ROBONIK®

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prietest™ ...Clinical Chemistry Reagents

AMYLASE

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of activity of Amylase in serum, plasma or urine on photometric systems.

ORDERING INFORMATION	**Pack Size**	**Cat No.**
	2 X 10 ml	AMY 02 10
	5 X 10 ml	AMY 05 10

CLINICAL SIGNIFICANCE : α-Amylase is an enzyme from pancreatic or salivary origin that hydrolyses 1,4-α-glucosidic bonds, thus helping for starch digestion.
Analysis of serum amylase is mainly used in the diagnosis of the pancreatic diseases (acute or chronic pancreatitis and their complications, carcinoma). During acute pancreatitis, a transitory increase of serum amylase is observed, a peak being reached approximately 12h after the beginning, the activity returning to the normal after 3 or 4 days. However, a serum amylase increase is also observed in other intra-abdominal pathologies, ovary or lung cancers, salivary gland lesions, acute alcoholism, renal insufficiency or macroamylasemia (presence of a complex amylase-IgG not filtered by the glomerulus).

METHOD :
Enzymatic, Kinetic, CNP-G_3

PRINCIPLE :
Substrate CNP-G_3 is hydrolyzed by catalitic action of α-amylase to produce CNP (2-chloro-4-nitrophenol).

$$5\ \text{CNP-G}_3 \xrightarrow{\alpha\text{-amylase}} 3\ \text{CNP} + 2\ \text{CNP-G2} + 3\ \text{Maltotriose} + 2\ \text{Glucose}$$

CNP-G2 = 2-Chloro-4-nitrophenyl-α-maltoside

REAGENTS :
COMPONENTS AND CONCENTRATIONS:
N.B: Concentrations are those in the final test mixture.

Phosphate Buffer	100 mmol/l
Sodium Chloride	50 mmol/l
Magnesium Chloride	>10 mmol/l
α-Glucosidase	>2000 U/l
2-chloro-4-nitrophenyl-alpha-D-maltotrioside	1.6 mmol/l

STORAGE INSTRUCTIONS AND REAGENT STABILITY :
The reagents are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C, protected from light and contamination is avoided.
Do not freeze the reagents!

WARNINGS AND PRECAUTIONS :
1. Saliva and Skin contain α-Amylase therefore never pipette reagents by mouth and avoid skin contact with the reagents.
2. The reagents contain Sodium Azide (0.95 g/l) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :
Please refer to local regulation requirements.

REAGENT PREPARATION :
The reagent is ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED :
NaCl Solution 9 g/l, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :
Serum, Heparinized plasma, Urine
Stability in serum or plasma: Sample are stable 1 week at 20 to 25°C and 1 month at 4°C
Stability in urine: 2 days at 20 to 25°C, 10 days at 4 to 8°C
Discard contaminated specimens.

ASSAY PROCEDURE :
Application sheets for automated systems are available on request.
Wavelength : Hg 405 nm
Optical Path : 1 cm
Temperature : 37°C
Mode : Kinetic
Read rate of change of absorbance of sample against Distilled Water or Air.
Label the test tube as sample, control and pipette into respective test tube the reagent, sample, control sample as per the table given below :
Prewarm working reagent at 37°C for Two minutes prior to addition of sample.

	Serum or plasma	**Urine**
Reagent	1000 µl	1000 µl
Sample / Control	20 µl	10 µl

Mix and after a 120 seconds incubation at 37°C measure the change of absorbance per minute (ΔA/minute) during 180 seconds.

CALCULATION :
Activity of Sample (Serum or Plasma) (U/L) = (Δ A/Min) X 3954
Activity of Sample (Urine) (U/L) = (Δ A/Min) X 7908

CONVERSION FACTOR :
U/L X 0.01667 = µKat/L.

CALIBRATION :
For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :
To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :
MEASURING RANGE :
The test has been developed to determine Amylase activities within a measuring range from 3 to 1000 U/L. If such value is exceeded higher limit of the range, such samples should be diluted 1 + 10 with NaCl solution (9 g/l) and results multiplied by 11.

SPECIFICITY / INTERFERENCES :
No interference was observed by Bilirubin up to 30 mg/dl and Lipemia up to 1000 mg/dl Triglycerides. Hemoglobin interferes even at low concentrations. A list of drugs and other interfering substances with Amylase determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :
The lower limit of detection is 3 U/l.

PRECISION :

Intra-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	246.4	2.64	1.07
Sample 2	539.0	4.84	0.89
Sample 3	92.32	1.70	1.84

Inter-assay precision n = 20	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	92	0.7	0.76
Sample 2	223	1.5	0.67
Sample 3	842	6.0	0.71

METHOD COMPARISON :
A comparison between Robonik Prietest Amylase (y) and a commercially available test (x) using 20 samples gave following results:
Linear Regression : y = 1.11 x - 0.5 U/L
Correlation Coefficient : r = 0.9994

REFERENCE RANGE :
Serum / Plasma Up to 90 U/L **Urine** Up to 450 U/L
It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Henderson, A.R., Moss, D.W., *Enzymes*, Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burtis, C.A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 352.
2. Tietz, N.W., Clinical guide to laboratory tests. 3rd Ed., (W.B. Saunders eds. Philadelphia USA), (1995), 46.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995.

INSTRUMENT APPLICATION ***prietest TOUCH***
Name : AMYLASE , Mod : KIN
Pri.: 405 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 500ul , Unit : U/L
Lag : 120 , Read : 180
Blk : N, QC : Y, Norm : Y
Std : N , Factor : 3954
Normal HI = 90
Normal LO = 0
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Init. OD : = 0.4 H
Max Delta/Min : = 0.25
Rgnt. Linearity : : 1000
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	AMYLASE
Reaction	Kinetic
Reaction Slope	Increasing
Wavelength 1	405 nm
Temperature	37°C
Zero Setting	Distilled Water
Factor	3954 for Serum 7908 for Urine
Units	U/L
Sample Volume	20 µl for Serum 10 µl for Urine
Reagent Volume	1000 µl
Lag Time	120 seconds
Read Time	180 seconds
Reference Range	0 to 90 for Serum 0 to 450 for Urine
Reagent Linearity	1000
Initial OD	< 0.4
Max Delta/Min	0.25

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