BIOBASE

α -Amylase (AMY) Test Kit
(EPS-G7 Method)

【NAME】
α-Amylase (AMY) Test Kit (EPS-G7)

【INTEND USE】
The reagent is intended for the in vitro quantitative determination of α-Amylase (AMY) in human serum or plasma. Alpha amylase is unusual, found in the following diseases such as mumps, acute appendicitis, intestinal obstruction, pancreatic cancer, cholelith disease, ulcerative perforation, pancreatic tissue necrosis, hepatitis, cirrhosis, liver cancer, acute cholecystitis, a dirty gland function, severe burns, pre-eclampsia, acute alcohol intoxication etc.

【METHODOLOGY】
Use of Ethylidene blocking p-Nitrophenyl Maltoheptaoside as the substrate,amylase hydrolysis to substrate generate Et - Gy and Gx - pNP,Gy - pNP can be α-glucosidase hydrolyzed to glucose and pNP - gluconic glycoside, the end result Amylase hydrolysis reaction and α-glucosidase reaction is the free p - NP. p-Np has maximum absorbance at 510 nm , the absorbance is proportional to the α-Amylase vitality.

【STABILITY AND STORAGE】
Unopened, avoid light preservation in 2 ~ 8 ℃, valid for 12 months;
Opened, avoid light preservation in 2 ~ 8 ℃, valid for 1 month.
Reagent is not allowed frozen.

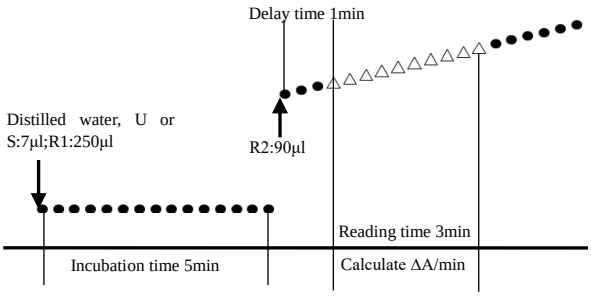
【SPECIMEN COLLECTION AND HANDLING】
It is best to fresh serum or heparin plasma or Urine .
Serum or plasma stability: 2~ 8℃ preservation stability in 3h.

【APPLICABLE INSTRUMENT】
Fully automatic biochemical analyzer.

【TESTING SPECIFICATION】
The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group

Temperature	37° C
Cuvette light path	1.0cm
Primary Wavelength	405nm
Secondary Wavelength	700nm
Assay Type	Rate Method
Direction	Increase
Sample : Reagent1 : Reagent2Ratio	7:250:90
eg : Sample Vol.	7 μL
Reagent1 Vol.	250 μL
Reagent2 Vol.	90 μL
Linearity	0～2000U/L
Testing	Deducting the reagent blank

【OPERATION STEPS】
Double reagent operation:
R1:Reagent 1 R2:Reagent 2 S:Calibrator U:Sample



【CALCULATION】
Use the Calibrator

$$\text{Sample Concentration} = \frac{\text{Sample } \Delta\text{Abs/min}}{\text{Calibrator } \Delta\text{Abs/min}} \times \text{Calibrator Concentration}$$

【REFERENCE RANGE】
Serum or plasma:25～104U/L Urine<450U/L
By clinical trials, choose no less than 100 women or men blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.
Recommendation: The laboratory set up its own reference range!

【THE LIMITATION OF TEST RESULTS】
α-Amylase (AMY)testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

【THE INTERPRETATION OF TEST RESULTS】
Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result; When one sample deviates from the expected value too far, need to be tested again.

【PERFORMANCE INDEX】
1.Reagent blank absorbance≤0.5, (405nm ,lcm optical path).
2.Precision: repeatability CV≤5%;batch variations R≤5%.
3.Accuracy: relative deviation ≤10%.
4.Linearity range: 0～2000U/L, r≥0.990.
5. Stability:All package reagent, unopened and avoid light, preservation in 2~8 ℃, stable 12 months, once opened, avoid light, preservation in 2~8 ℃,stable 30 days.

【ATTENTION】
1.Reagent contains sodium azide (toxic) preservatives, avoid contact with skin and mucous membrane.If necessary preventive measures should be taken use of reagents, reagent contact with skin and mucous membrane, please rinse with water, please go to a doctor if necessary.
2.The maximum linearity is 2000U/L. If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.
3.Liquid waste disposal: Suggest follow local regulations
4.Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

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