



α-Amylase CC* FS**

In-vitro-Diagnostic for veterinary use only

Diagnostic reagent for quantitative in vitro determination of α-amylase in serum or plasma on DiaSys respons[®]910 VET

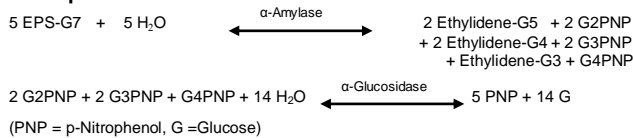
Order Information

Cat. No. 1 0501 99 11 921
4 twin containers for 120 tests each

Method

Enzymatic photometric test, in which the substrate 4,6-ethylidene-(G7)-p-nitrophenyl-(G1)-α-D-maltoheptaoside (EPS-G7) is cleaved by α-amylases into various fragments. These are further hydrolyzed in a second step by α-glucosidase producing glucose and p-nitrophenol. The increase in absorbance represents the total (pancreatic and salivary) amylase activity in the sample.

Principle



Reagents

Components and Concentrations

R1:	Good's buffer	pH 7.15	0.1 mol/L
	NaCl		62.5 mmol/L
	MgCl ₂		12.5 mmol/L
	α-Glucosidase		≥ 2 kU/L
R2:	Good's buffer	pH 7.15	0.1 mol/L
	EPS-G7		8.5 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 35.6 – 46.4°F, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

- Saliva and skin contain α-amylase, therefore, avoid contact with the reagents.
- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- In very rare cases, samples of animals with gammopathy might give falsified results.
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the animal's medical history, clinical examinations and other findings.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly onto the reagent rotor.

Specimen

Serum, heparin plasma or EDTA plasma

Stability :

2 days at 39.2°F to 46.4°F

Discard contaminated specimens.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. This method has been standardized against the original IFCC [International Federation of Clinical Chemistry and Laboratory Medicine] formulation from 1998. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 11 063	20 x 3 mL
TruLab N	5 9000 99 11 062	20 x 5 mL
TruLab P	5 9050 99 11 062	20 x 5 mL

Performance Characteristics

The performance characteristics were evaluated with human samples and might differ from results obtained with various animal specimen.

Measuring range up to 2000 U/L α-amylase (in case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).	
Limit of detection***	3 U/L α-amylase
On-board stability	4 weeks
Calibration stability	2 weeks

Interfering substance	Interferences < 10%	α-amylase [U/L]
Ascorbate	up to 30 mg/dL	96.3
Hemoglobin	up to 550 mg/dL	63.6
	up to 550 mg/dL	229
Bilirubin, conjugated	up to 70 mg/dL	86.3
	up to 70 mg/dL	194
Bilirubin, unconjugated	up to 70 mg/dL	84.3
	up to 70 mg/dL	192
Lipemia (triglycerides)	up to 1000 mg/dL	82.4
	up to 1000 mg/dL	150



For further information on interfering substances refer to Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.

*** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion Factor:

α-Amylase [U/L] x 0.0167 = α-Amylase [µkat/L]

Reference Range

		Unit
DOG	CAT	U/L
207 – 1085	504 – 1745	

Source:

Reference ranges have been validated by DiaSys USA according to National Reference Laboratory standards.

Each laboratory should check if the reference ranges are transferable to its own animal population and determine own reference ranges if necessary.

Manufacturer

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