SyRe

TBA-120FR

AGAPPE

AMYLASE

4 x 54 mL
12011004

Intended Use
This reagent is intended for *in vitro* quantitative determination of Amylase in serum, plasma & urine.
-CNPG3 methodology
-Linear up to 2000 U/L

Clinical Significance
Amylase occurs in the salivary glands, fallopian tubes & in pancreas. a -amylase is secreted by the pancreas from where it enters the duodenum, through the pancreatic duct. Any obstruction in these ducts cause a-amylase enzyme to enter the blood stream.
Elevated levels are seen in acute pancreatitis, peptic ulcers, biliary disease, parotitis & other intestinal obstructions.
Decreased levels are seen in chronic pancreatic disorders involving pancreatic cell destruction.

Principle

$5CNPG_3 \xrightarrow{Amylase}$ > 3 CNP +$2CNPG_2$+3 Maltotriose + 2 Glucose.
CNP : Chloro-4-nitrophenol
CNP-G2 : 2-chloro -4-nitrophenyl-a maltoside

Kit Components

Reagent/ Component	Product Code 12011004	Description	
Alpha Amylase Reagent	4 x 54 mL	MES Buffer (pH6.0)	50 mmol/L
		CNPG3	2.27 mmol/L
		Calcium chloride	60 mmol/L
		Sodium chloride	70 mmol/L
		Activator	900 mmol/L

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation
Alpha Amylase Reagent is ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8^{o}C.

Open Vial Stability
Once opened the reagents are stable up to 90 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 20 days.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum / plasma (Do not use lipemic or hemolysed sample), Urine (1/3 diluted)

Interferences
No interference for
Bilirubin up to 10 mg/dL
Haemoglobin up to 1000 mg/dL
Ascorbic acid up to 50 mg/dL

Materials provided
Alpha Amylase Reagent

Reagents required but not provided
Multicalibrator (Product Code: 11610002), Qualicheck Norm (Product Code: 11601003), Qualicheck Path (Product Code: 11601002)

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
U/L	µKat/L	x 0.017

Calibration
Agappe Multicalibrator (Product Code: 11610002) is recommended for calibration of the assay.

Quality control
It is recommended to use Qualicheck Norm (Product Code: 11601003) or Qualicheck Path (Product Code: 11601002) to verify the performance of the measurement procedure. Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should establish its own reference values.
The following value may be used as guide line.
Serum , plasma 25 - 86 U/L
Urine < 470 U/L
Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 2000 U/L. If the concentration is greater than linearity (2000 U/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.9909 and a regression equation of y = 1.0464x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (U/L)	73.9	860.8	74.3	854
SD	2.0	10.1	2.0	22.6
CV(%)	2.7	1.2	2.7	2.6

Accuracy (U/L)		
Control	Expected Value	Measured Value
Control Level 1	64.7 ± 23	65
Control Level 2	425 ± 75	430.3
Qualicheck Norm	77 ± 14.80	73
Qualicheck Path	175± 23	183

4. Sensitivity
Lower detection Limit is 2.0 U/L

Bibliography

1. Junge, W. *et al.*, Clin. Biochem. 22, 109(1989)
2. Hohenwallnern, W., J.Clin. chem.. Clin. Biochem. 27,97(1989)

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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CE ISO 9001:2015
EN ISO 13485:2016