| **Protein in CSF and Urine** |
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| **Purpose** | This procedure provides instructions for performing CSF AND URINE PROTEIN on Abbott Instrumentation. The Alinity c Urine/CSF Protein assay is used for the quantitation of protein in human urine or cerebrospinal fluid (CSF) on the Alinity c analyzer. |
| **Policy Statements** | This procedure applies to all personnel who run the Abbott Alinity c in Saint Paul Laboratory or the Alinity ci in Minneapolis. |
| **Principle** | The Alinity c Urine/CSF Protein assay is a turbidimetric procedure in which benzethonium chloride is used as the protein denaturing agent. Proteins present in the urine or CSF are denatured by benzethonium chloride, resulting in the formation of a fine suspension which is quantitated turbidimetrically at 404 nm.**Methodology**: Benzethonium Chloride  |
| **Clinical Significance** | CSF protein measurements are used in the diagnosis and treatment of conditions such as meningitis, brain tumors, and infections of the central nervous system.The role of the renal system in the conservation of plasma proteins has been recognized for some time. Under normal physiological conditions small molecular weight proteins, such as insulin, pass through the glomeruli in relatively large amounts. Intermediate size proteins, such as transferrin and albumin, also pass through in relatively small amounts. Most of these proteins are reabsorbed in the renal tubules.Most CSF protein originates by diffusion from plasma across the blood-CSF barrier. Elevated levels occur as a result of increased permeability of the blood-CSF barrier or with increased local synthesis of immunoglobulins.  |
| **Analyzer** | **PRIMARY METHOD:** Abbott Alinity ci in Minneapolis (Sunquest method code MACC) and Abbott Alinity c in Saint Paul (Sunquest method code SALIC)**SECONDARY (BACKUP) METHOD:** Alinity on the opposite campus |
| **Sunquest Test Codes** | **CTP:** CSF protein**UTPQ**: Timed Urine protein, (mg/collection)**UTPR:** Urine protein, random, (mg/dL): |
| **Specimens** | Refer to Specimen Collection procedures for collecting and storing urine and cerebrospinal fluid. * **Urine:** Timed (24 hour) preferred or random collection; no preservative required during collection.
* **CSF**: Cerebrospinal fluid specimens should be collected with care to avoid contamination with plasma proteins. Blood present in the cerebrospinal fluid invalidates the protein values since it reflects contamination with plasma proteins. Optimally, protein analysis should be performed on the same tube as the cell count.

**Minimum volume:**200 µL cerebrospinal fluid or urine, 125 µL minimum, **Stability**:24-hr urine collection: No preservative is required. Urine aliquots stable at 2 - 4°C for 3 days/ <-20°C for up to one year.Cerebrospinal fluid stable at 4°C for up to 3 days/<-20°C for 6 months.**Rejection criteria:**  Unlabeled specimens, clotted specimens, specimens other than CSF or urine**Preparation**1. Timed urine collections are measured for total volume (TV), and the collection date and time recorded for the start and end of the collection. Enter collection information into Sunquest by ordering the test PV on the same accession number.
2. Split urine for **day** and **night** urine proteins and a combined creatinine. Follow these instructions:
	1. Measure **Day** collection volume. Record TV, start time and end time. Pour off a 1 mL aliquot and run a quantitative **urine protein** on the Abbott Alinity c.
	2. Measure the **Night** collection volume. Record TV, start time, and end time. Pour off a 1 mL aliquot and run a quantitative **urine protein** on the Alinity c.
	3. Combine the **Day and Night** collections. Pour off an aliquot and run a **creatinine** on the combined sample.
		1. Total volume = Day collection volume + Night collection volume.
		2. Period (time) = start time of first collection to end time of second collection.
3. Urine and CSF specimens should be free of particulate matter, and centrifuged according to Specimen Processing procedures prior to analysis. See Processing Procedure Manual.
4. Transfer Urine or CSF to a properly labeled pilot tube. Minimum labeling includes sample accession ID, and/or patient name, medical record number, collection date and time. For small volumes, pipette the remaining sample into the bottom of the sendout tube when testing is completed and ensure the cap is tight.
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| **Reagents** |

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Alinity Urine/CSF Protein (UPro) Reagent | 07P5920 | **Store at:** 15 - 25°C.**Unopened:** Refer to carton for expiration date of individual unopened reagent cartridges. **On-board:** 41 days |
| Abbott Alinity Urine/CSF Protein (UPro) Calibrator | 08P7101 | **Store at:** 2 - 8 °C.**Unopened:** Refer to carton for expiration date.**Opened:** Once the cap is removed, the assigned values are stable for 41 days when recapped and stored at 2 - 8 °C.  |

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| **Safety** | Safety data sheets (MSDS/SDS) available on Children’s Starnet intranet |
| **Calibration** |

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| Assay Range/AMR:  | 8 - 200 mg/dL |
| Reference Material:  | UPro Calibrators |
| Suggested Calibration Levels: |  10, 20,40, 80,200 |
| Calibration Scheme:  | Five levels, n=5 |
| Calibration Frequency:  | * For each new lot of reagent cartridges
* Every 41 days
* After major maintenance or service, if indicated by QC results
* As indicated in laboratory quality control procedures
* When required by government regulations
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| **Analytical Measuring Range (AMR)** | Cal Verification and AMR verification meet regulatory requirements with each calibration using 5 calibrators that span the full measuring range. |
| **Quality Control****(CSF)** | Biorad Liquichek™ **Spinal Fluid** Control Levels 1 & 2 for use with body fluid samples, contained in Vista Vials.**Frequency:** Two levels daily**Stability:** Expiration date on vial when stored unopened at 2 to 8°C and the stopper not punctured. Once the product stopper is punctured or opened, all analytes will be stable for 30 daysBefore loading vials onto the instrument, swirl gently to ensure homogeneity and minimize exposure to room temperature daily.**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](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.18-westgard-rules-in-chemistry.pdf) 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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| **Quality Control (Urine)** | Biorad Liquichek® **Urine Chemistry** Control Levels 1 & 2 for use with urine samples**Frequency:** Two levels daily**Stability:** Expiration date on vial when stored unopened at 2 to 8°C. Once the product stopper is punctured, all analytes will be stable for 30 days.Swirl gently before aliquoting and minimize time at room temperature. **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](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.18-westgard-rules-in-chemistry.pdf) 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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| **Calculations** | 24 HR urine protein (UTP) = UPro (mg/dL) x mL urine collected in 24 hours = mg/collection 100**UPCR** = Urine Protein/Creatinine ratio= Urine Protein (mg/dL)/Urine Creatinine (mg/dL)  |
| **Interferences** | Hemolysis, Icterus & Lipemia (HIL) Index Values:

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* Hemolyzed samples should be avoided since hemolysis increases UPro results. Hemoglobin at 10 mg/dL increases UPro result by 22% at UPro level of 48 mg/dL.
* Homogentisic acid in urine samples at concentrations above 0.37 g/L

(2.2 mmol/L) can cause incorrect results. * Xanthochromic specimens may falsely depress results.
* Samples for urinary/CSF protein should be collected before fluorescein is given or at least 24 hours later.

Refer to the Abbott IFU for a list of non-interfering substances. |
| **Reference Ranges (Urine)** | * **Urine, random**: 1-14 mg/dL.
* **Urine, timed**: 0-99 mg/collection. *The reference range is for a 24-hour collection. Collections for other than 24 hours do not have reference ranges established.*
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| **Reference Ranges (CSF)** |

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| Age | **CSF**: Spinal Fluid |
| 0 - 2 days | 40-120 mg/dL  |
| 3 days-1 month | 20 - 80 mg/dL |
| >1 month | 15 – 40 |

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| **Critical Values** | **CSF:** > 150 mg/dL. Call result according to Critical Results Reporting Policy |
| **Limitations** | Linear range of detection: 8 - 200 mg/dLThe instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in UPro results. Refer to your Alinity Operator’s Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed and not reported. |
| **Dilutions** |

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| Initial Vista Dilution: | None |
| Automated Dilution: | 1:2 and 1:10 maximum |
| Manual Dilution: | * Do not manually dilute
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| **Result Reporting** | * Results between 8 - 200 mg/dL without error messages are released
* Results below 8 mg/dL: report as less than (<) 8 mg/dL.
* Results >200 mg/dL without error messages are reported following a maximum dilution of 1:10
* Results with above assay range errors following a 1:10 dilution: Report as >2000 mg/dL
* Samples with hemolysis should have a comment code appended to the result.

HP = hemolysis present, may affect results* Urine results: The Laboratory Information System calculates urine protein on timed collections when all necessary information is present. Report the numerical value.
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in numbered specimen rack by accession number. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. Abbott Alinity Urine/CSF Protein Reagent Instructions for Use, Abbott Diagnostics, Abbott Park, IL, USA. March 2018
2. Abbott Alinity Urine/CSF Protein Calibrator Instructions for Use, Abbott Diagnostics, Abbott Park, IL, USA. May 2018
3. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc, Hudson, OH, 5th Edition, 2001
4. Bio-Rad Liquichek™ Spinal Fluid Control Product insert, Bio-Rad Laboratories
5. Bio-Rad Liquichek™ Urine Chemistry Control Product insert, Bio-Rad Laboratories
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Erin Bartos | 10/28/2020 | Initial Version |
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