AMYLASE TEST KIT

CNPG3 Substrate Method (Kinetic)

Product Code: 10006 / 11006 / 12006	**Reaction Type:** Kinetic with Factor
Pack Size: 10ml / 5x10 ml / 6x30 ml	**Matrix Target:** Human Serum & Plasma
Storage Temp: 2-8°C (Protected from Light)	**Wavelength:** 405 nm (Light Path: 1 cm)

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This liquid diagnostic reagent system is configured for the direct quantitative in vitro kinetic determination of α-Amylase activity in human serum or plasma specimens.

Clinical Significance: α-Amylase is synthesized primarily by the exocrine pancreas and salivary glands. Quantification of its catalytic concentration serves as a vital marker in the diagnosis, monitoring, and control of pancreatic disorders, such as acute and chronic pancreatitis.

METHOD PRINCIPLE

This formulation utilizes the direct substrate 2-chloro-4-nitrophenyl-β-D-maltotrioside (CNPG3). α-Amylase hydrolyzes CNPG3 specifically to release 2-chloro-4-nitrophenol (CNP) and form secondary molecules:

> 5 CNP-G3 → [α-Amylase] → 3 CNP (Yellow) + 2 CNP-G2 + 3 Maltotriose + 2 Glucose

The catalytic rate of 2-chloro-4-nitrophenol formation is tracked photometrically via the rate of absorbance increase at 405 nm. This continuous kinetic shift is directly proportional to the α-amylase concentration present in the sample.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Reagent Handling: The liquid system is ready to use and stable at 2-8°C until the expiration date. Opened vials remain stable for up to 4 weeks if contamination is strictly avoided. Bring to RT before running the assay.

Reagent/Component Line	Test Vector Volume
R1 - Amylase CNPG3 Reagent	1000 µl
Patient Serum / Plasma Sample (Heparinized)	25 µl

Operational Directive: Mix thoroughly and record the initial absorbance against distilled water exactly after 60 seconds. Read again at constant intervals of 60 seconds for a duration of 3 minutes (total 4 data points) to establish the kinetic delta.

STEP 2: CALCULATIONS & DATA TRACKING

Determine the mean absorbance change per minute (ΔA/min) across the monitoring timeline. Compute the total catalytic α-Amylase activity using the programmed matrix multiplier factor (3178):

$$\text{α-Amylase Activity (U/L)} = \Delta A/min \times 3178$$

TECHNICAL PARAMETERS & CLINICAL SUPPORT MATRIX

Universal Safeguards	Professional in vitro diagnostic use. Contains less than 0.1% sodium azide. **CRITICAL CRITERIA:** Human saliva and sweat contain high concentrations of α-amylase. Avoid skin contact, mouth pipetting, and direct reagent exposure to light or skin contamination.
Expected Range	α-Amylase: 25 – 98 U/L. Each laboratory should establish its own normal reference boundaries to counter variation in internal operating conditions.
Analytical Linearity	Linear up to 2000 U/L. If the tracking value exceeds this limit, dilute the clinical sample matrix with saline, re-assay, and multiply the final output by the appropriate dilution factor.

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