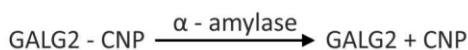


**INTENDED USE :** This Reagent kit is intended for "*In Vitro*" quantitative determination of Alpha - Amylase activity in serum and urine using GalG2 - CNP substrate.

**CLINICAL SIGNIFICANCE :** Measurements of Amylase are used primarily in the diagnosis and treatment of the diseases of the pancreas.

Amylase is found primarily in the pancreas and salivary glands. When released in the digestive tract, the enzyme hydrolyzes starch. Amylase determinations are useful in the diagnosis of diseases of the pancreas & parotids. Elevated serum level are associated with acute pancreatitis and other pancreatic disorders as well as mumps and bacterial parotitis.

**PRINCIPLE :** Alpha - Amylase hydrolyzes 1,4 - glucosidic linkages in starch & other polysaccharides to form short chain oligosaccharides. The substrate used in reagent is 2 - chloro - 4 - nitrophenyl-  $\alpha$  - galactosylmaltoside ( 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 spectrophotometrically at 405 nm.



## REAGENT COMPOSITION :

Reagent 1 : Amylase Substrate Reagent

## MATERIALS REQUIRED BUT NOT PROVIDED :

- Clean & Dry Glassware.
- Micropipettes & Tips.
- Colorimeter or Bio-Chemistry Analyzer.

**SAMPLES :** Serum free of haemolysis urine.

Urine : collect in clean and dry equipments and keep at 2 to 8°C until determination. Chelating agents interfere with the reaction. Do not use citrate, oxalate or EDTA anti - coagulant. The reagent contains calcium, which can cause the precipitation of the fibrinogen from plasma. Do not pipette by mouth and avoid contamination with skin! (Sweat and saliva contain Alpha - Amylase!)

**WORKING REAGENT PREPARATION & STABILITY :** This Reagent is ready for use. When Stored tightly closed at 2 to 8°C temperature protected from light and contaminations prevented during their use; reagents are stable up to the expiry date stated on the label.

## ASSAY PROCEDURE :

Working Reagent	1000 $\mu$ l
Sample	20 $\mu$ l

Mix and after 60 second incubation, measure the change in absorbance every minute during 3 minutes at 37°C.

Determine the  $\Delta$  A/min.

**CALCULATION :** Alpha-Amylase Activity (U/I) =  $\Delta$  A/min. X 3954

## GENERAL SYSTEM PARAMETERS :

Reaction Type	Kinetic Reaction
Wavelength	405 nm
Light Path	1cm
Reaction Temperature	37°C
Blank / Zero Setting	With Distilled Water
Reagent Volume	1000 $\mu$ l
Sample Volume	20 $\mu$ l
Lag / Delay Time	60 Sec.
Read Time	180 Sec.
Interval Time	60 Sec.
Factor	3954
Low Normal at 37°C	0 U/I
High Normal at 37°C	90 U/I
Urine	0-480 U/L
Linearity	1500 U/I

**LINEARITY :** Reagent is Linear up to 1500 U/I.

Dilute the sample appropriately and re-assay if Alpha Amylase Activity exceeds 1500 U/I or  $\Delta$  Abs / min. Exceeds 0.379. Multiply result with dilution factor.

## REFERENCE NORMAL VALUE :

Serum : Up to 90 U/I

Urine : Up to 480 U/I

**QUALITY CONTROL :** For accuracy it is necessary to run known controls with every assay.

**SENSITIVITY / LIMIT DETECTION :** The Lower Limit of detection is 3 U/L.

## LIMITATION & PRECAUTIONS :

- Storage conditions as mentioned on the kit to be adhered.
- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Before the assay bring all the reagents to room temperature.

## BIBLIOGRAPHY :

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