LIPASE

BioSystems

COD 11760 1 x 30 mL
Only for *in vitro* use in the clinical laboratory

CE

LIPASE
DGGR

INTENDED USE

Reagent for the measurement of lipase concentration in human serum or plasma for the assessment of its variations in general population.

CLINICAL BENEFIT

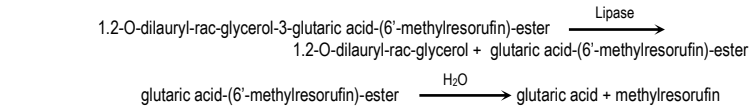
Serum lipase concentration increases after an attack of acute pancreatitis. In general, increases in amylase and lipase run in parallel course, but the elevation of lipase persists for a longer period of time. Elevations in serum lipase concentration may be also due to obstruction of the pancreatic duct by a calculus or by carcinoma, in acute and chronic renal disease as well as in treatments with opiates[1,2,3].

Based on clinical guidelines and textbooks, and when used in conjunction with other diagnostic technologies and options, this medical information is useful for the assessment of Lipase variations.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Lipase catalyzes the hydrolysis of the chromogenic substrate 1.2-O-dilauryl-rac-glycerol-3-glutaric acid-(6'-methylresorufin)-ester to 1.2-O-dilauryl-rac-glycerol and an unstable intermediate, glutaric acid-(6'-methylresorufin)-ester. This descomposes spontaneously in alkaline solution to form glutaric acid and methylresorufin. The catalytic concentration is determined from the rate of the red dye formation measured at 560 nm[1,4].



CONTENTS AND COMPOSITION

A. Reagent: 1 x 20 mL. Bicine buffer 50 mmol/L, colipase ≥ 1 mg/L, deoxycholate 1.6 mmol/L, calcium chloride 10 mmol/L, pH 8.0.

B. Reagent: 1 x 10 mL. Tartrate buffer 10 mmol/L, 1.2-O-dilauryl-rac-glycerol-3-glutaric acid-(6'-methylresorufin)-ester ≥ 0.3 mmol/L, taurodesoxycholate 8.0 mmol/L, pH 4.0.

WARNING: H226: Flammable liquid and vapour. H317: May cause an allergic skin reaction. P210: Keep away from heat, sparks, open flames or hot surfaces. P261: Avoid breathing vapours. P280: Wear protective gloves, protective clothing, eye protection, face protection. P403+P235: Store in a well-ventilated place. Keep cool.

For further warnings and precautions, see the product safety data sheet (SDS).

S. Lipase Standard: 1 for 5 mL. Human lipase in human serum matrix. Concentration is given on the label.

Components from human origin have been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for Hbs antigen. However, they should be handled cautiously as potentially infectious.

STORAGE AND STABILITY

Store at 2-8ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

Reagent B may present aggregates which do not affect its functionality.

Indications of deterioration. Absorbance of the blank over 0.80 at 560 nm.

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to Biosystems S.A.

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

- Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).
- Analyzer, spectrophotometer or photometer with cell holder thermostatable at 37ºC and able to read at 580 nm. Cuvettes with 1 cm light path.

REAGENT PREPARATION

Reagents are provided ready to use.

SAMPLES

Serum or plasma collected by standard procedures. Heparin may be used as anticoagulant.

Lipase concentration in the sample is stable for 7 days at 20-25 ºC, 21 days at 4-8ºC and 12 months at -20ºC[5].

PROCEDURE

1. Bring the reagents and the instrument to reaction temperature.
2. Pipette into a cuvette (Note 1):

Reagent A	850 µL
Sample/Standard	15 µL

3. Mix and insert the cuvette into the instrument. Start the stopwatch.
4. After 1 minute, pipette into a cuvette:

Reagent B	500 µL

5. Mix and after 3 minutes, record initial absorbance and at 1 minute intervals thereafter for 3 minutes.
6. Calculate the difference between consecutive absorbances, and the average absorbance difference per minute (ΔA/min).

CALCULATIONS

The lipase concentration in the sample is calculated using the following general formula:

$$\frac{\Delta A/min_{Sample}}{\Delta A/min_{Standard}} \times C_{Standard} = U/L$$

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007, 18010 and 18043) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

REFERENCE VALUES[2]

Serum or plasma: 13-60 U/L = 0.22-1.00 µkat/L.

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

- Detection limit: 4.89 U/L = 0.08 µkat/L. Quantification limit: 8.52 U/L = 0.14 µkat/L.
- Linearity limit: 250 U/L = 4.17 µkat/L. For higher values dilute sample 1/2 with distilled water and repeat measurement. Measuring range: (8.52 U/L = 0.14 µka/L) - (250 U/L = 4.17 µkat/L).
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
52.1 U/L = 0.86 µkat/L	1.4 %	4.1 %
67.2 U/L = 1.11 µkat/L	2.2 %	5.3 %
122 U/L = 2.03 µkat/L	1.6 %	5.0 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Lipase values for human serum and heparin plasma samples obtained on BA400 analyzer (y) were compared with those determined on a Roche Cobas 8000 analyzer (x). Serum: Sample size (n)=88; Linear regression y=5.99+0.993x, r=0.971. The sample concentrations were between 15 and 240 U/L. Plasma: Sample size (n)=57; Linear regression y=5.59+0.964x, r=0.996. The sample concentrations were between 12 and 285 U/L.

LIMITATIONS OF THE PROCEDURE

- Interferences: hemolysis (hemoglobin up to 500 mg/dL), bilirubin (up to 30 mg/dL) and lipemia (triglycerides up to 300 mg/dL) do not interfere. Other drugs and substances may interfere[6].
- The triglycerides reagent contains a very high lipase concentration that could interfere in lipase measurements. Current versions of Software solve the contamination by means of protocols already programmed by default in the analyzer. It is recommended to perform lipase measurements in series without triglycerides assays when abnormal results are detected.

NOTES

1. This reagent may be used in several automatic analyzers. Instructions for many of them are available upon request.

BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 6th ed. Rifai N, Horvath AR, Wittwer CT. WB Saunders Co, 2018.
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3. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
4. Panteghini M, Bonora R, Pagani F. Measurement of pancreatic lipase activity in serum by a kinetic colorimetric assay using a new chromogenic substrate. *Ann Clin Biochem* 2001;38:365-370.
5. World Health Organization (WHO). Use of anticoagulants in diagnostic laboratory investigations. Document WHO/DIL/LAB/99.1, Rev.2; 2002.
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