AMMONIA TEST KIT

Enzymatic Glutamate Dehydrogenase Method (Kinetic UV)

SAWIN BIOMEDICALS PVT LTD.

Product Code: 10005	**Reaction Type:** Fixed Time / Kinetic UV Decrease
Pack Size: 20 ml System Configuration	**Matrix Target:** Human Plasma Matrices (EDTA / Heparin)
Storage Temp: 2–8°C (Do Not Freeze)	**Wavelength:** 340 nm Target Path Node | Standard Conc: 500 µg/dl

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This diagnostic enzyme reagent system is intended for the quantitative in vitro fixed-time determination of Ammonia levels in human plasma matrices.

Clinical Significance: Ammonia is produced via amino acid catabolism and intestinal bacterial action. It is rapidly converted to urea by hepatic parenchymal pathways to maintain exceptionally low circulating concentrations (< ***90 µg/dl***). Free ammonia is neurotoxic and precipitates heavy neurological disturbances. Accelerated blood ammonia is a vital indicator of inborn metabolic defects (such as urea cycle enzyme deficiencies) or severe secondary liver failure states, including Reye's syndrome, viral hepatitis, and advanced cirrhosis.

METHOD PRINCIPLE

This automated procedure operates via a rapid enzymatic coupled UV system utilizing Glutamate Dehydrogenase (GLDH). GLDH catalyzes the reductive amination of α-ketoglutarate with ammonia and NADH to generate L-glutamate and NAD^+:

$$\alpha\text{-Ketoglutarate} + NH_4^+ + NADH \; \&xrightarrow{[ext{GLDH}]} \; \text{L-Glutamate} + NAD^+ + H_2O$$

The rate of decrease in optical absorbance at 340 nm, caused by the continuous oxidation of NADH to NAD^+, is measured photometrically. This kinetic drop scales directly with the ammonia content in the specimen.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Critical Pre-Analytical Handling: Blood must be collected from a completely stasis-free vein and stored immediately inside an ice bath. Plasma must be completely separated within 30 minutes, and the assay must be executed immediately to avoid false-positive elevations from red blood cell deamination.

Reagent / Component Line	Standard Track	Patient Test Track
R1 - GLDH Reagent Mixture	1000 µl	1000 µl

Reagent / Component Line	Standard Track	Patient Test Track
Ammonia Standard (500 µg/dl Ready-to-Use)	100 µl	—
Patient Plasma Specimen (Chilled/Fresh)	—	100 µl

Operational Directive: Mix well and record the initial optical absorbance exactly 60 seconds post-addition of sample (A_1) against air or water at 340 nm. Read secondary absorbance exactly 120 seconds later (A_2). Compute the kinetic drop ($\Delta A = A_1 - A_2$).

STEP 2: CALCULATIONS & DATA TRACKING

> Plasma Ammonia Concentration (µg/dl) = $[\Delta A \text{ of Sample} / \Delta A \text{ of Standard}] \times 500$

TECHNICAL PARAMETERS & DIAGNOSTIC SUPPORT LIMITS

Expected Normal Range	Ammonia in Plasma: 17 to 90 µg/dl. Custom reference parameters should be established locally by individual clinical sites.
Linearity Range Ceiling	Valid up to **1500 µg/dl.**
Over-Limit Protocol	If a clinical measurement exceeds 1500 µg/dl, dilute the patient sample with sterile normal saline, re-run the entire assay sequence, and multiply the outcome parameter by the dilution factor.
Quality & Biosafety	Professional use only. Run certified normal and pathological controls within every analytical batch. Utilize fresh, completely separate micro-pipette tips for reagents, standards, and patient specimens to avoid cross-contamination.

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