ANTI-CCP ANTIBODIES TEST KIT

Latex-Enhanced Immunoturbidimetric Method (LETIA)

SAWIN BIOMEDICALS PVT LTD.

Product Codes: 10007 / 11007 / 12007	**Reaction Type:** Fixed Time / Multi-Point Linear Spline
Pack Sizes: 10 ml / 20 ml / 40 ml	**Matrix Target:** Human Serum
Storage Temp: 2–8°C (Do Not Freeze)	**Wavelength:** 546 nm | Reaction Slope: Increasing Optical Density

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This diagnostic reagent is engineered for the direct, quantitative determination of Anti-Cyclic Citrullinated Peptide (CCP) Antibodies in human serum samples.

Clinical Significance: Rheumatoid arthritis (RA) is a chronic autoimmune condition affecting roughly 1% of the population. Classical rheumatoid factor (RF) tracking features high sensitivity but restricted diagnostic specificity, occasionally appearing in non-RA syndromes and normal aging cohorts. Anti-CCP antibodies display excellent diagnostic specificity for RA. They manifest remarkably early in the clinical timeline, appearing in 70% of confirmed RA cohorts while remaining completely absent in 98% of healthy control panels. Synchronized screening of RF and Anti-CCP delivers profound diagnostic accuracy, providing predictive screening before joint-erosion symptoms appear.

METHOD PRINCIPLE

This kit adopts an advanced latex-enhanced immunoassay system. Homogeneous polystyrene particles are chemically coated with highly purified synthetic cyclic citrullinated peptides. When patient serum containing specific anti-CCP antibodies is introduced, an antigen-antibody immunoturbidimetric cross-linking reaction takes place:

> Anti-CCP Antibodies + Latex-Bound Citrullinated Peptides → Immuno-Agglutination Matrix

The creation of this macro-immunological grid yields a distinct increase in optical absorbance at 546 nm, which scales directly with the absolute concentration of Anti-CCP antibodies in the sample.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Critical Interference Restriction: Utilize strictly non-hemolyzed, fresh serum matrices. Samples displaying severe lipidemia, gross hemolysis, visible chylomicron turbidity, or deep jaundice must be rejected to prevent optical tracking distortions.

Reagent / Component Line	Calibrator Track	Patient Test Track
R1 - Buffer Reagent Matrix	400 µl	400 µl

Reagent / Component Line	Calibrator Track	Patient Test Track
Patient Serum Vector / Calibrator	07 µl	07 µl
Mix smoothly and incubate on-board. Then add:		
R2 - Purified Latex Suspension	100 µl	100 µl

Operational Directive: Mix properly. Record initial absorbance exactly 10 seconds post-addition of R2 (A_1). Measure secondary absorbance exactly 300 seconds later (A_2) at 37°C. Compute the change in optical density ($\Delta A = A_2 - A_1$).

STEP 2: CALCULATIONS & DATA TRACKING

> Anti-CCP Activity (U/ml) = ***[ΔA of Sample / ΔA of Calibrator] × Calibrator Unit Value***

TECHNICAL PARAMETERS & DIAGNOSTIC SUPPORT LIMITS

Expected Threshold	**Normal healthy limits:** < 35 U/ml. Certain highly sensitive instruments may register slightly negative or suppressed absorbances for specific negative samples; report these as negative configurations.
Linearity Range Barrier	Completely valid and linear up to **200 U/mL.**
Curve Stability	The multi-point linear spline curve remains fully stable for 14 days. Re-calibrate settings if control outputs shift or major instrument part replacement occurs.
Quality Control	Process certified normal and pathologically elevated control matrices in every analytical run. Prevent baseline contamination and preserve surfactant matrix selectivity by deploying separate micro-pipette tips for all parameters.

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