AMYLASE

4 x 5 mL, 4 x 10 mL, 1 x 50 mL, 1 x 100 mL
51402005, 51402002, 51402006, 51402007

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. Alpha-amylase is secreted by the pancreas from where it enters the duodenum, through the pancreatic duct. Any obstruction to these ducts causes alpha-amylase enzyme to enter the blood stream.

Elevated levels seen in acute pancreatitis, peptic ulcers, biliary disease, parotitis & other intestinal obstructions.

Decreased levels are seen in chronic pancreatic disorders having pancreatic cell destruction.

Principle

$$5CNPG3 \xrightarrow{\text{Amylase}} 3\ CNP + 2CNPG2 + 3\ Maltotriose + 2\ Glucose.$$

CNP = 2-Chloro-4-nitrophenol

CNP-G2= 2-chloro -4-nitrophenyl-a-maltoside

Kit Components

Reagent/ Component	Product Code				Description
	51402005	51402002	51402006	51402007	
Alpha Amylase (S.L) R1	4 x 5 mL	4 x 10 mL	1 x 50 mL	1 x 100 mL	MES Buffer (pH6.0) 50 mmol/L CNPG3 2.27 mmol/L Calcium chloride 60 mmoL Sodium chloride 70 mmol/L Activator 900 mmol/L

Risk & Safety

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

Reagent Preparation

Amylase reagent is ready to use.

Reagent Storage and Stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8°C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks if contamination is avoided.

On-board Calibration Stability

On-board Calibration stability is 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 Qualichek 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. Use clean, dry disposable pipette tips for dispensing. 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 (free of hemolysis) / Urine (1/3 diluted).

Interferences

No interference for

Bilirubin up to	10 mg/dL
Ascorbic acid up to	50 mg/dL
Hemoglobin up to	1000 mg/dL

Materials Provided

Amylase Reagent .

Materials required but not provided

- Pipettes& Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameters

Mode of Reaction	Kinetic
Slope of reaction	Increasing
Wavelength	405 nm
Temperature	37°C
Factor	3178
Linearity	2000 U/L
Blank	DI water
Delay time	60 sec
No.of readings	3
Interval	60 sec
Sample volume	25 µL
Reagent volume	1000 µL
Cuvette	1 cm light path

Application parameters for various instrument are available. Please contact customer support department for specific information.

Unit Conversion

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

Calibration

Agappe multicalibrator is recommended for calibration of this assay on fully auto analyzer.

Use provided factor (3178) for estimation of Amylase on semi auto analyzer.

Procedure notes

Laboratory Procedure for Semi Auto Analyzer

Reagent (R1)	1000 µL
Sample	25 µL
Mix and incubate for 1 min. at 37°C . Measure the change in absorbance per minute (△ OD/min) during 3 minutes.	

Calculation

Alpha-Amylase activity (U/L) = (△OD/ min.) x 3178.

Quality Control

It is recommended to use Agappe Qualicheck Norm & Path (51601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

It is recommended that each laboratory 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.

SYMBOLS USED ON THE LABELS

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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ADS/V.02/060114

CE ISO 9001 : 2008
ISO 13485 : 2003

Performance

1. Linearity

The reagent is linear, upto 2000 U/L.

If the concentration is greater than linearity (2000 U/L), dilute the sample with normal saline & 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

	Control Level 1	Contro Level 2
n	20	20
Mean (U/L)	73.9	860.8
SD	2.0	10.1
CV(%)	2.7	1.2

Inter Run

	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	74.3	854.9
SD	2.0	22.6
CV(%)	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
Qualichek Norm	70 ± 14.80	73
Qualichek 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)

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