LIP - LIPASE

Intended Use

LIP reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Enzyme Validator Set, is intended for the quantitative determination of Lipase activity in human serum or plasma in random access mode.

Clinical Significance

Lipase measurements are used primarily in the diagnosis and treatment of pancreatic disorders.

Methodology

The Random Access Lipase reagent utilizes the methodology of Panteghini to determine pancreatic lipase activity in serum and plasma. The SYNCHRON® System(s) monitors the rate of formation of methylresorufin which forms spontaneously from two coupled reactions which utilize a 1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin)-ester as a substrate. The measured rate of color formation at 560 nm is directly proportional to the pancreatic lipase activity.

The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 54 parts reagent. The system monitors the change in absorbance at 560 nanometers. The rate of formation of the methylresorufin is directly proportional to the activity of LIP in the sample and is used by the System to calculate and express the LIP activity.

One unit (U) is defined as the amount of enzyme activity which liberates 1 µmol of methylresorufin from 1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6`-methylresorufin)-ester per minute at +37°C.

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Specimen

Type of Specimen

PST (Lithium Heparin) is the specimen of choice

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells as soon as possible. A maximum limit of eight hours from the time of collection is recommended.
2. Separated serum or plasma should not remain at room temperature longer than 4 hours. If assays are not completed within 4 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

Sample Volume

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample. For optimum primary sample tube volumes and minimum volumes, refer to the Primary Tube Sample Template for your system.

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Reagents

Reagent Preparation

No preparation is required.

Reagent Storage and Stability

LIP reagent when stored unopened at +2°C to +8°C will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 21 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.

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Calibration

Calibration Required

SYNCHRON® Systems Enzyme Validator Set

Calibration Preparation

No preparation is required.

Calibration Storage and Stability

SYNCHRON® Systems Enzyme Validator Set when stored unopened at -15°C to -20°C will remain stable until the expiration date printed on the label. Once opened, resealed calibrators are stable for 60 days at -15°C to -20°C unless the expiration date is exceeded.

Quality Control

See Beckman / Policy LCHS-5020

Specimen Processing

See Beckman / Policy LCHS-5020

Reference Range

16 – 63 U/L

Analytic Range

Sample Type	Conventional Units
Serum or Plasma	10 – 20000 U/L
Serum or Plasma (ORDAC)	180 – 400 U/L

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Dilutions

Diluent	Samples with activities exceeding the high end of the analytical range should be rerun with ORDAC enabled or diluted with a patient sample of Low Lipase value, and reanalyzed.
Calculation	*Result = Diluted Inst. Conc.- (Diluent Conc. x Parts Diluent/Parts Patient)*

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Reviewed and approved by:

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HISTORY PAGE

Effective Date**:** __12/17/13__

Change type: New, major, minor	Changes made to SOP - describe	Signature responsible person/date	Medical Director review/date	Laboratory Director review/date	Date change implemented
New	New Format	B. Salas 11/07/13	D. Quach 12/16/13	D. Topliff 11/07/13	12/17/13
Minor	New Directorship	B. Salas 02/24/14	M. Taira 02/24/14	D. Topliff 03/14/14	03/14/14