FERRITIN TEST KIT

Latex-Enhanced Immunoturbidimetric Method (LETIA)

SAWIN BIOMEDICALS PVT LTD.

Product Codes: 10025, 11025, 12025	**Reaction Type:** Fixed Time / Turbidimetric Kinetic
Pack Sizes: 10 ml, 20 ml, 40 ml	**Matrix Target:** Human Serum & Plasma
Storage Temp: 2–8°C (Do Not Freeze)	**Wavelength:** 540 nm (500–600 nm) Flow Cell: 37°C

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This latex-enhanced immunoturbidimetric diagnostic reagent kit is intended for the quantitative in vitro determination of Ferritin levels across human serum or plasma matrices using photometry-based biochemistry platforms.

Clinical Significance: Serum ferritin levels serve as a highly dependable clinical marker for evaluating body iron stores and diagnosing underlying iron mobilization anomalies. Abnormally low ferritin levels ($< 10\ \mu g/L$) are highly indicative of early iron deficiency anemia. Conversely, markedly increased serum ferritin profiles can emerge during macro-level medical disorders including aplastic anemia, sideroblastic anemia, chronic hemolytic anemia, chronic liver disease, persistent systemic inflammation, and various tissue malignancies.

METHOD PRINCIPLE

This assay applies a latex-enhanced immunoturbidimetric technique (LETIA). When a patient sample containing human ferritin is combined with the uniform latex suspension sensitized with anti-human ferritin antibodies, a specific immuno-agglutination reaction takes place:

> Ferritin Antigens + Latex-Bound Anti-Ferritin Antibodies → Immuno-Agglutinated Grid (Turbidity)

This structural aggregation creates a progressive increase in system turbidity that restricts light transmission. The resulting rate of increase in optical density (absorbance), measured at 540 nm, is directly proportional to the absolute concentration of Ferritin present in the clinical sample.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Reagent / Component Line	Calibrator Track	Patient Test Track
R1 - Buffer Reagent	400 µl	400 µl
Patient Sample / Calibrator	40 µl	40 µl
Mix thoroughly and prime sample on the system. Then add:		

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

Operational Directive: Mix well and record the initial absorbance exactly 10 seconds after adding R2 (A_1). Read the secondary absorbance exactly 120 seconds later (A_2) at 37°C. Determine the change in optical density ($\Delta A = A_2 - A_1$).

STEP 2: CALCULATIONS & DATA TRACKING

> Ferritin Level (µg/L) = ***[ΔA of Sample / ΔA of Calibrator] × Calibrator Benchmark Value***

TECHNICAL PARAMETERS & DIAGNOSTIC SUPPORT LIMITS

Expected Range	**Adult Males:** 20–250 µg/L | **Adult Females:** 10–150 µg/L. These values are guidelines; individual laboratories must establish locally validated reference parameters.
Linearity Boundary	Dependably linear across a dynamic range up to **600 µg/L.**
Over-Limit Protocol	If a clinical sample processes beyond 600 µg/L, pre-dilute the sample with normal saline (1:5 or 1:10), repeat the assay, and multiply the resolved outcome by the appropriate dilution factor.
Quality & Safety	Professional in vitro diagnostic use. Contains <0.1% sodium azide. Avoid using specimens showing prominent bacterial contamination or extensive lipemia to prevent distortion of the optical path.

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