

# AMMONIA TEST KIT

Enzymatic Glutamate Dehydrogenase Method (Kinetic UV)



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

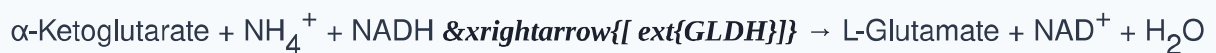
## INTENDED USE & CLINICAL SIGNIFICANCE

**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<sup>+</sup>:



The rate of decrease in optical absorbance at 340 nm, caused by the continuous oxidation of NADH to NAD<sup>+</sup>, 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
<b>Ammonia Standard</b> (500 µg/dl Ready-to-Use)	100 µl	—
<b>Patient Plasma Specimen</b> (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

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

## TECHNICAL PARAMETERS & DIAGNOSTIC SUPPORT LIMITS

<b>Expected Normal Range</b>	Ammonia in Plasma: 17 to 90 µg/dl. Custom reference parameters should be established locally by individual clinical sites.
<b>Linearity Range Ceiling</b>	Valid up to <b>1500 µg/dl</b> .
<b>Over-Limit Protocol</b>	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.
<b>Quality &amp; Biosafety</b>	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.

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

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