Alinity c LIPASE-26

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BIENNIAL REVIEW:

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SUPERSEDES: Procedure titled _____

INTENDED USE

To be used on CHEMISTRY DEPARTMENT – ALINITY-c

PRINCIPLE

The Lipase NG OC assay is an in vitro diagnostic test used for the determination of the Lipase activity in serum. 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.

Methodology: Kinetic colorimetric method

CLINICAL SIGNIFICANCE

Lipase enzymes are produced in the pancreas and 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.

SPECIMEN REQUIREMENTS

Specimen Type and Condition

Follow the normal procedures for collecting and processing a serum specimen for analysis.
Serum is the verified specimen type.
Sample volume for a single test is 2 µL.
Samples free of fibrin, red blood cells and other particulate matter and bubbles.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum	2 to 8°C	7 days
	-20°C	1 year

REAGENTS

Handling

REAGENT 1 and REAGENT 2 are liquid and ready to use.

Invert vials gently before removing screw caps.

Remove screw caps from the reagent vials.
Transfer R1 to the empty R1 bottle assembly of a black reagent cartridge

Transfer R2 to the empty R2 bottle assembly of the same black reagent cartridge

Check each compartment for bubbles and remove any bubbles present.

Create barcode and label

REAGENT 1 is in a clear liquid form, discard if turbid.

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.

Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

SUPPLIES AND EQUIPMENT

Materials Provided

04Y85-20 Lipase NG OC Reagent Kit

Materials Required but not Provided

04Y85-01 Lipase NG OC Cal

04Y85-10 Lipase NG OC CTRL 1

04Y85-11 Lipase NG OC CTRL 2

Saline (0.85% to 0.90% NaCl) for specimen dilution

CALIBRATION

Calibration Frequency

Calibration is stable for approximately **30 days (720 hours),** if contamination is avoided but is required with each change in reagent lot. Verify calibration with at **least 2 levels** of controls according to the laboratory quality control policy. 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.

Required Calibrators

04Y85-01 Lipase NG OC Cal

Calibrator Preparation

Follow the package insert included with every Calibrator set.

QUALITY CONTROL

QC Materials

Use Lipase NG OC CTRL 1 & 2 or other appropriate material to monitor assay performance.

QC Frequency

Analyze Quality Control material minimum of 2 every day test performed.
Analyze all levels of quality control material each time a calibration is performed.
Analyze all levels when instructed by service personnel.
Refer to Chemistry Quality Control SOP if QC is out of range.

ANALYSIS

Sampling, reagent delivery, mixing, separation, processing and printing of results are automatically performed by the instrument. For a detailed description of how to run an assay, **refer to the Anility ci-series Operations Manual, Section 5.**

RESULTS

Analytical Measurement Range (AMR): 4.0 U/L – 300 U/L
Lipase: < 4.0 is reported as < 4.0 U/L.
Lipase: > 3,000 is reported as > 3,000 U/L

Reference Range:

≤ 60 U/L

Critical Values:

N/A

DILUTION

Auto dilution 1:10

LIMITATONS OF THE PROCEDURE

Flags
Some results may contain information in the Flags field. For a description of the flags that may appear in this field, **refer to the Alinity ci-series Operations Manual, Section 5**.

Interference
Potentially Interfering Endogenous Substances:
Interference studies were conducted using an acceptance criterion of
± 10% or 6.0 U/L deviation, whichever is greater, from the target value.
The test is not affected by the presence of unconjugated bilirubin up to **66** mg/dL, conjugated bilirubin up to **66** mg/dL, hemoglobin up to **500** mg/dL and lipids up to **1000** mg/dL.

REFERENCES

Lipase NG OC Reagent Kit package insert. Sentinel Diagnostics, Distributed by Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064. Jan 2019.

Lipase NG OC Cal package insert. Sentinel Diagnostics, Distributed by Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064. Feb 2019.

Lipase NG OC CTRL 1 package insert. Sentinel Diagnostics, Distributed by Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064. Feb 2019.

Lipase NG OC CTRL 2 package insert. Sentinel Diagnostics, Distributed by Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064. Feb 2019.

Alinity ci-series Operations Manual. Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064. Sept. 2018