台塑生醫科技股份有限公司
FORMOSA BIOMEDICAL TECHNOLOGY CORP.

α-AMYLASE TEST AMY

FOR BECKMAN CX AND LX SYSTEMS

INTENDED USE
For the quantitative determination of α-amylase activity in serum.

INSTRUCTIONS AND CLINICAL SIGNIFICANCE
α-amylase catalyzes the hydrolysis of oligsaccharides, polysaccharides, starches and glycogen with formation of maltose and dextrins. The tissue sources of human serumα-amylase activity is therefore interested clinically in relation to diseases of the pancrease and evaluation of pancreatic function. α-amylase activity increased considerably in acute pancreatitis and obstruction of the pancreatic ducts. α-amylase activity also increase in acute abdominal pain associated with peptic ulcer, empyea of the gallbladder and intestinal obstruction.

PRINCIPLE
Substrate Galactose-Glucose-Glucose-Chloronitrophenol(Gal-G_2-α-CNP) is hydrolyzed byα-amylase to G_2 and CNP stochiometrically. The rate of CNP formation due to substrate hydrolysis by α-amylase is proportionally correlated with α-amylase activity which is measured by following the rate of absorbance increase at 410nm. The reaction is shown as follows:

$$\text{Gal-}G_2\text{-α-CNP} + H_2O \xrightarrow{\text{α-amylase}} \text{Gal-}G_2 + \text{CNP}$$

SPECIMEN COLLECTION AND PREPARATION
Serum plasma, or urine samples may be used. Anticoagulant such as citrate, oxalate or ETDA must be avoided because of binding of calcium ion, which is essential forα-amylase activity. α-amylase activity in serum or urine sample, without bacterial contamination, are stable for 7 days at room temperature and several months at 4℃.

REAGENT
1. Package: α-amylase substrate: 2×20ml For Beckman CX-4 and LX-20
2. Components: Gal-G_2-α-CNP 0.3mmol/L
   $CaCl_2$ 10 mmol/L
   Phosphate buffer 50 mmol/L

   Store the reagent at: 2~8℃

PRECAUTIONS
1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. saliva contains very highα-amylase activity, **avoid to bring any saliva into the substrate.**
1. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

PROCEDURE
Use open channel and follows the attached parameters and procedures to perform the tests.

EXPECTED VALUES
Serum < 220 u/l, Urine < 1000 u/l
*If α-amylase activity higher than 4500 units, the sample should be diluted with saline and do the test again.

REFERENCES
1. Richterich R. 1969. Clinical chemistry. Theory and Practice, A.P. New York.
2. Caraway W.T. 1959. Am. Clin.32:97.