

Amylase

α -Amylase. CNPG3. Kinetic. Liquid

Product information

24AMY01-UN	Meditest Amylase	6x40 mL
24AMY01-AU	Meditest Amylase	6x40 mL
24AMY01-AB	Meditest Amylase	6x40 mL
24AMY01-ER	Meditest Amylase	6x40 mL
24AMY01-AR	Meditest Amylase	6x40 mL

Purpose

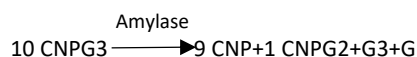
In vitro assay for the quantitative determination of α -Amylase in human serum, plasma and urine.

Summary

α -Amylase (Amy) is an enzyme that helps digest glycogen and starch. It is mainly produced by the exocrine pancreas and salivary glands. This determination is mainly made in diagnosis or to control pancreatic diseases such as acute or chronic pancreatitis. It may also reflect biliary or gastrointestinal disorders and other complications^{2,5,6}. Clinical diagnosis should not be based on a single test result, but clinical and other laboratory data should be integrated.

Test principle

α -Amylase hydrolyzes 2-chloro-4-nitrophenyl- α -D-maltotriose (CNPG3), releasing 2-chloro-4-nitrophenol (CNP) and forming 2-chloro-4-nitrophenyl- α -D-maltoside (CNPG2), maltotriose (G3) y glucose (G) according to the following reaction:



The rate of formation of 2-chloro-4-nitrophenol, measured photometrically, is proportional to the catalytic concentration of α -amylase present in the sample¹.

Reagents - working solutions

R 1	Diethanolamine (DEA) pH 10.4	1 mmol/L
Buffer	Magnesium chloride	0.5 mmol/L
R 2	p-Nitrophenylphosphate	10 mmol/L
Substrate	(pNPP)	

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).

If there is any damage on the package, do not use it. Read the user manual carefully before use, do not use the expired assay kit. Do not mix different lot reagents.

All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.

Take the necessary protective measures to prevent users from becoming infected during operation.

This kit contains components classified according to regulation (EC) 1272/2008 as follows:



Warning

H317 May cause allergic skin reaction.

Prevention:

P261 Avoid inhaling mists or vapors.

P272 Contaminated work clothing should not be allowed outside the work area.

P280 Wear protective gloves.

Response:

P333 + P313 Skin irritation or rash: Seek medical advice.

P362 + P364 Remove contaminated clothing and wash it before reuse.

Annihilation:

P501 Dispose of the contents/container at an approved waste disposal facility.

Use of reagents

Ready to use.

Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contamination is avoided during their use.

Do not use reagents after the expiration date. Signs of reactive decay: Presence of particles and turbidity- 1.00 < empty absorbance (A) at 340 nm.

Sample collection and preparation

Use only suitable tubes and collection containers to collect and prepare specimens. Only the samples listed below have been tested and found acceptable.

Serum/Plasma: Liheparin and K2EDTA plasma

Centrifuge samples containing precipitate before performing the test. For detailed information on possible sample interactions, see the limitations and interactions section. Sample stability claims were determined by the manufacturer based on experimental data or reference literature and only for the temperatures/time frames specified in the method sheet. It is the responsibility of each laboratory to use all available references and/or their own work to determine specific stability criteria for their laboratory.

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Stability in serum or plasma:

7 days at 1525 °C

1 month at 28 °C

Urinary stability:

2 days at 1525 °C

10 days at 28 °C

Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diachem Control L1
3. Cat# 24BIO02-DQ Meditest Diachem Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1. Test Conditions:

Wavelength: . 405 nm

Cuvette: 1 cm light path

Temperature: . 37°C

2. Set the appliance to zero with distilled water.

3. Place the pipettes in a cuvette.

	Serum or plasma	Urine
R (mL)	1,0	1,0
Sample (μL)	20	10

4. Mix, incubate for 1 minute.

5. Read the initial absorbance (A) of the sample, start the stopwatch, and read the absorbances at 1-minute intervals for 3 min.

6. Calculate the difference between absorbances and the average absorbance differences per minute ($\Delta A/\mu\text{min}$).

Calculation

Serum/Plasma $\Delta A/\mu\text{min} \times 3954 = \text{U/L of Amy}$

Urine $\Delta A/\mu\text{min} \times 7908 = \text{U/L of Amy}$

One international unit (IU) is the amount of enzyme that converts 1 μmol substrate per minute under standard conditions. The concentration is expressed in units per liter of sample (U/L).

Conversion factor: $\text{U/L} \times 0.0167 = \mu\text{kat/L}$

Expected values

Serum/plasma

Men/women 0.471.67 $\mu\text{kat/L}$ 28100 U/L

Spontaneous urine

Men: 0.278.20 $\mu\text{kat/L}$ 16491 U/L

Women 0.357.46 $\mu\text{kat/L}$ 21447 U/L

α amylase/creatinine ratio

Men 0.974.73 $\mu\text{kat/g}$

58283 U/g

Women 1,256.51 $\mu\text{kat/}$

75390 U/g

α Amylase/creatinine ratio

It is recommended to determine the α amylase/creatinine ratio to account for fluctuations in α amylase activity in urine. To do this, determine the concentration of α amylase activity and creatinine in spontaneous urine.

$$\text{Ratio [U/g or } \mu\text{kat/mmol]} = \frac{\alpha\text{amylase [U/L or } \mu\text{kat/L}]}{\text{creatinine [g/L or mmol/L]}}$$

Amylase/Creatinine Clearance Ratio (ACCR)

The ACCR value is calculated from amylase activity and creatinine concentration. Both serum and urine samples should be taken at the same time.

$$\text{ACCR [\%]} = \frac{\text{urine amylase [U/L]} \times \text{serum creatinine [mg/L]}}{\text{serum amylase [U/L]} \times \text{urine creatinine [mg/L]} \times 100}$$

The ACCR is approximately equal to 25%.

Each laboratory should investigate the transferability of the expected values to its patient population and, if necessary, determine its own reference intervals.

Limitations

Haemolysis interferes with outcomes. α -Amylase activity can be inhibited by chelating agents such as citrate and EDTA. A list of drugs and other substances that interact with the determination of amylase has been reported by Young et al.^{3,4}.

Performance characteristics

Measuring range: 0.2439-2200 U/L

If the results obtained are greater than the linearity limit, dilute the sample by 1/2 with 9 g/L NaCl and multiply the result by 2.

Precision

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (U/L)	77	194	77	197
SD	1,12	2,22	1,08	2,96
CV (%)	1,45	1,15	1,39	1,50

Sensitivity: 1 U/L = 0.00025 $\Delta A/\text{min}$

Accuracy: Results obtained using Meditest reagents (y) showed no systematic differences when compared to other commercial reagents (x). The results obtained using 50 samples are as follows:

Correlation coefficient (r^2): 0.98628.

Regression equation $y = 0.746x - 1.2697$

The results of the performance characteristics depend on the analyzer used.

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References

1. Ying Foo A et al. Amylase measurement with 2-chloro-4-nitrophenyl maltotrioxide as substrate. Clin Chim 272, 1998; 137-147.
2. McNeely M. Amylase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1112-1116.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.



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