| **Lipase** |
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| **Purpose** | This procedure provides instructions for LIPASE on ABBOTT INSTRUMENTATION. The Lipase method is an *in vitro* diagnostic test for the quantitative measurement of albumin in human serum and plasma on the Abbott Architect c4000 or Abbott Alinity c automated chemistry analyzers. |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Abbott Alinity c or Alinity ci integrated system at Children’s Minnesota Laboratory.  |
| **Principle** | The method for 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-Odiauryl-rac-glycerol and glutaric acid-6’-methylresorfin-ester which decomposes spontaneously in glutaric acide and metylresorufin. The increase of absorbance, due to methylresorufin formation, is proportional to the activity of lipase in the sample.Methodology: Kinetic colorimetric |
| **Clinical Significance** | Pancreatic lipase degrades dietary triglycerides to glycerol and free fatty acids in the presence of bile salts. Lipase measurements are used in the diagnosis of diseases of the pancreas, such as acute pancreatitis and obstruction of the pancreatic duct.**Acute Pancreatitis**: By far the most important use of the serum amylase and lipase assays is elucidation of the cause of acute abdominal pain. One possible cause is acute pancreatitis, a disease in which the pancreatic enzymes leak out of the cells into the gland itself, causing varying degrees of self-digestion accompanied by inflammation and hemorrhage. There are a number of different causes of acute pancreatitis, including ingestion of large amounts of alcohol and sudden obstruction of the duct through which pancreatic secretions pass on their way to the small intestine. The most common manifestations of this disease are severe abdominal pain and shock (fall in blood pressure). Acute pancreatitis from any cause is a serious disease with a high mortality rate. Treatment, which is often ineffective, is to minimize the secretion of pancreatic juice and maintain the blood pressure. Any kind of stress, including surgery is to be avoided. The physician uses serum lipase and amylase values to help in differentiating this problem from the more common bowel disorders which may produce the same symptoms but which require immediate surgery (example - acute appendicitis). In acute pancreatitis the serum amylase rises within a few hours after the onset of pain. Typically peak activity is reached within twelve hours, and there is a rapid fall to normal levels within two to five days, In general, increases in amylase and lipase run a parallel course in acute pancreatitis, but the elevation of lipase persists for a longer time.**Other Diseases Of The Pancreas**: Transient rises in serum amylase may occur during the course of chronic pancreatitis, but lipase is only occasionally elevated. In carcinoma of the pancreas, lipase may be elevated because the tumor obstructs the common bile duct or pancreatic duct.**Salivary Gland Disease**: It is of some importance that serum amylase may be substantially elevated in diseases of the salivary glands as well as in pancreatic disease. The two diseases can often be distinguished by the fact that lipase does not rise in diseases of the salivary glands. |
| **Analyzer** | **Minneapolis: Abbott Alinity c (Sunquest method code: MALIC) and Abbott Alinity ci (Sunquest method code: MALCI; MACC for c-side.)****St. Paul: Abbott Architect c4000 (Sunquest method code: ARCH4) and Abbott Alinity c (Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | LIPA: Lipase in serum and plasma |
| **Specimen** | Sample: Plasma (lithium heparin with or without gel) preferred. Sodium heparin plasma or serum (with or without gel) also acceptable. Refer to specimen collection procedures.**Minimum sample volume:** 200 µL preferred, 150 µL minimum**Stability when separated from cells/gel:** RT/ 12 hours, 2-8 °C / 7 Days, < -20°C / 12 months**Rejection criteria:** Unlabeled tube, sample type other than serum or heparinized plasma. EDTA inhibits the LPS activity.**Patient Preparation:** None**Preparation:** 1. Whole blood specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis.
2. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
3. Specimens should be free of particulate matter.
4. Transfer serum or plasma to a properly labeled pilot tube, sendout tube, or Abbott sample cup. Architect and Alinity systems utilize a specimen level detect mechanism, so special racks specific to tube-type are not required. Very low volumes should be pipetted into an Abbott sample cup and placed on top of a pilot or sendout tube. Both sample cup and carrier tube must be properly labeled. After testing, if there is any volume left, pipette the remaining amount into the sendout or pilot tube and cap tightly.
5. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
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| **Reagents** | **Reagent Handling** This is a third party assay manufactured by Sentinel Diagnostics and distributed through Abbott Diagnostics for use on the Abbott platform. Printing a barcode specific to each reagent loaded is required. See the [Alinity Operating Procedure](https://starnet.childrenshc.org/References/labsop/chem/procedure/ch5.108-abbott-alinity-c-operating-procedure.pdf) for more information.Reagent 1 is in clear liquid form. Discard if turbid. Carefully pour the entire 55 mL R1 reagent into the larger side of the black Alinity cartridge.Reagent 2 is an orange-colored micro-emulsion. Gently mix to re-suspend the microparticles prior to placing carefully pouring the 20 mL R2 into the smaller black Alinity cartridge bottle. Avoid bubbles.If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate. 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. Use a pipette to remove all bubbles prior to loading on the Alinity or Architect system.* Do not use reagents beyond the expiration date.
* Do not pool reagents within a kit or between kits.
* Do not use components from one lot with components from another lot.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Sentinel Diagnostics Lipase NG OC Reagent | 04Y85-20 | **Store at:** 2 – 8 °C**Unopened:** Manufacturer’s printed expiration date**On-board: 30 days****Opened, off the analyzer (with clean caps):** Manufacturer’s printed expiration date. (Reagents may be stored on or off the system. The system tracks time onboard.) |
| Sentinel Diagnostics Lyophilized Lipase NG OC Controls, 1 and 2 | Control 1: 04Y85-10 Control 2: 04Y85-11 | **Store at:** 2 – 8 °C**Unopened:** Manufacturer’s printed expiration date**Reconstituted Expiration:** Refer to the packaging TcA insert for stability of controls when stored at 2 – 8 °C. Typically5 days @2 – 8 °C |
| Sentinel Diagnostics Lyophilized Lipase Calibrator | 04Y85-01 | **Store at:** 2 – 8 °C**Unopened:** Manufacturer’s printed expiration date**Reconstituted expiration:** Refer to the packaging TcA insert for stability of calibrator when stored at 2 – 8 °C. Typically 2 days. Add exactly 3.0 mL of deionized water, being careful not to lose any of the lyophilized pellet in the process. Replace the stopper and gently swirl. Let stand for 30 minutes.**Calibration Stability**: 30 days |

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| **Risk and Safety** |

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| **CAUTION:** For in vitro diagnostic use. This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Appropriate Personal Protective Equipment (PPE) must be worn according to Children’s Minnesota Laboratory policies. Current SDSs are kept on the [Children’s StarNet](https://msdsmanagement.msdsonline.com/a07dc954-23d8-42a9-b591-ef5763cdfd33/ebinder/?nas=True) pageDispose of unused materials in regular waste. |

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| **Calibration** | **Alinity c:**

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| Assay Range: | 4.0 U/L – 300.0 U/L |
| Reference Material: | Sentinel Diagnostics Lipase NG OC Lyophilized Calibrator |
| Suggested Calibration Levels: |  See lot-specific assay set point documentation. Typically 96 U/L |
| Calibration Scheme: | 1 Standard, Linear Rate Up Reaction |
| Calibration Frequency: | 30 Days |
| AMR | AMR is verified twice annually using the Maine Standards GC3 Product # 1300ab by running all applicable levels in triplicate. Assay results are submitted to Maine Standards for compilation and comparison to peers. Results are reviewed and approved by the Technical Specialist. Any questionable results are investigated and corrective actions documented.  |

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| **Quality Control** | Sentinel Diagnostics Lipase NG OC Controls, Level 1 and Level 2**Frequency:** Two levels each day of use**Stability:** Check current package insert in control box, “TcA”. Typically, 5 days when stored tightly capped at 2 to 8°C.**Preparation**: This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used. * Each control vial must be reconstituted using exactly 5.0 mL of lab-grade de-ionized water and allow to completely dissolve. Swirl gently and let stand for 30 minutes. Set a timer.
* For optimal analyte stability in the reconstituted state, promptly return to 2 to 8°C storage after each use and minimize the time at room temperature to no more than 20 minutes daily.
* **Before each use**, allow to come to room temperature. Gently swirl the contents until homogeneous with no visible signs of precipitate. Avoid bubbles; do not shake.

**Acceptable ranges:** * Non-Bio-Rad controls will utilize manufacturer ranges and 2 SD Westgard rules. See TcA package insert for targets.
* New lots of Bio-Rad controls should be run for 20 days in parallel with the current lot whenever possible prior to switching to the new lot.
* Refer to the [Westgard Rules in Chemistry](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.18-westgard-rules-in-chemistry.pdf) procedure for current Westgard rules in place for each analyte.
* **Acceptable ranges are current in Unity Real Time only.** Quality Control results must be rejected in Sunquest when the results cross the interface.
* In the event of a QC failure, refer to the [Unity Real Time QC Review, General User](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.17-unity-real-time-qc-review-general-user.pdf) and navigate to the QC Troubleshooting section.
* Do not load or release patients until QC is acceptable in Unity Real Time.
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| **Interferences** | **Hemolysis, Icterus & Lipemia (HIL) Index Values:**

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At HIL levels at or above the specified cutoff value, append the appropriate comment AFTER visually confirming presence of interferent: -HP for “Hemolysis present, may affect results.” -BIN for “Bilirubin Interference”-LINT for “Lipid Interference”Interference studies were conducted by Abbott Diagnostics Division using NCCLS EP7-P. Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte. Interference is less than 10% at an Albumin concentration level of 4 g/dL for:* Hemoglobin: up to 500 mg/dL
* Bilirubin: up to 66 mg/dL
* Lipemia (Intralipid®): up to 1000 mg/dL

Interferences from medication or endogenous substances may affect results.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.  |
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| **Reference Intervals** |

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| Age | Lipase U/L |
| 0 – 18 years | 4.0 to 40.0 |
| Adult | 4.0 to 60.0 |
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| **Critical Values** | None specified. |
| **Limitations** | The instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in albumin results. Refer to the [Abbott Architect](https://starnet.childrenshc.org/References/labsop/chem/operator/abbott-architect-operations-manual.pdf) or [Alinity](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) Operator’s Guides for the meaning of report flags and comments, and instructions for addressing them. Do not report results until a report containing flags and/or comments is resolved.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.  |
| **Dilutions** |

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| Max Auto Dilution: | none |
| Maximum Manual Dilution: | 1:10 |
| Diluent: | Saline |
| Manual Dilution: | Follow Abbott [Alinity Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) instructions for programming automated dilutions. The system will automatically calculate the concentration of the sample and report the result.  |

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| **Result Reporting** | **All analyzers:** * Results between 4.0 – 300.0 U/L without error messages are released
* Results below 4.0 U/L: report as < 4.0 U/L instead of the numerical value.
* Results >300.0 should be manually diluted 1:10 with saline. After dilution, results 300.0 to 3000.0 are reported as the numerical value.
* Results >3000.0 U/L without error messages are reported as > 3000.0 U/L
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in a specimen rack. Every 8 hours, remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. Sentinel Diagnostics Lipase NG OC Calibrator Kit Package Insert and TcA, Sentinel Diagnostics, Distributed by Abbott Diagnostics.
2. Sentinel Diagnostics Lipase NG OC Control 1 Kit Package Insert and TcA. Sentinel Diagnostics, Distributed by Abbott Diagnostics.
3. Sentinel Diagnostics Lipase NG OC Control 2 Kit Package Insert and TcA. Sentinel Diagnostics, Distributed by Abbott Diagnostics.
4. Sentinel Diagnostics Lipase NG OC Reagent Kit Instructions for Use, Sentinel Diagnostics, Distributed by Abbott Diagnostics 04Y85-20 – 2.0/02, 3/18/2019.
5. CALIPER pediatric reference range database. (2019). Retrieved October 3, 2020, from https://caliper.research.sickkids.ca/#/
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Erin Bartos | 10/18/2020 | New Procedure for Abbott Alinity c |
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