LIPASE

BioSystems

COD 12760 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. The obtained values are useful as an aid in the evaluation of pancreatic disorders.

This reagent is for use in the BioSystems A25 and A15 analyzers.

CLINICAL BENEFIT

Lipases hydrolyzes glycerol esters of long-chain fatty acids. Although lipase can be secreted by other glands and mucosa, only pancreatic lipase is of interest in medical diagnosis. Therefore, lipase measurements on serum are used exclusively to investigate pancreatic disorders.

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 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].

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].

1,2-O-dilauryl-rac-glycerol-3-glutaric acid-(6'-methylresorufin)-ester $\xrightarrow{\text{Lipase}}$ 1,2-O-dilauryl-rac-glycerol + glutaric acid-(6'-methylresorufin)-ester

glutaric acid-(6'-methylresorufin)-ester $\xrightarrow{H_2O}$ glutaric acid + methylresorufin

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. Avoid breathing vapours. P280: Wear protective gloves, protective clothing, eye protection, face protection. P403+P235: Store in a well-ventilated place. Keep cool.

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 the limit indicated in "Test Parameters".

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 30 days.

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

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.

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 20-25ºC, 21 days at 4-8ºC and 12 months at -20ºC[5].

CALIBRATION

A reagent blank should be done every day and a calibration at least every 30 days, after reagent lot change or as required by quality control procedures.

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

The metrological characteristics described below have been obtained using an A25 analyzer and following the guidelines of the Clinical & Laboratory Standards Institute (CLSI). Results are similar with A15.

- Detection limit: 2.86 U/L = 0.05 μkat/L. Quantification limit: 9.84 U/L = 0.16 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: (9.84 U/L = 0.16 μka/L) - (250 U/L = 4.17 μkat/L).
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
48.9 U/L = 0.81 μkat/L	2.2 %	4.7 %
64.9 U/L = 1.08 μkat/L	2.4 %	4.6 %
122 U/L = 2.03 μkat/L	1.8 %	4.5 %

- 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.

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 interferes in lipase measurements by contamination of the reaction cuvette that is not eliminated with ordinary washing. It is recommended to perform lipase measurements in series without triglycerides assays and using a new cuvettes rotor.

BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 6th ed. Rifai N, Horvath AR, Wittwer CT. WB Saunders Co, 2018.
2. Junge W, Abicht K, Goldman J et al. Evaluation of the colorimetric liquid assay for pancreatic lipase on Hitachi analyzers in clinical centers in Europe, Japan, and USA. *Clin Chem Lab Med* 1999;37, special suppl:469.
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.
6. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS

R1: Use Reagent A

R2: Use Reagent B

	A25	A15
GENERAL		
Name	**LIP DGGR**	**LIP DGGR**
Sample type	SER	SER
Analysis mode	kinetic bireagent	kinetic bireagent
Units	U/L	U/L
Turbidimetry test	no	No
Decimals	2	2
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	monochromatic	monochromatic
Main filter	560	560
Reference filter	-	-
Sample	3	3
Vol. R1	170	170
Vol. R2	100	100
Washing	1.2	1.2
Reading 1 (cycle)	19	12
Reading 2 (cycle)	27	17
Reagent 2 (cycle)	7	5
Predilution factor	-	-
Postdilution reduced factor	2	2
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	1	1
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.800	0.800
Kinetic blank limit	-	-
Linearity limit	250	250
Substrate depletion	-	-

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