LIPASE FL

LP F060 CH	6 x 10 ml
LP F125 CH	5 x 25 ml

INTENDED USE

Reagent for quantitative in vitro determination of lipase in biological fluids.

SUMMARY OF TEST

Human lipase is a glycoprotein with a molecular weight of 48000 and an isoelectric point of about 5.8. For full catalytic activity and greatest specificity, the presence of bile salts and a cofactor, called colipase, is required. Lipase measurement on serum, plasma, and ascitic and pleural fluid is used to investigate pancreatic disorders, usually pancreatitis.

PRINCIPLE OF THE METHOD

The colorimetric substrate 1,2-O-Dilauryl-rac-glycero-3-glutaric acid-(6'methyl-resorufin)-ester is cleaved by pancreatic lipase and the resulting dicarboxilic acid ester is hydrolysed under the 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 sample.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label. Keep away from direct light sources.

LIP R1 **F060: 6 x 8 ml (liquid) blue cap**
F125: 4 x 25 ml (liquid) blue cap

Composition: Good's Buffer pH 8.0, colipase ≥ 1 mg/l, desoxycholate ≥ 1.0 mM, taurodesoxycholate ≥ 1.0 mM, calcium ions ≥ 1 mM, detergent and preservative.

LIP R2 **F060: 1 x 12 ml (liquid) red cap**
F125: 1 x 25 ml (liquid) redcap

Composition: Tartrate buffer pH 4.0, lipase substrate ≥ 0.1 mM, stabilizer and preservative.

Calibrator: lyophilized (value on label) - 3 ml

Store all components at 2-8°C and do not freeze.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Use separate reagents ready to use.
Stability: up to expiration date on labels at 2-8°C;
Stability since first opening of vials: use preferably within 60 days at 2-8°C.
Caution: reagent R2 is a microemulsion. 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.

PRECAUTIONS

LIP R1: It is not classified as hazardous.

LIP R2: Danger. Causes serious eye damage (H318).

Wear protective gloves. Eye protection (P280). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). Immediately call a doctor (P310).

Calibrator: It is not classified as hazardous.

Some commercial reagents for triglycerides, HDL and LDL determination could contain microbial lipases, whose could stick on surface of instrument plastic cuvettes. It is recommended to program a "wash" procedure before lipase determination, if a contamination is suspected.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum, plasma heparinate.
Samples are stable 7 days at 2-8°C.

TEST PROCEDURE

Wavelength: 580 nm
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	calibrator	sample
reagent R1	1 ml	1 ml	1 ml
water	20 µl	-	-
calibrator	-	20 µl	-
sample	-	-	20 µl

Mix carefully (do not shake), incubate at 37°C for 5 minutes.

dispense:	blank	calibrator	sample
reagent R2	250 µl	250 µl	250 µl

Mix, execute a first reading of absorbance after 2 minute, incubating at 37°C. Perform other 2 readings at 60 seconds intervals. Calculate the ΔA/min.

RESULTS CALCULATION

$$\Delta A/min = \Delta A/min_{(calibrator\ or\ sample)} - \Delta A/min_{(blank)}$$

serum/plasma sample:

$$U/l\ (methylresorufin\ 37°C) = \frac{\Delta A/min_{(sample)}}{\Delta A/min_{(calibrator)}} \times Calibrator\ value$$

EXPECTED VALUES

normal subjects: ≤ 60 U/l (methylresorufin 37°C)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QUANTINORM CHEMA
with normal or close to normal control values
QUANTIPATH CHEMA
with pathological control values.
If required, a multiparametric, human based calibrator is available:
AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity
The method is linear up to 300 U/l.
If the limit value is exceeded, it is suggested to dilute sample 1+1 with saline solution (9 g/l) and to repeat the test, multiplying the result by 2.

Sensitivity/limit of detection (LOD)
The limit of detection is 1 U/l.

Interferences
No interference was observed by the presence of:

ascorbic acid	≤ 50 mg/dl
hemoglobin	≤ 400 mg/dl
bilirubin	≤ 50 mg/dl
lipids	≤ 1000 mg/dl

Precision

intra-assay (n=10)	mean (U/l)	SD (U/l)	CV%
sample 1	49.9	0.65	1.30
sample 2	110.5	1.69	1.53

inter-assay (n=20)	mean (U/l)	SD (U/l)	CV%
sample 1	50.0	1.43	2.87
sample 2	110.9	3.91	3.53

Methods comparison
A method comparison with the previous generation product gave the following results:

Chema current formulation = y
Chema previous formulation = x
n = 76

$y = 1.017x - 1.452$ U/l $r^2 = 0.990$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, Sixth Edition, Rifai-Horvath-Wittwer (2017) 421-424
Tietz N. and Shuey DF. - Clin. Chem. 1993, 39, 746-756

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use-by date
	caution
	consult instructions for use

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