CREATININE TEST KIT

Jaffe's Kinetic Method (Fixed Time)

Product Code: 10019	**Reaction Type:** Kinetic with Standard
Pack Size: 2 x 100 ml	**Matrix Target:** Human Serum, Plasma & Urine
Storage Temp: Room Temperature (RT)	**Wavelength:** 520 nm (Green Filter)

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This diagnostic system is configured for the discrete quantitative kinetic determination of Creatinine in human serum, plasma, and urine matrices.

Clinical Significance: Serum creatinine determination is a core baseline indicator for diagnosing acute and chronic renal diseases. As an endogenous Non-Protein Nitrogen (NPN) waste product of muscle metabolism, creatinine is filtered by the glomerulus and is not significantly reabsorbed by the renal tubules. Consequently, urine creatinine clearance acts as a direct measure of Glomerular Filtration Rate (GFR).

METHOD PRINCIPLE

Creatinine reacts directly with sodium picrate under optimized alkaline conditions to form a reddish-orange coordination complex (the Jaffe reaction):

> Creatinine + Sodium Picrate → ***[Alkaline Medium]*** → Reddish-Orange Creatinine-Picrate Complex

The initial formation rate of this complex is measured through a precise differential increase in optical density across a prefixed time interval. This kinetic acceleration is directly proportional to the creatinine concentration within the specimen matrix.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Working Reagent Preparation: Mix equal volumes of Picric Acid Reagent (R1) and Alkaline Buffer Reagent (R2) in a clean amber glass container. This working reagent is stable for 10 days when stored at Room Temperature. Do not mouth pipette the picric acid reagent.

Reagent / Component Line	Manual Calibration Volume
Prepared Jaffe Working Reagent	1000 µl
Patient Matrix or Calibrator (Serum or 1:100 Diluted Urine)	100 µl

STEP 2: CALCULATIONS & DATA TRACKING

Operational Directive: Mix well and launch a stopwatch immediately. Record the initial absorbance reading exactly 30 seconds after sample addition (A_0) for both the Test vector and the Standard vector. Record the second absorbance reading exactly 60 seconds later (A_1). Compute the kinetic absorbance delta:

$$\Delta A_{Test} = A_1(Test) - A_0(Test) \quad | \quad \Delta A_{Std} = A_1(Std) - A_0(Std)$$

$$\text{Serum Creatinine (mg\%)} = (\Delta A_{Test} / \Delta A_{Std}) \times 2 \text{ (Standard Concentration)}$$

$$\text{Urine Creatinine (g/L)} = (\Delta A_{Test} / \Delta A_{Std}) \times 2$$

$$\text{Urine Creatinine (g/24 Hours)} = \text{Urine Creatinine (g/L)} \times \text{24h Urine Volume in Liters}$$

SI Conversion Factor: µmol/L = mg% × 88.4

TECHNICAL PARAMETERS & CLINICAL SUPPORT MATRIX

Universal Safeguards	Professional use only. Adherence to reaction time milestones is critical and must be strictly monitored. Hemolysed or lipemic serum samples generate false kinetic parameters and must not be analyzed. Dilute urine samples exactly 1:100 using fresh distilled water prior to the assay. Contains sodium azide.
Expected Range	**Serum:** Male: 0.9–1.5 mg% | Female: 0.8–1.3 mg% **Urine (24h excretion):** Male: 1.1–3.0 g/24h | Female: 1.0–1.8 g/24h
Analytical Linearity	Linear up to 20 mg%. If the specimen parameter limits exceed 20 mg%, dilute the sample, execute the assay again, and multiply by the appropriate dilution factor.

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