AGD

CliniPak

α AMYLASE

(GAL G2-CNP)

Code	AGDSP-AM50
Pack Size	10 x 5 ml

INTENDED USE

This reagent kit is intended for in vitro quantitative determination of α-Amylase activity in serum.

CLINICAL SIGNIFICANCE

Measurement of Amylase are used primarily in the diagnosis and treatment of the diseases of the pancreas. Amylase is found in pancreas and salivary glands.

When released in the digestive tract, the enzyme hydrolyzes starch. Amylase determination is useful in the diagnosis of pancreas and parotids.

Increased levels: are observed in acute pancreatitis and other pancreatic disorder as well as mumps and bacterial parotitis.

PRINCIPLE

α-Amylase hydrolyzes1,4-glucosidic linkages in starch and other polysaccharides to form short chain oligosaccharides.The subst- rate used in reagent is 2-chloro-4-nitrophenyl-α- galactosylm- altoside (GALG2-CNP).The rate at which P-nitrophenol is formed is directly proportional to the amylase activity in the sample. The resulting increase in absorbance can be measured spectrophoto- metrically at 405nm.

$$\text{GALG2-CNP} \xrightarrow{\alpha\text{-Amylase}} \text{GALG2+CNP}$$

PROCEDURE

Reagent1 + Incubation + Sample → Measurement
(300µL) (60 sec) (6 µL) (240Sec) (450nm)

REAGENT COMPOSITION

Buffer pH 6	≈ 100 mmol/L
GALG 2- α CNP	≈ 3.0 mmol/L
Sodium Azide	≈ 152 mmol/L

STORAGE AND STABILITY

Amylase is single reagent ready to use.
The reagents are stable till the expiry date stated on the bottle label when stored at 2-8°C and protected from light.

SAMPLES

Serum free of hemolysis, Duodenum fluid and urine. Chelating agents interfere with the reaction. Do not use citrate, oxalate or EDTA anticoagulant. The reagent contains calcium, which can cause precipitation of fibrinogen from plasma. Do not Pipette by mouth and avoid contamination with skin.

BASIC PARAMETERS

SHORT NAME	α AMYLASE
NAME	α AMYLASE
METHOD	GAL G2-CNP
ASSAY	KINETIC (RATE A)
MAIN WAVE	405nm
SUB WAVE	0
DECIMAL	2
UNIT	IU/L
R1 VOLUME	300µL
INCUBATION	60 secs
R2 VOLUME	0
SAMPLE VOLUME	6µL
INCUBATION	0
MIXING SPEED	0
REACTION TIME (Delay)	60 secs
CHECK TIME (Read)	180 secs
LINEAR RANGE	1500
ABSORBANCE RANGE	0-2.5
LINEARITY LIMIT	40
SUBSTRATE SHORTAGE	>2.0
CALIBRATION TYPE	SINGLE SPOT LINEARITY
DILUTION RATIO	6
SAMPLE VOLUME	50

LINEARITY

Reagent is linear up to 1500 IU/L. Dilute the sample appropriately and re assay if α-Amylase activity exceeds 1500 IU/L . Multiple result with dilution factor.

REFERENCE NORMAL VALUE

Serum: up to 90 IU/L Urine: up to 480 IU/L

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

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