


# Lipase Kit

## CliniQuant – FSR

### Advanced Homogeneous Micelle Technology

 For *in vitro* diagnostic use.  
Read this pack insert thoroughly before use

REF	Pack Size	R1 Lipase Reagent	R2 Lipase Reagent	R3 Lipase Standard
LIPFSR-01	1 x 16 / 1 x 10ml	1 x 16ml	1 x 10ml	1 x 3ml

#### INTENDED USE

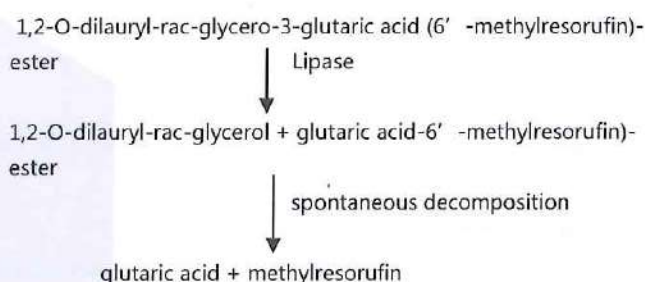
This reagent is intended for quantitative analysis of pancreatic lipase in human serum.

#### CLINICAL SIGNIFICANCE

Lipase is a glycoprotein of pancreatic enzyme necessary for the absorption and digestion of lipids. Elevated serum lipase levels are associated with pancreatic diseases such as acute and chronic pancreatitis & obstruction of the pancreatic duct.

#### PRINCIPLE OF THE METHOD

Serum lipase hydrolyzes the substrate 1,2-O-dilauryl-rac-glycero-3-glutaric acid- (6' -methylresorufin)-ester to liberate glutaric acid-6' -methylresorufin, which in turn is reduced to glutaric acid and methylresorufin. The rate of formation of methylresorufin is measured photometrically. The rate of color change is proportional to the lipase activity in the sample.



#### KIT COMPONENTS

Composition :

R1 - Lipase Reagent : Tris Buffer 40 mmol/l pH 8.3, Colipase > 1 mg/l, Deoxycholate 1.8 mmol/l, Taurodeoxycholate 72 mmol/l

R2 - Lipase Reagent : Tartrate pH 4.0, Lipase > 0.7 mmol/l, Calcium Chloride 0.1 mmol/l

R3 - Lipase Standard : Standard Lyophilized Human Serum. Concentration is lot specific, see vial label.

#### MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

#### REAGENT PREPARATION, STORAGE & STABILITY

Reagent 1 and Reagent 2 are ready to use.

Standard should be reconstituted by adding distilled or deionized water mentioned on the vial label. Close the vial and let stand for 5 minutes. Dissolve the contents of the vial by swirling gently avoiding formation of foam. Do not shake.

Stability: unopened reagents and standard are stable up to expiration date on labels at 2-8 °C. Do not freeze the reagents. Once opened reagents are stable up to 4 weeks at 2-8 °C. Once reconstituted, standard is stable for 2 weeks at 2-8 °C. Reconstituted standard may be aliquoted and stored for 30 days at -80 °C.

#### REAGENT DETERIORATION

Discard the reagent if absorbance exceeds 0.7 against distilled water at 578 nm.

#### WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

#### SPECIMEN

Use unhemolysed serum, plasma (Li, Na or Heparin only). Lipase is stable up to 7 days at 2-8°C and one year at -20°C. EDTA, oxalate, fluoride or citrate plasma inhibit the lipase activity leading to decreased results. Centrifuge samples containing precipitate before performing assay.

### Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc.	(U/l) See vial label
Filter - 1 (nm)	578
Filter - 2 (nm)	670
Temperature	37 °C
Volume (µl)	450
Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	13
Reference High	60
Linearity Limit	300

### TEST PROCEDURE

Dispense	Blank	Test
Reagent 1	300 µl	300 µl
Standard/ Sample	-	5 µl
Mix, incubate for 5 min at 37°C.		
Reagent 2	180 µl	180 µl
Mix, incubate for 5 min at 37°C. Read absorbance of standard (As) and samples (Ax) at 578/670 nm against reagent blank.		

### RESULT CALCULATION

Serum/plasma:

Lipase mg/dl =  $A_x/A_s \times$  Concentration of Standard

### EXPECTED VALUES

13 - 60 U/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

### QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

When using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

- When using a new reagent or lot
- When QC values are out of range

### TEST PERFORMANCE

#### 1. Linearity

The linearity is up to 300 U/l.

#### 2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 2 U/l.

The limit of quantification is 5 U/l.

#### 3. Interferences

No interference has been observed for the following Hemoglobin up to 50 mg/dl; Bilirubin up to 25 mg/dl Triglycerides up to 1000 mg/dl

#### 4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	50.35	0.32	0.64
sample 2	118.77	0.60	0.51

Inter-assay precision

	Mean	SD	CV
n = 20	U/l	U/l	%
sample 1	52.22	1.44	2.75
sample 2	121.86	2.37	1.94

#### 5. Methods Comparison

Comparison was done between reference Lipase Reagent and CliniQuant - FSR Lipase Reagent (test)

$N = 20$                        $y = 1.012x + 1.331$

$r^2 = 0.997$

### LIMITATIONS

Samples with values above 300 U/l it should be diluted with 0.9% saline 1:1, re-run and multiply results by 2.

### WASTE DISPOSAL


This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

### REFERENCES

- Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 863 - 871.
- Data on file: Meril Diagnostics.

Symbols used on Meril Diagnostics labels:

 Catalogue No.	 Attention See Instruction for Use
 Batch No.	 <i>In vitro</i> Diagnostics
 Expiry Date	 Consult Instruction for Use
 Manufacturer	 Storage Temperature
 Keep Dry	 Keep Away from Sunlight
 Manufacturing Date	 Do not use if package is damaged

 Authorized European Representative in the European Community

IFU/LIPFSR01/00

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