| **Lactate Dehydrogenase** |
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| **Purpose** | This procedure provides instructions for performing LACTATE DEHYDROGENASE (LDH) ON ABBOTT INSTRUMENTATION. The Alinity c Lactate Dehydrogenase assay is used for the quantitation of lactate dehydrogenase in human serum, or body fluid plasma on the Alinity c analyzer. |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children’s Minnesota Laboratory. |
| **Principle** | Lactate dehydrogenase is a hydrogen transfer enzyme that catalyzes the oxidation of L-lactate to pyruvate with the mediation of NAD+ as a hydrogen acceptor.Lactate dehydrogenaseL-Lactate + NAD+ → Pyruvate + NADH H+**Methodology**: IFCC-recommended forward reaction: Lactate to Pyruvate.For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section |
| **Clinical Significance** | LDH is an enzyme found in the cells of many body tissues, including the heart, liver, kidneys, skeletal muscle, brain, red blood cells, and lungs. It is responsible for converting muscle lactate into pyruvate, an essential step in producing cellular energy. It is composed of four peptide chains of two subunits (M form and H form) which results in up to five different isoenzymes which can be separated and quantitated by electrophoresis. Measurement of the total LDH activity in serum or plasma is non-specific and cannot differentiate the tissues of origin of the component isoenzymes. LDH is used in the differential diagnosis of hemolytic anemia and as a tumor marker in some malignancies, such as germ cell tumors. LDH is elevated in hepatitis, glomerular nephritis, pulmonary embolism, muscle disease, and many leukemias and lymphomas. As LDH is a non-specific marker, it is used in combination with other markers in diagnosis and patient management. |
| **Analyzer** | **Minneapolis: Abbott Alinity c (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code:SALIC)** |
| **Sunquest Test Codes** | **LDH** Lactate Dehydrogenase, serum or plasma**FLDH** Lactate Dehydrogenase Body Fluid |
| **Specimen** | Sample: Plasma or Serum **Preferred:** Lithium Heparin (with or without gel barriers)**Alternative:** Serum (with or without gel), Sodium HeparinSee procedure [CH 4.021 Body Fluid Chemistry Testing](https://starnet.childrenshc.org/References/labsop/chem/collect/ch-4.021-body-fluid-chemistry-testing.pdf) for information on specimen for LDH Body Fluid.Hemolyzed specimens should not be used because erythrocytes contain approximately 150 times more LDH activity. Accurate results cannot be obtained on hemolyzed samples. Request redraw. **Minimum sample volume:** 0.6 mL blood, 0.2 mL serum/plasma**Plasma/Serum Stability when separated from cells/gel:** **20 to 25°C:** 7 days**2 to 8°C:** 4 days **-20°C**: 6 weeksBody Fluids should be stored at refrigerated temperatures for up to 7 days. Integrity decreases rapidly for LDH, and should be interpreted with caution if testing does not occur within 48 hours of collection. Store at 2-8° C if there will be any delay in testing.**Rejection criteria:** Unlabeled tube, sample type other than serum or acceptable plasma, hemolysis.**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.
5. Architect and Alinity systems utilize a specimen level detect mechanism, so special racks specific to tube-type are not required.
6. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
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| **Reagents** | **Reagent Handling** Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate. 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.
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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Alinity c Lactate Dehydrogenase Reagent Kit | 07P7420 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board**: 30 days |

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| **Risk and Safety** | Product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens.The following warnings and precautions apply to R1Contains diethanolamine and sodium azide.Suspected of causing cancerMay cause damage to organs through prolonged or repeated exposure.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 30 to 4500 U/L**LDH Body Fluid** AMR: 30 to 1000 U/L  |
| Reference Material: | Water Blank and Lactate Dehydrogenase Reagent  |
| Suggested Calibration Levels: | 2 levels of calibration |
| Calibration Scheme: | The calibration factor was established based on the IFCC methodology. The calibration factor for the Alinity c Lactate Dehydrogenase assay is 11180. |
| Calibration Frequency: | 30 Days, with every new reagent lot, after maintenance to critical parts, and any time QC results indicate need for calibration |
| AMR | AMR is verified twice annually using the Maine Standards GC3 Product # 1300ab by running all applicable levels in triplicate. LDH Body Fluid AMR is verified twice annually using the Maine Standards Body Fluid Product # 205bf. Assay results are submitted to Maine Standards for compilation and comparison to peers. Results are reviewed and approved by the Technical Specialist. Questionable results are investigated and corrective actions documented. |

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| **Quality Control** | **QC Material**: Bio-Rad Liquichek Multiqual Unassayed Control Levels 1 & 3**Frequency:** Two levels each day of use **Stability:** Once thawed, opened, and stored tightly capped at 2 to 8°C, product will be labeled with an expiration date equal to the shortest stability of the included analytes, which is **7 days.** **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. * To thaw the product, allow it to stand at room temperature (18° to 25°C) until completely thawed but no longer than one (1) hour
* After thawing, the products **MUST** be gently swirled and inverted several times to ensure homogeneity.
* For optimal analyte stability in the thawed 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**, gently swirl the contents until homogeneous with no visible signs of precipitate.

**Acceptable ranges:** * Non-Bio-Rad controls will utilize manufacturer ranges and 2 SD Westgard rules.
* 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 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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| **X** | **-** | **-** |

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”Hemolyzed specimens should not be used because erythrocytes contain approximately 150 times more LDH activity. Accurate results cannot be obtained. Request redraw. Provider may request the sample be run; ensure –HP comment is appended to applicable results. |
| **Reference Intervals** | Female and Male LDH:0 to < 15 Days: 309 - 1222 U/L15 Days to < 1 Year:163 - 452 U/L1 to < 10 Years: 192 - 321 U/LFEMALE: 10 to < 15 Years: 157 - 272 U/L15 to < 19 Years: 130 - 250 U/LMALE: 10 to < 15 Years: 170 - 283 U/L15 to < 19 Years: 130 -250 U/LADULT MALE AND FEMALE: 125 - 220 U/LNo claims are made for reference intervals on LDH in body fluids. |
| **Critical Values** | None specified. |
| **Limitations** | Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.See interferences section regarding hemolysis. Do not dilute body fluids for LDH.  |
| **Dilutions** |

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| Max Auto Dilution: | Serum or Plasma: 1:5 Do not dilute body fluids. |
| Maximum Manual Dilution: | Not specified |
| Diluent: | Onboard Saline |
| Automated 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. If a diluted sample result is less than the lower value of the measuring interval of 30, do not report the result. Rerun and/or investigate for other possible causes of error. |

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| **Result Reporting** | Serum or Plasma:* Results between 30 and 4500 without error messages are released
* Results below 30 without error messages are reported as < 30 U/L.
* Results > 4500 should be diluted using the onboard automated dilution of 1:5. Release results without error messages following this dilution.
* Results > 22500 following automated dilution are reported as > 22500.

Body Fluid LDH:* Results between 30 and 1000 u/L are released.
* Results <30 should be reported as <30 U/L.
* Results >1000 U/L should be reported as >1000 U/L.
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| **Specimen Storage** | Serum or Plasma:Promptly stopper tested specimen and store upright in a specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 14 days in specimen storage freezer.Body Fluid: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 refrigerator. |
| **References** | 1. Abbott Alinity c Lactate Dehydrogenase Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018.
2. Bio-Rad Liquichek Multiqual 1,2,3, Unassayed Control Package Insert, Bio-Rad Laboratories, Irvine CA, USA.
3. CALIPER Reference Range Studies. Accessed October 27, 2020.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Elauteria Earnhardt | April 21, 2020 | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Added AMR, dilutions, reference intervals, references, interferences section, corrected Alinity in Mpls. |