D-DIMER TEST KIT

Latex-Enhanced Immunoturbidimetric Method (LETIA)

SAWIN BIOMEDICALS PVT LTD.

Product Codes: 10023 / 11023 / 12023	**Reaction Type:** Fixed Time / Multi-Point Non-Linear Spline
Pack Sizes: 10 ml / 20 ml / 40 ml	**Matrix Target:** Human Serum and Plasma Matrices
Storage Temp: 2–8°C (Do Not Freeze)	**Wavelength:** 630 nm Photometric Path | Reaction Vector: Increasing Absorbance

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This latex-enhanced immunoturbidimetric diagnostic reagent system is intended for the quantitative in vitro determination of D-Dimer levels in human serum and plasma matrices.

Clinical Significance: D-Dimer contains two cross-linked D fragments and represents the smallest plasmin-resistant molecular subunit present within cross-linked fibrin degradation products. Quantification of circulating D-Dimer is highly invaluable as a negative predictive and diagnostic marker for acute thrombotic conditions such as Disseminated Intravascular Coagulation (DIC), Deep Vein Thrombosis (DVT), and Pulmonary Embolism (PE). Elevated concentrations directly reflect accelerated thrombin activity and intravascular fibrin formation, serving as an indirect marker for Venous Thrombotic Events (VTE). Concurrently, D-Dimer levels can increase due to non-thrombotic situations such as malignant tumors, liver cirrhosis, or severe systemic infections, which necessitates a coordinated multi-marker approach for definitive diagnostic classification.

METHOD PRINCIPLE

The system utilizes polystyrene latex particles coated with highly specific monoclonal antibodies targeted against the cross-linked D-Dimer domain. When the reagent comes into contact with human specimens containing D-Dimer, agglutination occurs:

> Fibrin D-Dimer Segments + Latex-Bound Anti-D-Dimer Monoclonal Ab → Aggregate Network Complex

This specialized particle aggregation changes light transmittance at 630 nm. The rate of increase in optical density scales directly with the concentration of cross-linked D-Dimer molecules in the patient sample.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Critical Sample Contamination Restrictions: Do not process clinical samples displaying obvious microbial contamination, gross red cell hemolysis, or distinct icteric statuses. Ruptured cellular debris heavily compromises optical transparency and distorts light transmission paths.

Reagent / Component Line	Calibrator Track	Patient Test Track
R1 - Reaction Buffer Reagent	400 µl	400 µl
Sample Matrix / Reconstituted Calibrator	08 µl	08 µl
Mix carefully and balance optics. Then add:		
R2 - Monoclonal Latex Suspension	100 µl	100 µl

Operational Directive: Mix gently. Record the initial absorbance exactly 10 seconds post-addition of R2 (A_1). Take the secondary absorbance reading exactly 120 seconds later (A_2) at 37°C. Compute the differential optical density ($\Delta A = A_2 - A_1$).

STEP 2: CALCULATIONS & DATA TRACKING

D-Dimer Concentration (µg/ml) = ***[ΔA of Sample / ΔA of Calibrator] × Calibrator Target Value***

TECHNICAL PARAMETERS & DIAGNOSTIC SUPPORT LIMITS

Expected Cut-Off	Normal Clinical Exclusion Cut-off Threshold: ≤ 0.5 µg/ml (or instrument-specific setting). Values above this threshold suggest hyper-coagulable states and require further imaging/clinical correlation.
Linearity Range Boundary	Valid and linear between a range of **0.1 to 8.0 µg/ml.**
Re-calibration Guidelines	Calibrate the assay every 14 days. Re-calibration must be repeated immediately following major analyzer maintenance, component replacements, or when internal control metrics shift significantly.
Universal Standards	Professional in vitro diagnostic use. Handle all components and blood samples in strict compliance with universal biosafety precautions. Process certified normal and abnormal assayed control matrices with each analytical batch.

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