LIP – LIPASE

Intended Use

The Lipase NG OC assay is an in vitro diagnostic test used for the determination of the Lipase activity in serum and plasma by kinetic colorimetric method. The assay is intended for professional use only.

Clinical Significance

Lipase enzymes are produced in the pancreas and also secreted in small amounts by the salivary glands as well as by gastric, pulmonary and intestinal mucosa. Determination of lipase is used for diagnosis and treatment of diseases of pancreas such as acute and chronic pancreatitis and obstruction of the pancreatic duct.

Methodology

The method for the determination of lipase is based on the cleavage of specific chromogenic lipase substrate 1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin)-ester emulsified in stabilized micro-particles. In the presence of specific activators of pancreatic lipase as colipase, calcium ions and bile acids, the substrate is converted in 1,2-O-dilauryl-rac-glycerol and glutaric acid-6'-methylresorufin-ester which decomposes spontaneously in glutaric acid and methylresorufin. The increase of absorbance, due to methylresorufin formation, is proportional to the activity of lipase in the sample.

Specimen

Type of Specimen

Specimen Type	Collection Vessel
• Serum	Serum Tubes (with or without gel barrier)
• Plasma	Collection tubes Acceptable anticoagulants are: Lithium Heparin (with or without gel barrier) Sodium Heparin

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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 within two hours from the time of collection.
2. For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation. For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets. Specimens should be free of bubbles.

Specimen Type	Temperature	Maximum Storage Time
Serum/ Plasma	2 to 8°C	7 days
	-20°C	12 months

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Sample Dilution Procedures

Serum/Plasma

Samples with lipase values exceeding 300 U/L are flagged ">300 U/L".

Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl). The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

Reagents

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Reagent Handling

- Reagents, stored at 2-8 °C in unopened vials, are stable up to the expiry date indicated on the package. Components of the kit and initial concentration of reactive ingredients:
  - REAGENT 1 (green cap): tris buffer 40 mmol/L pH 8.0, colipase ≥ 1 mg/L, desoxycholate ≥ 0.9 mmol/L, taurodesoxycholate ≥ 7.0 mmol/L

  - REAGENT 2 (red cap): tartrate buffer 10 mmol/L pH 4.0, lipase substrate □ 0.7 mmol/L, calcium ions □ 1 mmol/L, taurodesoxycholate □ 3.0 mmol/L
- **PREPARATION OF REAGENTS FOR USE**
  1. REAGENT 1 and REAGENT 2 are liquid and ready to use.
  2. Invert vials gently before removing screw caps.
  3. Remove screw caps from the reagent vials.
  4. Check each compartment for bubbles and remove any bubbles present.
- **NOTES AND LIMITATIONS**
  1. REAGENT 1 is in a clear liquid form, discard if turbid.
  2. REAGENT 2 is an orange-colored micro-emulsion. In some storage conditions (i.e. storage at a temperature lower than the one indicated) a precipitate may appear in the vial that will not influence the reagent performance; however, it is recommended to resuspend the product with a slight rotation of the vial before carrying out the analysis. Some lipases of microbial origin, used in the manufacturing reagents for enzymatic determination of triglycerides, may result in a strong adhesion to the plastic cuvettes of the instruments. Therefore it is recommended to verify on random access analyzers any possible lipase contamination by performing a test with a reagent for lipase determination before its routine use and to adopt suitable actions (i.e. washing with acid solution) to avoid this problem.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results

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Reagent Storage and Stability

	Storage Temperature	Maximum Storage Time
Unopened	2 to 8°C	Until expiration date
Onboard	System Temperature	30 days

Calibration

Calibration Required

Calibration is stable for approximately 30 days (720 hours), but is required with each change in reagent cartridge or lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary. This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed. Calibration material is the Lipase NG OC Cal.

Calibration Preparation

Calibration material is the Lipase NG OC Cal.

1. Remove from refrigerator
2. Reconstitute 3.0mL of DI water
3. Gently swirl
4. Leave to stand for 30 minutes
5. Gently invert; avoid foaming

Calibration Storage and Stability

	Calibrator Storage	Stability Once OPEN
Lipase Cal	Unopened: 2 to 8 (until expiration date)	2 to 8: 2 days -20 °C: 2 weeks

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Quality Control

See Policy Chemistry Quality Control Policy

Sample Processing

See Policy RIV-PPP-1199

Reference Range

Test unit=U/L for all ages and both sexes

Age Year Low	Age year High	Ref Low	Ref High
0	250	0	60

Analytic Range

AMR Low	AMR High	CRR Low	CRR High
4	300	4	7500

Author

Melanie Beermann, CLS

Distributions

Kaiser Permanente Riverside Service Area Laboratory

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