AMYL2

cobas®

α-Amylase EPS ver.2

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08056811190	08056811500	α-Amylase EPS ver.2 (750 tests)	System-ID 2017 001	**cobas c** 303, **cobas c** 503, **cobas c** 703

Materials required (but not provided):

10759350190	Calibrator f.a.s. (12 x 3 mL)	Code 20401	
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391	
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391	
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392	
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392	
08063494190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	

English

System information

AMYL2: ACN 20170 (Serum/plasma)

AMYL2U: ACN 20171 (Urine)

Intended use

In vitro test for the quantitative determination of α-amylase in human serum, plasma and urine on **cobas c** systems.

Summary

Measurements of α-amylase in human serum, plasma and urine with this assay are used in conjunction with other parameters to aid in the diagnosis and management of pancreatic diseases, such as acute pancreatitis, in suspected patients.

The α-amylases (1,4-α-D-glucanohydrolases, EC 3.2.1.1) are digestive enzymes that catalyze the hydrolytic degradation of polymeric carbohydrates such as amylose, amylopectin and glycogen by cleaving 1,4-α-glucosidic bonds. Linear and branched polyglucans are hydrolyzed at different rates. End products for linear polyglucans (amylose) are maltose and some residual glucose; if branched-chain polyglucans are used as substrate, a residue of dextrins is formed in addition to maltose and glucose.[1]

Amylases are present in many organs and tissues. They are predominantly produced by salivary glands and pancreas and can be released into the digestive tract or transported to other organs via the bloodstream.[2] Due to its small size, amylase is able to pass through the glomeruli of the kidneys and is the only plasma enzyme normally found in the urine.[1] The two predominant types present in serum and urine are the pancreatic type (P-type) and the salivary type (S-type). The P-type is almost exclusively synthesized by the pancreas and the S-type is mainly secreted by the salivary glands.[1] Amylase activity is also found in tears, sweat, human milk, the lungs, thyroid, tonsils and the fallopian tube.[3]

Because of the sparsity of specific clinical symptoms of pancreatic diseases, α-amylase determinations are of considerable importance in pancreatic diagnostics. Elevated levels of amylase activities in serum or urine are characteristics of acute pancreatitis, and therefore they are mainly used in the diagnosis and monitoring of this disease.[4,5,6,7] Hyperamylasemia does not, however, only occur with acute pancreatitis, but also in renal failure (reduced glomerular filtration), tumors of the lungs or ovaries, pulmonary inflammation, diseases of the salivary gland, diabetic ketoacidosis, cerebral trauma, surgical interventions or in the case of macroamylasemia.[1,3,8,9,10,11,12]

Numerous methods have been described for the determination of α-amylase. These either determine the decrease in the amount of substrate viscometrically, turbidimetrically, nephelometrically and amyloclastically or measure the formation of degradation products saccharogenically or kinetically with the aid of enzyme-catalyzed subsequent reactions.[13,14] The kinetic method described here is based on the well-proven cleavage of 4,6-ethylidene-(G7)-1,4-nitrophenyl-(G1)-α,D-maltoheptaoside (Ethylidene Protected Substrate = EPS) by α-amylase and subsequent hydrolysis of all the degradation products to p-nitrophenol with the aid of α-glucosidase (100 % chromophore liberation).[15] The results of this method correlate with those obtained by HPLC. This assay follows the recommendation of the IFCC, but was optimized for performance and stability.[16]

Test principle[17,18]

Enzymatic colorimetric assay acc. to IFCC.

Defined oligosaccharides such as 4,6-ethylidene-(G_7) p-nitrophenyl-(G_1)-α-D-maltoheptaoside (ethylidene-G_7PNP) are cleaved under the catalytic action of α-amylases. The G_2PNP, G_3PNP and G_4PNP fragments so formed are completely hydrolyzed to p-nitrophenol and glucose by α-glucosidase.

Simplified reaction scheme:

$$5\ \text{ethylidene-}G_7\text{PNP}^{a)} + 5\ H_2O \xrightarrow{\alpha\text{-amylase}} 2\ \text{ethylidene-}G_5 + 2\ G_2\text{PNP} + 2\ \text{ethylidene-}G_4 + 2\ G_3\text{PNP} + \text{ethylidene-}G_3 + G_4\text{PNP}$$

a) PNP ≙ p-nitrophenol

$$2\ G_2\text{PNP} + 2\ G_3\text{PNP} + G_4\text{PNP} + 14\ H_2O \xrightarrow{\alpha\text{-glucosidase}} 5\ \text{PNP} + 14\ G^{b)}$$

b) G ≙ Glucose

The color intensity of the p-nitrophenol formed is directly proportional to the α-amylase activity. It is determined by measuring the increase in absorbance.

Reagents - working solutions

R1 HEPES: 52.4 mmol/L; sodium chloride: 87 mmol/L; calcium chloride: 0.08 mmol/L; magnesium chloride: 12.6 mmol/L; α-glucosidase (microbial): ≥ 66.8 µkat/L; pH 7.0 (37 °C); preservatives; stabilizers

R3 HEPES: 52.4 mmol/L; ethylidene-G_7-PNP: 22 mmol/L; pH 7.0 (37 °C); preservatives; stabilizers

R1 is in position B and R3 is in position C.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

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

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317 May cause an allergic skin reaction.

Prevention:

P261	Avoid breathing mist or vapours.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves.

Response:

P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.

Disposal:

P501	Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	26 weeks

Specimen collection and preparation[16,19]

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum
Plasma: Li-heparin plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Urine: Collect urine without additives. α-Amylase is unstable in acid urine. Assay promptly or adjust pH to alkaline range (just above pH 7) before storage.[20]
If stabilizers are added to the sample, the sample index feature must not be used.

See the limitations and interferences section for details about possible sample interferences.

Stability in *serum or plasma*:[20]	7 days at 15-25 °C 1 month at 2-8 °C
Stability in *urine*:[21]	2 days at 15-25 °C 10 days at 2-8 °C

Materials provided

See “Reagents – working solutions” section for reagents.

Materials required (but not provided)

See “Order information” section

General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for serum, plasma and urine

Test definition

Reporting time	10 min
Wavelength (sub/main)	700/415 nm

Reagent pipetting		Diluent (H_2O)	
R1	78 µL	–	
R3	16 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	3.1 µL	–	–
Decreased	3.1 µL	20 µL	80 µL
Increased	3.1 µL	–	–

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

Calibration

Application for serum/plasma (ACN 20170)

Calibrators	S1: H_2O S2: C.f.a.s.
Calibration mode	Linear
Calibration frequency	Automatic full calibration - after reagent lot change Full calibration - as required following quality control procedures

Application for urine (ACN 20171)
Transfer of calibration from serum/plasma application (ACN 20170)

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against Roche system reagent using calibrated pipettes together with a manual photometer providing absolute values and substrate-specific absorptivity, ε.

Quality control

For quality control, use control materials as listed in the “Order information” section. In addition, other suitable control material can be used.

Serum/plasma:	PreciControl ClinChem Multi 1 PreciControl ClinChem Multi 2
Urine:	Quantitative urine controls are recommended for routine quality control.

The control intervals and limits should be adapted to each laboratory’s individual requirements. It is recommended to perform quality control always after lot calibration and subsequently at least every 26 weeks. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

cobas c systems automatically calculate the analyte activity of each sample in the unit U/L (µkat/L).

Conversion factor: U/L × 0.0167 = µkat/L

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Limitations - interference

A slight change in the yellow coloration of solution 2 does not interfere with the performance of the test.

Do not pipette by mouth, and ensure that the reagent does not come into contact with the skin. **Saliva and sweat** contain α-amylase!

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[22]

Serum/plasma

Criterion: Recovery within ± 10 U/L of initial values of samples ≤ 100 U/L and within ± 10 % for samples > 100 U/L.

Icterus:[23] No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[23] No significant interference up to an H index of 500 (approximate hemoglobin concentration: 311 µmol/L or 500 mg/dL).

Lipemia (Intralipid):[23] No significant interference up to an L index of 1500. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

In rare cases, samples with a combination of elevated turbidity (L-index) and high Amylase activity may cause a >React or >Abs flag.

Highly turbid and grossly lipemic samples may cause Abs. flags.

Anticoagulants: Interference was found with citrate, fluoride, and EDTA.[19]

Glucose: No significant interference from glucose up to a concentration of 111 mmol/L (2000 mg/dL). Approximately 10 % higher recovery was found at glucose concentrations of 250 mmol/L (4500 mg/dL).

Ascorbic acid: No significant interference from ascorbic acid up to a concentration of 5.68 mmol/L (100 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.[24,25]
Exception: Icodextrin-based drugs may lead to decreased amylase results.[26]

Urine

Criterion: Recovery within ± 46 U/L of initial values of samples ≤ 460 U/L and within ± 10 % for samples > 460 U/L.

Hemolysis: No significant interference up to an H index of 500 (approximate hemoglobin concentration: 311 µmol/L or 500 mg/dL).

Phosphate: No significant interference from phosphate up to a concentration of 70 mmol/L (217 mg/dL).

Urea: No significant interference from urea up to a concentration of 1500 mmol/L (9009 mg/dL).

Ascorbic acid: No significant interference from ascorbic acid up to a concentration of 2.27 mmol/L (40 mg/dL). Approximately 15 % lower recovery was found at ascorbic acid concentrations of 22.7 mmol/L (400 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.[25]

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. All special wash programming necessary for avoiding carry-over is available via the **cobas** link. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SCCS Method Sheet. For further instructions, refer to the operator's manual.

Limits and ranges

Measuring range

Serum, plasma and urine

3-1500 U/L (0.05-25.0 µkat/L)

Determine samples having higher activities via the rerun function. Dilution of samples via the rerun function is a 1:5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank	= 3 U/L (0.05 µkat/L)
Limit of Detection	= 3 U/L (0.05 µkat/L)
Limit of Quantitation	= 3 U/L (0.05 µkat/L)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the activity below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low activity samples.

The Limit of Detection corresponds to the lowest analyte activity which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte activity that can be reproducibly measured with a total error of 20 %. It has been determined using low activity α-amylase samples.

Expected values[16]

U/L

Serum/plasma	Men/Women	28-100 U/L
Spontaneously voided urine	Men	16-491 U/L
	Women	21-447 U/L
α-amylase/ creatinine quotient	Men	58-283 U/g
	Women	75-390 U/g

µkat/L*

Serum/plasma	Men/Women	0.47-1.67 µkat/L
Spontaneously voided urine	Men	0.27-8.20 µkat/L
	Women	0.35-7.46 µkat/L
α-amylase/ creatinine quotient	Men	0.97-4.73 µkat/g
	Women	1.25-6.51 µkat/g

*calculated by unit conversion factor

α-Amylase/creatinine quotient

To allow for fluctuations in the α-amylase activity in urine, it is advisable to determine the α-amylase/creatinine quotient. To do this, determine the α-amylase activity and creatinine concentration in spontaneously voided urine.

$$\text{Quotient [µkat/mmol or U/g]} = \frac{\text{α-amylase [µkat/L or U/L]}}{\text{creatinine [mmol/L or g/L]}}$$

Amylase/Creatinine Clearance Ratio (ACCR)[20]

The ACCR is calculated from amylase activity and creatinine concentration. Both the serum and urine samples should be collected 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 2-5 %.

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

Specific performance data

Representative performance data on the analyzers are given below. These data represent the performance of the analytical procedure itself.

Results obtained in individual laboratories may differ due to heterogenous sample materials, aging of analyzer components and mixture of reagents running on the analyzer.

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Precision

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas c** 503 analyzer.

Serum/plasma

Repeatability	*Mean U/L*	*SD U/L*	*CV %*
PCCC1[c)]	76.9	0.438	0.6
PCCC2[d)]	193	0.831	0.4
Human serum 1	7.38	0.231	3.1
Human serum 2	63.9	0.345	0.5
Human serum 3	509	1.63	0.3
Human serum 4	771	2.67	0.3
Human serum 5	1395	4.13	0.3

Intermediate precision	*Mean U/L*	*SD U/L*	*CV %*
PCCC1[c)]	76.9	0.713	0.9
PCCC2[d)]	194	1.51	0.8
Human serum 1	7.38	0.263	3.6
Human serum 2	63.6	0.409	0.6
Human serum 3	509	2.51	0.5
Human serum 4	771	4.13	0.5
Human serum 5	1395	6.04	0.4

c) PreciControl ClinChem Multi 1

d) PreciControl ClinChem Multi 2

Urine

Repeatability	*Mean U/L*	*SD U/L*	*CV %*
Control 1[e)]	56.3	0.327	0.6
Control 2[e)]	180	0.707	0.4
Human urine 1	7.78	0.257	3.3
Human urine 2	263	0.913	0.3
Human urine 3	408	1.13	0.3
Human urine 4	766	1.96	0.3
Human urine 5	1385	3.62	0.3

Intermediate precision	*Mean U/L*	*SD U/L*	*CV %*
Control 1[e)]	56.3	0.370	0.7
Control 2[e)]	180	0.801	0.4
Human urine 1	7.74	0.403	5.2
Human urine 2	263	2.09	0.8
Human urine 3	409	10.6	2.6
Human urine 4	767	4.41	0.6
Human urine 5	1385	5.66	0.4

e) commercially available control material

The data obtained on **cobas c** 503 analyzer(s) are representative for **cobas c** 303 analyzer(s) and **cobas c** 703 analyzer(s).

Method comparison

Amylase values for human serum, plasma and urine samples obtained on a **cobas c** 503 analyzer (y) were compared to those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

Serum/plasma

Sample size (n) = 85

Passing/Bablok[27]	Linear regression
y = 1.006x - 0.00259 U/L	y = 1.008x - 0.399 U/L
τ = 0.993	r = 1.000

The sample activities were between 10.3 and 1439 U/L.

Urine

Sample size (n) = 67

Passing/Bablok[27]	Linear regression
y = 0.997x + 0.221 U/L	y = 0.996x + 0.571 U/L
τ = 0.985	r = 1.000

The sample activities were between 6.90 and 1467 U/L.

Amylase values for human serum, plasma and urine samples obtained on a **cobas c** 303 analyzer (y) were compared to those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

Serum/plasma

Sample size (n) = 73

Passing/Bablok[27]	Linear regression
y = 1.013x - 0.271 U/L	y = 1.012x - 0.182 U/L
τ = 0.993	r = 1.000

The sample activities were between 9.10 and 1460 U/L.

Urine

Sample size (n) = 71

Passing/Bablok[27]	Linear regression
y = 1.014x - 0.186 U/L	y = 1.019x - 0.515 U/L
τ = 0.991	r = 1.000

The sample activities were between 4.80 and 1444 U/L.

Amylase values for human serum, plasma and urine samples obtained on a **cobas c** 703 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 503 analyzer (x).

Serum/plasma

Sample size (n) = 73

Passing/Bablok[27]	Linear regression
y = 1.009x + 0.257 U/L	y = 1.006x + 0.976 U/L
τ = 0.995	r = 1.000

The sample concentrations were between 20.3 and 1412 U/L.

Urine

Sample size (n) = 75

Passing/Bablok[27]	Linear regression
y = 0.993x - 0.0323 U/L	y = 0.992x + 0.111 U/L
τ = 0.994	r = 1.000

The sample concentrations were between 5.20 and 1494 U/L.

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

CE 0123

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