| **Ethanol** |
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| **Purpose** | This procedure provides instructions for performing ETHANOL ON ABBOTT INSTRUMENTATION. The Alinity c Ethanol assay is used for the quantitative determination of ethanol in human serum or 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** | The Alinity c Ethanol Reagent Kit is a liquid, ready-to-use, kinetic assay based on the high specificity of alcohol dehydrogenase (ADH) for ethyl alcohol. In the presence of ADH and nicotinamide adenine dinucleotide (NAD), ethanol is readily oxidized to acetaldehyde and NADH. The enzymatic reaction can be monitored spectrophotometrically at 340/416 nm.**Methodology**: Enzymatic (Alcohol Dehydrogenase) |
| **Clinical Significance** | In addition to beverages, ethanol (ethyl alcohol or alcohol) can also be found in high concentrations in a variety of products such as mouthwashes, colognes, candies, and medicinal preparations. When alcohol is ingested, it will permeate all tissues of the body within one hour. About 95% of the alcohol is metabolized in the liver, and the remainder is excreted unchanged. Alcohol intoxication can lead to birth defects (e.g., fetal alcohol syndrome), loss of alertness, stupor, coma, and death. Determination of ethyl alcohol concentration is commonly used for measuring legal impairment, investigating forensic evidence, diagnosing and/or treating alcohol dependency, as well as detecting alcohol poisoning.  |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | **ALCO** |
| **Specimen** | Sample:

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| LiHep Plasma (NO GEL) preferred. Serum (NO GEL), citrate (blue top), and oxalate (grey top) tubes are also acceptable. Skin must not be cleaned with alcohol or betadine. Do not use alcohol as a disinfectant when collected or storing blood specimens. |

**Minimum sample volume:** 200 µl preferred, 150 µL minimum.**Stability when separated from cells/gel and tightly capped:** RT/ 2 weeks, 4 to 8°C/ 6 months, -20°C/ 6 months**Whenever possible, avoid prolonged exposure to air after opening the primary draw container. Do not delay testing if sample is exposed to air as evaporation will cause loss of any volatile substance present.****Rejection criteria:** Unlabeled tube, sample type other than sample types listed above, tubes containing gel**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 directly 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** Reagent is shipped refrigerated or on wet ice/cold packs.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 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.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 Ethanol Reagent Kit | 08P4120 | **Store at:** 2 to 8°C**Unopened:** 2 to 8°CUntil manufacturer’s printed expiration date**On-board**: System temperature for 56 days |
| Abbott Alinity c Ethanol Calibrator Kit | 08P4101 | **Store at:** 2 to 8°C **Unopened:** 2 to 8°C until the printed expiration date **Opened expiration:** Immediately store tightly capped with new replacement cap. Return to refrigerated storage to prevent evaporation |

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| **Risk and Safety** | 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 handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.R1 contains tris hydroxymethyl aminomethane and sodium azide.Dispose of contents / container in accordance with local regulations.Safety data sheets (MSDS/SDS) available on  |
| **Calibration** |

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| Assay Range: | 10 - 600 mg/dL |
| Reference Material: | Ethanol Calibrator Kit |
| Suggested Calibration Levels: | 2 Levels |
| Calibration Scheme: | Linear data reduction method |
| Calibration Frequency: | Stable for 13 days (312 hours) |
| AMR | AMR is verified twice annually using the Maine Standards GC2 Product # 1200ab 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. Questionable results are investigated and corrective actions documented. |

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| **Quality Control** | Bio-Rad Liquichek™ Ethanol/Ammonia Control Levels 1 & 3**Frequency:** Two levels each day of use**Stability:** Stable two years when stored refrigerated between 2 and 8°C. Once opened, and stored tightly capped at 2 to 8°C, this product is stable for 20 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. * 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 (insert hyperlink) 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”At n-Propanol levels of 2000 mg/dL, there is 10.7% cross reactivity with this assay. The following potential cross-reactants at the same level yielded less than 10% cross-reactivity: acetaldehyde, acetone, n-Butanol, ethylene glycol, isopropanol, methanol.Grossly hemolyzed (800 mg/dL hemoglobin), icteric (30 mg/dL bilirubin), and lipemic (1000 mg/dL triglycerides) samples were found to have no interference with the assay.The drugs Sulfasalazine (300 mg/L) and Sulfapyridine (300 mg/L) were found to have no interference with the assay. |
| **Reference Intervals** | Less than 10 mg/dL |
| **Critical Values** | None specified |
| **Limitations** | The test result should be interpreted in light of clinical signs and symptoms. This test should be used for medical purposes only and is not intended for legal purposes.The test is designed for use with human samples only.Increased levels of lactic acid and LDH in postmortem samples may cause elevated ethyl alcohol results.It is possible that other substances and/or factors (e.g., technical or procedural errors) not listed in the Analytical Specificity table may interfere with the test and cause false results.Temozolomide at elevated concentrations (20 mg/L; 103 µmol/L) may lead to falsely low results |
| **Dilutions** | Do not dilute. |
| **Result Reporting** | * Results between 10 and 600 mg/dL without error messages are released
* Results below 10 without error messages are reported as < 10 mg/dL.
* Results > 600 following automated dilution are reported as > 600 mg/dL.
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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. Abbott Alinity c Ethanol Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park IL, USA. Revised December 2017.
2. Abbott Alinity c Ethanol Calibrator Kit Package Insert, Abbott Diagnostics Division, Abbott Park IL, USA. Revised January 2018
3. Bio-Rad Liquichek Ethanol/Ammonia Control Package Insert. Bio-Rad Laboratories, Irvine CA, USA.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Michelle Anton |  | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Added results reporting, AMR, references, cal ver material, interferences, etc. for new procedure. |