DIAGNOSTICA PRODUCTS

Liquid Reagents – ready to use

LIPASE
Enzymatic colorimetric

2 Reagents

Diagnostic reagent for quantitative in vitro determination of lipase in human serum or plasma on photometric systems.

Ref.No.	Kit Size	Content
DIA010160	50 ml	2x20 ml R1 + 1x10 ml R2
DIA010162	5 x 20 ml	4x20 ml R1 + 1x20 ml R2
DIA010163	5 x 25 ml	4x25 ml R1 + 1x25 ml R2

Additionally offered:

DIA040012	1 x 3 mL	**Diacal Auto** (Calibrator)
DIA030012	1 x 5 mL	**Diacon N** (Control Normal)
DIA030022	1 x 5 mL	**Diacon P**(Control Abnormal)

TEST PARAMETERS

Method: Enzymatic colorimetric, kinetic, increasing reaction

Temperature: 37°C

Wavelength: 580 nm

Sample: Serum, heparinized plasma

Linearity: up to 300 U/L

Sensitivity: The lower limit of detection is 1 U/L

SUMMARY [1,2]

Lipases are enzymes which hydrolyze glycerol esters of long fatty acids. The enzyme and its cofactor colipase are produced in the pancreas.In small amounts, lipase is also secreted by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Bile acids and colipase form micellar complexes with the lipids and bind lipase on the substrate/water interface.
Determination of lipase is used for investigation of pancreatic disorders. In acute pancreatitis the lipase concentrations rise to 2 – 50 fold the upper reference limit within 4 – 8 hours after the beginning of abdominal pain peaking at 24 hours and decrease within 8 to 14 days. Elevated lipase values can lso be observed in chronic pancreatitis and obstruction of the pancreatic duct.

TEST PRINCIPLE

The colour substrate 1,2-o-dilauryl-rac-glycero-3-glutaric acid-(-6-methylresorufin) ester is cleaved by pancreatic lipase in the presence of colipase and bile acids, and the resulting dicarboxilic acid ester is hydrolysed under alkaline test conditions to yield the chromophore methylresorufin.
The kinetic of colour formation at 580 nm is monitored and it is proportional to lipase activity in the sample.

1,2-o-Dilauryl-rac-glycero-3-glutaric acid (6-methylresorufin) ester < Lipase / Colipase >

1,2-o-Dilauryl-rac-glycerol + Glutaric acid-(6-methylresorufin)-ester

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

REAGENT PREPARATION

Reagents are ready to use. **Avoid strong shaking !**

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

REAGENT COMPOSITION

COMPONENTS		CONCENTRATION	
Reagent 1:			
Goods Buffer	pH 8.0		
Colipase		≥ 2	mg/L
Desoxycholate		≥ 1.0	mmol/L
Taurodesoxycholate		≥ 1.0	mmol/L
Calcium ions		≥ 1.0	mmol/L
Detergent			
Preservative			
Reagent 2:			
Tartrate Buffer	pH 4.0		
Colour Substrate		≥ 0.1	mmol/L
Stabilyser			
Preservative			

REAGENT STABILITY AND STORAGE

Conditions: protectfrom light
avoidcontamination
closeimmediately after use
do not freeze!

Storage: at 2 – 8°C

Stability: up to the expiration date

After first opening use preferably within 90 days when stored at 2 – 8 C.
Reagent 2 is a microemulsion. Therefore, a slight precipitation can occur, showing a light red deposit on the bottom of the vial. This is normal. It is recommended to resuspend the solution before analysis, with a mild shaking.

SAMPLE STABILITY AND STORAGE

Stability: at 2 - 8 °C 7 days

Discard contaminated specimens.

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Calibrator	Sample
Reagent 1	1000 µL	1000 µL	1000 µL
Sample	-		20 µL
Calibrator	-	20 µL	-
Dist. water	20 µL	-	-
Mix carefully (do not shake!), incubate 5 min. at 37°C. Then add:			
Reagent 2	250 µl	250 µl	250 µl
Mix. Incubate 2 min. (37°C), read absorbance against Reagent blank and start stop watch. Read absorbance again after exactly 1 and 2 minutes. Calculate: ΔA/min = [ΔA/min sample or calibrator] – [ΔA/min blank]			

CALCULATION

$$\text{Lipase [U/L]} = \frac{\Delta A/\text{min Sample}}{\Delta A/\text{min Calibrator}} \times \text{Conc. Cal [U/L]}$$

UNIT CONVERSION

U/L x 0.01667 = µkatal/L

REFERENCE RANGE [8]*

≤60 U/L (≤ 1.00 µkat/L)

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

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

The assay is linear up to 300 U/L.
If this value is exceeded, samples should be diluted 1 + 1 with saline solution (9 g/L NaCl in dist. water) and the results multiplied by 2.

SENSITIVITY/LIMIT OF DETECTION

The limit of detection is 1 U/L.

PRECISION (at 37°C)

Intra assay n = 10	Mean [U/L]	SD [U/L]	CV [%]
Sample 1	60.6	0.54	0.89
Sample 2	90.4	0.70	0.77
Inter assay n = 20	**Mean [U/L]**	**SD [U/L]**	**CV [%]**
Sample 1	59.9	1.76	2.94
Sample 2	90.3	1.80	1.99

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SPECIFICITY/INTERFERENCES

No interference was observed in the presence of:

Ascorbic acid	≤ 50 mg/dL
Blirubin	≤ 50 mg/dL
Hemoglobin	≤ 400 mg/dL
Triglycerides	≤ 1000 mg/dL

For further information on interfering substances refer to Young DS [10]:

METHOD COMPARISON

A comparison between Diagnostica Lipase (y) and a commercially available colorimetric test (x) using 89 samples gave following results: $y = 0.93 x + 0.50$ U/L; $r^2 = 0.99$.

QUALITY CONTROL

All control sera with Lipase values determined by this method can be used.

We recommend the Diagnostica serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range).

Each laboratory should establish corrective action in case of deviations in control recovery.

CALIBRATION

We recommend the Diagnostica multi calibration serum **Diacal Auto**.

AUTOMATION

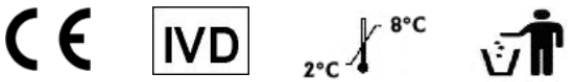
Special adaptions for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. Reagent 2: Warning.
   H319: Causes serious eye irritation.
   P280: Wear protective gloves/protective clothing/eye protection/face protection.
   P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lanses, if present and easy to do. Continue rinsing.
   P337+P313: If eye irritation persists: Get medical advice/attention.
2. Reagent 1 contatins sodium azide (0.95 g/L) as prewervative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Many other clinical reagents contain lipase or high concentrations of detergents. Avoid contamination and carry over!
4. Special care should be taken in combination with triglycerides, HDL and LDL reagents containing microbial lipases thatcould stick on the surface of instrument cuvettes. Cuvettes and other glassware must be cleaned thoroughly after being used for other assays. In case of automated measurement refer to the instrument manual for special washing programs before lipase determination.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
6. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.



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