization or hyper-IgE states. Each laboratory must define its native validated reference parameters.
Linearity Range Limit	Dependably linear and valid up to a threshold of **400 IU/mL.**
Over-Limit Protocol	If sample readouts exceed 400 IU/mL, dilute the serum specimen 1:5 or 1:10 with normal saline, repeat the assay, and multiply the final arithmetic result by the chosen dilution factor.
Warnings & Control	For professional in vitro diagnostic use. Contains <0.1% sodium azide. Avoid using specimens showing significant bacterial contamination or prominent red cell hemolysis to avoid distortion of the light path.

Manufactured by: M/s. SAWIN BIOMEDICALS PVT. LTD.
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