



α-Amylase CC* FS**

Order Information

 Cat. No.
 Kit size

 1 0501 99 11 921
 √√√ 480 (4 x 120)

Intended Use

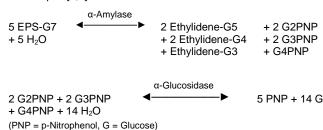
Diagnostic reagent for quantitative in vitro determination of α -amylases in serum or heparin plasma on automated DiaSys respons®910 VET.

For veterinary use only.

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. [3,4]



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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 35.6 - 46.4°F and contamination is avoided. Protect from light.

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative.
 Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains animal and biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- Saliva and skin contain α-amylases, consequently never pipette the reagents by mouth and avoid skin contact with these reagents.
- 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.
- 6. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Serum or heparin plasma

Stability:

2 days at 39.2 – 46.4°F

Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable against the original IFCC [International Federation of Clinical Chemistry and Laboratory Medicine] formulation from 1998. Use DiaSys TruLab N and P for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.		Kit si	ze
TruCal U	5 9100 99 11 063	20	Х	3 mL
TruLab N	5 9000 99 11 062	20	Х	5 mL
TruLab P	5 9050 99 11 062	20	Х	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. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.			
Limit of detection***	3 U/L		
Onboard stability	4 weeks		
Calibration stability	2 weeks		

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Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	96.3
Bilirubin (conjugated)	70 mg/dL	86.3
	70 mg/dL	194
Bilirubin (unconjugated)	70 mg/dL	84.3
	70 mg/dL	192
Hemoglobin	550 mg/dL	63.6
	550 mg/dL	229
Lipemia (triglycerides)	1000 mg/dL	82.4
	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.

Conversion Factor

 α -Amylase [U/L] x 0.0167 = α -Amylase [μ kat/L]

Reference Range

M		
DOG	CAT	Unit
207 - 1085	504 - 1745	U/L

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.



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^{***} according to CLSI document EP17-A, Vol. 24, No. 34

^{*} Complete Color

^{**} Fluid Stable