LIPASE
LIPASE COLORIMETRIC

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
AD2270	5X25ML	TLP20	4000 Tests	DMLP20	528 Tests	SLP20	2077 Tests
AD2271	5X50ML	TLP21	2083 Tests	BYL2270	5455 Tests	SLP21	1246 Tests
NLP20	400 Tests	MLP20	1697 Tests	RLP20	2769 Tests	KLP20	5455 Tests
LLP20	2400 Tests	MLP21	848 Tests	RLP21	923 Tests		

INTENDED USE

The test is applied for determination of Lipase concentration in human serum and plasma. Lipase measurements are used in the diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

TEST PRINCIPLE

The colorimetric substrate 1,2-O-Dilauryl-rac-glycero-3- glutaric acid-(6'methyl-resorufi n)-ester is cleaved by pancreatic lipase and the resulting dicarboxilic acid ester is hydrolysed under the alkaline test conditions to yield the chromophore methylresorufi ne. The kinetic of colour formation at 580 nm is monitored and it is proportional to lipase activity in sample.

TEST PARAMETERS

Method : Colorimetric
Wavelength : 578 – 700 nm
Temperature : 2 – 8°C
Sample : Serum, plasma
Linearity : 600 U/L

REAGENTS COMPOSITION

Reagent 1:
Composition:
Tris buffer 40 mM pH 8.30,
Colipase ≥ 1 mg/l,
Desoxycholate ≥ 1.8 mM,
Taurodesoxycholate ≥ 7.0 mM,
Colipase ≥ 1 mg/dl

Reagent 2:
Tartrate buffer 15 mM pH 4.00,
lipase substrate ≥ 0.70 mM,
calcium ions ≥ 1 mM.
Calibrator: lyophilized (value on label) - 3 ml

REAGENTS PREPARATION

Use separate reagents ready to use.
Stability: up to expiration date on labels at 2-8°C;
Stability since fi rst opening of vials: ≥ 90 days at 2-8°C. Caution: reagent B is a micro-emulsion. Therefore, a slight apparent precipitation could occur, showing a light red deposit on the bottom of vial. It is a normal behaviour and it is recommended to resuspend solution before analysis, with a mild shaking.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8 C at optimum conditions. On board stability is strongly related to auto analysers cooling specification and carry-over values.

SAMPLE

Serum and plasma are collected by standard procedure. Lipase in serum is stable for 7 days at 20-25ºC, 7 days at 2-8ºC and 1 year at -20ºC.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

ΔA/min(calibrator-net) = ΔA/min(calibrator) - ΔA/min(blank)
ΔA/min(sample-net) = ΔA/min(sample) - ΔA/min(blank)

Serum/plasma sample:

$$\frac{\Delta A/min\ (sample\text{-}net)}{\Delta A/min\ (calibrator\text{-}net)} \times \text{Concentration of STD}$$

= U/l (methylresorufine 37°C) for urine multiplies result by 10.

Unit Conversion

Lipase µkat/l*58.75= Lipase U/L

REFERENCE INTERVALS (NORMAL VALUES) (Based on rules CLSI C28-P Document)*

Normal Adults:		≤ 78 U/l (37°C)
Childs	1y:	0 – 10 U/L
	1 – 9y:	0 – 37 U/L
	10 –18y:	0 – 46 U/L

Each laboratory should establish appropriate reference intervals related to its population.
*It is recommended that each laboratory establish its own normal range.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control serums are available:
"ARCON N", Assayed Control Serum Normal
Cat.No. A3910
"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

Any commercially available Standard or Calibrator suitable for this method may be used.
*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 11 days.
*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.
Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low Linearity: 5 U/l

High Linearity: The method is linear up to 600 U/l. If the limit value is exceeded, it is suggested to dilute sample 1+9 with NaCl and to repeat the test, multiplying the result by 10.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run) (intra-assay):

Mean conc.	SD	CV	n
11.80 U/l	2.63	22.27 %	20
119.20 U/l	4.14	3.47 %	20
215.35 U/l	6.11	2.84 %	20

Reproducibility (run to run) (inter-assay):

Mean conc.	SD	CV	n
11.65 U/l	2.80	24.06	20
119.55 U/l	6.82	5.71	20
215.03 U/l	12.33	5.73	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 5 U/l.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Methods Comparison: A comparison between Archem and a commercially available product gave the following results:
Lipase Archem = y
Lipase competitor = x
n = 101
y = 0.50054x + 3.9443 U/l r2 = 0.997

Interferences: No interference was observed by the presence of:
Hemoglobin ≤ 150 mg/dl
Bilirubin ≤ 20 mg/dl
Lipids ≤ 300 mg/dl
(Lipids at concentration more elevated than 300 mg/dl give a - 6% negative interference)

NOTES

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
QC : Quality Control

REFERENCES

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog Number)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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