

Amylase Kit

CliniQuant - FSR

CNPG2 Method



Diagnostics

For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Amylase Reagent
AMYFSR-01	4 x 10ml	4 x 10ml

INTENDED USE

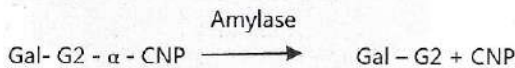
This reagent is intended for quantitative determination of amylase in human serum.

CLINICAL SIGNIFICANCE

α -Amylase originates from pancreas and parotid glands. Serum amylase is helpful for diagnosis of diseases of acute and chronic pancreatitis when serum levels may be grossly elevated. Non pancreatic cause elevated serum amylase activity includes salivary gland lesions, mumps, tumor of lungs and ovaries, urinary stones.

PRINCIPLE OF THE METHOD

2-Chloro-4-nitrophenol- α -1-4 galactopyranosylmaltotrioxide (CNP-G2) is a direct substrate for determination of α -amylase activity. The rate of 2-chloro-4-nitrophenol formation can be monitored at 405 nm and is proportional to the α -amylase activity.



KIT COMPONENTS

Composition

R1 - Amylase Reagent : MES buffer 45.75 mmol/l, Sodium Chloride 300 mmol/l, Potassium Thiocyanate 450 mmol/l, Calcium Chloride 3.8 mmol/l, CNPG2 0.9 mmol/l, Sodium Azide 0.1%

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent is ready to use. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Stability since first opening of vials: \leq 60 days at 2-8 °C.

REAGENT DETERIORATION

1. Discard the reagent if it turns turbid or its absorbance exceeds 1.0 against distilled water at 405 nm.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid reagent pipette by mouth since saliva is rich source of amylase.
4. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum, plasma (heparinate only). Amylase in serum is stable for one month at -20°C or 7 days at 2-8 °C.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Rate
Factor	3953
Filter - 1 (nm)	405
Temperature	37 °C
Volume (μ l)	500
Delay Time (Sec)	60
Test Time (Sec)	120
Unit	U/l
Reaction Direction	Increase
Reference Low	20
Reference High	115
Linearity Limit	2000

TEST PROCEDURE

Dispense reagent in tube	1000 μ l
Sample	20 μ l
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 2 readings at 60 seconds intervals. Calculate the $\Delta A/\text{min}$.	



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RESULT CALCULATION

Serum/plasma:

$$\text{Amylase U/l} = \Delta A/\text{min} \times 3953$$

$$\text{SI conversion factor: } 1 \text{ U/l} \times 0.017 = 1 \mu\text{kat/l}$$

EXPECTED VALUES

$$20 - 115 \text{ U/l} \quad \text{OR} \quad 0.34 - 2.0 \mu\text{kat/l}$$

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

When using the recommended Calibrator (BioCal), calibrate the assay:

- When using a new reagent or lot
- When QC values are out of range

TEST PERFORMANCE

1. Linearity

The linearity is up to 2000 U/l or 34 $\mu\text{kat/l}$.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.8 U/l.

The limit of quantification is 2.5 U/l.

3. Interferences

No interference has been observed for the following

Ascorbic up to 30 mg/dl

Bilirubin up to 40 mg/dl

Triglycerides up to 1000 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	71.81	0.71	0.99
sample 2	169.8	1.02	0.60

Inter-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	71.90	2.79	3.88
sample 2	173.72	2.69	1.55

5. Methods Comparison

Comparison was done between reference Amylase Reagent and CliniQuant - FSR Amylase Reagent (test).

N = 33

$$y = 1.183x - 3.812$$

$r^2 = 0.998$

LIMITATIONS

Samples with values above 2000 U/l, or if $\Delta A/\text{min}$ exceeds 0.500 it should be diluted with 0.9% saline, re-run and results multiplied by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

- Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 852 - 863.
- Data on file: Meril Diagnostics.

IFU/AMYFSR01/00

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Symbols used on Meril Diagnostics labels:

 REF	Catalogue No.		Attention See Instruction for Use
 LOT	Batch No.		In vitro Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged
	Authorized European Representative in the European Community		