Lipase DC* FS**

Order Information

Cat. No.	Kit size
1 4321 99 11 921	Σ 480 (4 x 120)

Intended Use

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

For veterinary use only.

Method

Enzymatic color test

A synthetically produced lipase substrate (1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6-methylresorufin) ester) is added to a micro-emulsion which is specifically split by lipase in the presence of colipase and bile acids. The combination of lipase and bile acids make this specific and reliable for pancreatic lipase without any reaction due to lipolytic enzymes or esterases. The reagent composition has been thoroughly optimized to avoid serum matrix effects. The generated methylresorufin-ester is spontaneously degraded to methylresorufin. The absorbance by this red dye is directly proportional to the lipase activity in the sample.

Lipase catalyses the reaction:

1,2-o-dilauryl-rac-glycero-3-glutaric acid (6-methylresorufin) ester —(Lipase/Colipase)→ 1,2-o-dilauryl-rac-glycerin + Glutaric acid-(6-methylresorufin) ester

Glutaric acid-(6-methylresorufin) ester —(spontaneous degradation)→ Glutaric acid + Methylresorufin

The increase in absorbance is measured photometrically.

Reagents

Components and Concentrations

R1:	Good's buffer	pH 8.0	50 mmol/L
	Taurodesoxycholate		4.3 mmol/L
	Desoxycholate		8.0 mmol/L
	Calcium chloride		15 mmol//L
	Colipase (porcine)		2.2 mg/L
R2:	Tartrate buffer	pH 4.0	7.5 mmol/L
	Taurodesoxycholate		17.2 mmol/L
	Color substrate		≤ 0.65 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. Do not freeze and protect from light.

Note: A slight apparent red precipitate may occur in reagent 2, which does not affect the performance of the test. Please do not resuspend before use.

Warnings and Precautions

1. ⚠ Reagent 2: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
2. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
4. In very rare cases, samples of animals with gammopathy might give falsified results.
5. 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 to the molar extinction coefficient of an available measuring method. 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 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 300 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***	5 U/L
Onboard stability	6 weeks
Calibration stability	2 weeks

Interfering substance	**Interferences ≤ 10% up to**	**Analyte concentration [U/L]**
Ascorbic acid	60 mg/dL	41.6
	60 mg/dL	129
Bilirubin (conjugated)	60 mg/dL	52.5
	60 mg/dL	146
Bilirubin (unconjugated)	70 mg/dL	52.5
	70 mg/dL	153
Hemoglobin	600 mg/dL	48.4
	600 mg/dL	145
Lipemia (triglycerides)	2000 mg/dL	41.7
	2000 mg/dL	100
NAC (N-acetylcysteine)	2000 mg/L	64.2
	2000 mg/L	156

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 CLSI document EP17-A, Vol. 24, No. 34

Conversion Factor
Lipase [U/L] x 0.0167 = Lipase [µkat/L]

Reference Range

				
DOG	**CAT**	**HORSE**	**CATTLE**	**Unit**
2 - 151	**0 - 100**	**7 - 16**[1]	**5 - 13**[1]	**U/L**

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

[1] Estimated: Based on preliminary results and findings in the literature.

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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* Direct Color

** Fluid Stable