

Intended Use

This reagent is intended for *in vitro* quantitative determination of lipase in human serum or plasma.

- Methyl resorufin method
- Linear up to 300 U/L
- Reagent is ready for use

Clinical Significance

Lipase is a pancreatic enzyme necessary for the absorption and digestion of nutrients that catalyses the hydrolysis of glycerol esters of fatty acids. Determination of lipase is used for diagnosis of diseases such as acute and chronic pancreatitis and obstruction of the pancreatic duct. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

In the presence of colipase and bile acids lipase splits the synthetic substrate (1,2-O-Dilauryl-rac-glycero-3-glutaricacid (6-methyl-resorufin-ester) to glycerol and methylresorufin-ester, which is spontaneously degraded to glutaric acid and methylresorufin. The rate of methylresorufin formation, measured photometrically is proportional to the catalytic concentration of lipase present in the sample.

Kit Components

Reagent/Component	Product Code 12011017	Description
Lipase R1	2 x 70 mL	Goods Buffer (pH 8.0) 40 mmol/L
		Taurodeoxycholate 3.4 mmol/L
		Deoxycholate 6.4 mmol/L
		Calcium chloride 12 mmol/L
		Colipase 1.7 mg/dL
Lipase R2	2 x 20 mL	Tartrate Buffer (pH 4.0) 1.5 mmol/L
		Taurodeoxycholate 3.4 mmol/L
		Color substrate 0.13 mmol/L

Risk & Safety

Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation

Lipase R1 & R2 Reagents are ready to use.

Reagent Storage and Stability

The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8°C, protected from light. Do not freeze.

Open Vial Stability

Once opened the reagents are stable up to 90 days if contamination is avoided.

On-board Calibration Stability

Calibration is stable for 15 days.

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management

Reagents must be disposed off in accordance with local regulations.

Sample

Serum / plasma (with Sodium Citrate, EDTA or Heparin).

Interferences

No interference for

Bilirubin up to 20 mg/dL
Haemoglobin up to 1000 mg/dL

Materials provided

Lipase R1 & R2 Reagents

Reagents required but not provided

Multicalibrator (Product Code: 11610002), Qualicheck Norm (Product Code: 11601003), Qualicheck Path (Product Code: 11601002)

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
U/L	µKat/L	x 0.017

Calibration

Agappe Multicalibrator (Product Code: 11610002) is recommended for calibration of the assay.

Quality control

It is recommended to use Qualicheck Norm (Product Code: 11601003) or Qualicheck Path (Product Code: 11601002) to verify the performance of the measurement procedure. Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range

It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.

Serum/Plasma: up to 60 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity

The reagent is linear up to 300 U/L. If the concentration is greater than linearity (300 U/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of $r^2 = 0.9579$ and a regression equation of $y = 1.0035x$.

3. Precision

Control	Intra Run		Inter Run	
	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (U/L)	30.2	55.4	30.74	55.39
SD	1.17	2.66	1.35	2.32
CV(%)	3.88	4.79	4.38	4.19

Accuracy (U/L)

Control	Expected Value	Measured Value
Control Level 1	43.2 ± 8.6	46.7
Control Level 2	71.8 ± 14.4	76.5
Qualicheck Norm	48.8 ± 9.2	50.7
Qualicheck Path	122 ± 20	122.1

4. Sensitivity

Lower detection Limit is 3 U/L

Bibliography

1. Mc Neely, M. ; Lipase. Kaplan, A. *et al.*; Clin. Chem. The C.V.Mosby Co. St Louis, Toronto. Princeton 1984, 1130-1135.
2. Burtis, A., *et al.* ; Tietz Textbook of Clinical chemistry, 3rd Ed. AACCC
3. Neumann, U., *et al.*; Methods of Enzymatic Analysis, Vol 4, 3rd Ed.

SYMBOLS USED ON THE LABELS

IN VITRO DIAGNOSTIC USE
 SEE PACKAGE INSERT FOR PROCEDURE
 LOT NUMBER
 MANUFACTURER'S ADDRESS
 MANUFACTURING DATE
 EXPIRY DATE
 TEMPERATURE LIMIT