UREA TEST KIT

Berthelot Salicylate Method (Colorimetric End Point)

SAWIN BIOMEDICALS PVT LTD.

Product Code: 10052 / 11052	**Reaction Type:** End Point with Standard
Pack Size: 2x50 ml / 2x100 ml	**Matrix Target:** Serum, Plasma & Diluted Urine
Storage Temp: 2–8°C (Protected from Light)	**Wavelength:** 570 nm (or Yellow Filter)

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This liquid diagnostic reagent system is configured for the quantitative in vitro determination of Urea concentrations in human serum, plasma, or urine specimens.

Clinical Significance: Urea is the primary nitrogenous waste product of protein catabolism, synthesized in the liver via the urea cycle. Elevated blood urea levels (uremia) occur in high-protein diets, acute or chronic renal disease, congestive heart failure, severe dehydration, or post-renal tract obstructions. Low levels are less common but can indicate severe liver disease, protein malnutrition, or normal fluid shifts during pregnancy.

METHOD PRINCIPLE

Urease specifically hydrolyzes urea into ammonia and carbon dioxide. The released ammonia molecules react in an alkaline medium with salicylate, hypochlorite, and a nitroprusside catalyst to form a blue-green indophenol complex:

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2\,NH_3 + CO_2$$

$$NH_3 + \text{Salicylate} + \text{Hypochlorite} \xrightarrow{\text{Nitroprusside}} \text{Blue-Green Indophenol Chromogen Complex}$$

The color density of the indophenol complex, measured at 570 nm (or using a yellow filter), scales linearly with the absolute concentration of urea in the sample.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Working Reagent Reconstitution: Transfer the entire contents of R2 Enzyme Concentrate into the R1 Urease Reagent bottle. Rinse the R2 vial with a small amount of R1 to ensure complete transfer. The prepared working reagent is stable for 4 months when stored at 2–8°C. *Note: The working reagent is pale yellow, giving a baseline blank absorbance around 0.200 against water, which is automatically corrected by blanking.*

Reagent / Component Line	Blank (B)	Standard (S)	Test (T)
Reconstituted Working Reagent	1000 µl	1000 µl	1000 µl
Urea Standard (40 mg%)	—	10 µl	—

Reagent / Component Line	Blank (B)	Standard (S)	Test (T)
Patient Specimen (Serum, Plasma, or 1:100 Diluted Urine)	—	—	10 µl
Mix well and incubate at 37°C for 5 minutes (or at Room Temperature for 10 minutes). Then add:			
R3 - Color Reagent	1000 µl	1000 µl	1000 µl

Operational Directive: Mix completely and incubate at 37°C for 5 minutes (or at Room Temperature for 10 minutes). Read the absorbance of the Standard and Test against the Reagent Blank at 570 nm within 30 minutes.

STEP 2: CALCULATIONS & DATA TRACKING

a) Serum / Plasma Urea (mg%) = ***(Abs. of Test / Abs. of Standard) × 40 (Standard Conc.)***

b) Blood Urea Nitrogen (BUN) (mg%) = ***Urea mg% × 0.467***

c) Urine Urea (gm/24 Hours) = ***[Serum Equiv. mg% / 100] × 24h Urine Volume in Liters***

TECHNICAL PARAMETERS & CLINICAL SUPPORT MATRIX

Universal Safeguards	Professional in vitro use. **PRE-ANALYTICAL RESTRICTION:** Do not use ammonium heparin or sodium fluoride as anticoagulants, as they interfere with the urease enzyme mechanism. Urine specimens must be diluted exactly 1:100 with distilled water before processing.
Expected Range	**Serum / Plasma Urea:** 10 – 50 mg% **Urine Urea Excretion:** 25 – 43 gm / 24 hours
Analytical Linearity	Linear up to 300 mg%. High specimens exceeding 300 mg% should be diluted with standard saline, re-assayed, and multiplied by the dilution factor.

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