| **Salicylate** |
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| **Purpose** | This procedure provides instructions for performing SALICYLATE on ABBOTT INSTRUMENTATION. The Alinity c Salicylate assay is intended for the quantitative determination of salicylate 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** | Salicylate hydroxylase catalyzes the conversion of salicylate and NADH to catechol and NAD+ in the presence of oxygen. The resulting decrease in absorbance at 340 nm, due to the conversion of NADH to NAD+, is directly proportional to the concentration of salicylate in the sample.**Methodology:** Enzymatic / ColorimetricFor additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3. |
| **Clinical Significance** | Salicylate is a common drug used for its analgesic and anti-inflammatory properties. Its accessibility leads to its implication in a large number of accidental ingestions by children and it is a common choice among adults and adolescents for attempted suicidal poisoning.Salicylate overdose results in disturbances of the central nervous system and the gastrointestinal tract, as well as encephalopathy and renal failure. Salicylate intoxication represents an acute medical emergency. Rapid quantitation of the drug is necessary for effective patient management.This enzymatic Salicylate assay provides a rapid, specific, and simplified method for salicylate determination. It is based on the action of salicylate hydroxylase on salicylate and NADH which results in a decrease in absorbance proportional to the amount of salicylate present. |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)**Backup: Opposite Campus |
| **Sunquest Test Codes** | **SALI** |
| **Specimen** | Sample: Plasma or Serum (with or without gel barrier)**Preferred:** Lithium Heparin**Alternative:** SST, EDTA, Sodium Heparin**Minimum sample volume:** 0.6 mL blood, 0.2 mL serum/plasma**Stability when separated from cells/gel:** **20 to 25°C:** Not tested**4 to 8°C:** 14 days**-20°C:** 6 months **Rejection criteria:** Unlabeled tube, sample type other than serum or acceptable plasma**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** Upon receipt, place reagent cartridges in an upright position for 24 hours before use to allow bubbles that may have formed to dissipate. If a reagent cartridge is dropped, place in an upright position for 8 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*** |
| Alinity c Salicylate Reagent Kit  | 08P5920 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board**: 43 days |
| Alinity c Salicylate Calibrator Kit | 08P5901 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**Opened expiration:** Until expiration date (store tightly capped with new replacement cap) |

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| **Risk and Safety** | 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.*The following warnings and precautions apply to:* **R2** Contains tris hydroxymethyl aminomethane\* and sodium azide. Causes mild skin irritation. Contact with acids liberates very toxic gas.The *Salicylate Calibrator* is traceable to a secondary reference material prepared gravimetrically from USP grade salicylate and verified with a manual Trinder absorbance reference method.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 5 to 100 mg/dL |
| Reference Material: | Abbott Alinity c Salicylate Calibrartor |
| Suggested Calibration Levels: | Concentration 20.7 mg/dL |
| Calibration Scheme: | 1 Level |
| Calibration Frequency: | 43 day stability |
| AMR | AMR is verified twice annually using the Maine Standards CHEM TDM1 Product # 301ab 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** | **QC Material:** Bio-Rad Liquichek™ Immunoassay Plus Control Levels 1 and 3**Frequency:** Two levels each day of use**Stability:** Stable until the expiration date when stored frozen between -20 and -40°C. Once thawed, opened, and stored tightly capped at 2 to 8°C, this product is stable for 5 days in Minneapolis (due to Estradiol on this control) and 14 days in Saint Paul. **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 product **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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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”You and Bittikofer tested 61 commonly administered drugs for potential interference in an evaluation of another assay using the same enzymatic methodology. None of the evaluated drugs interfered with the measurement of salicylate. Se exceptions below and Instructions for Use for more information.* Sulfapyridine at elevated levels (300 mg/L) may lead to falsely low results.
* Sulfasalazine at elevated levels (300 mg/L) may lead to falsely high results.
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| **Reference Intervals** | Therapeutic 15 – 30 mg/dL Toxic Levels > 30 mg/dL Lethal > 70 mg/dL |
| **Critical Values** | **>30 mg/dL**Critical Values must be documented and called according to the critical values policy. |
| **Limitations** | * Sulfapyridine at elevated levels (300 mg/L) may lead to falsely low results.
* Sulfasalazine at elevated levels (300 mg/L) may lead to falsely high results.
* Salicylate blood levels do not correlate well with degree of toxicity in chronic salicylism. Other drugs may displace protein-bound salicylate leading to increased toxicity. Salicylate doses in patients on chronic therapy may approach toxic levels. Salicylate levels in such patients are best performed just prior to the next dose.
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| Max Auto Dilution: | 1:5 |
| Maximum Manual Dilution: | None |
| Diluent: | Onboard Diluent |
|  | 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 5 mg/dL, do not report the result. Rerun and/or investigate for other possible causes of error. |

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| **Result Reporting** | * Results between 5 and 30 without error messages are released
* Results below 5 without error messages are reported as < 5 mg/dL.
* Results greater than 30 are called according to critical value policy.
* Results > 100 should be diluted using the onboard automated 1:5 dilution. Release results without error messages following this dilution.
* Results > 500 following automated dilution are reported as > 500 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 14 days in specimen storage freezer. |
| **References** | 1. Abbott Alinity c Salicylate Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018
2. Abbott Alinity c Multiconstituent Calibrator Package Insert, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018
3. Bio-Rad Liquichek Immunoassay Plus Package Insert, Bio-Rad Laboratories, Irvine CA USA.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Elauteria Earnhardt | April 24, 2020 | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Corrected Mpls analyzer name, corrected test name, added assay number, interferences, references, reference intervals, critical values, reagent numbers corrected, qc material changed, etc. |