**Purpose** To provide detailed lab specific information for Urine/CSF Protein performed at Einstein Medical Center Philadelphia and Einstein Medical Center Elkins Park.

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| **Intended Use** | The Urine/CSF Protein (UPro) assay is used for the quantitation of protein in human urine or cerebrospinal fluid (CSF). CSF protein measurements are used in the diagnosis and treatment of conditions such as meningitis, brain tumors, and infections of the central nervous systems. |

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| **Clinical Utility** | 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. |

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| **Methodology** | Benzethonium Chloride |

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| **Specimen Information** | **Sample Type** | **Tube Color(s) Anticoagulant(s)** | **Minimum Volume** |
| Urine | N/A | Standard: 9.6 μL |
| CSF | N/A | Standard: 9.6 μL |

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| **Storage** | **Temperature** | **Maximum Storage** | |
|  | **Urine** | **CSF** |
| 20 to 25°C | 1 day | 1 day |
| 2 to 8°C | 7 days | 6 days |
| -20°C | 1 month | > 1 year |

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| **Special Instructions** | Urine and cerebrospinal fluid are acceptable specimens. Samples for urinary/CSF protein should be collected before fluorescein is given or at least 24 hours later.  Urine: 24 hour timed urine specimens are preferred, with no preservative. Keep specimen on ice during collection. Centrifuge prior to analysis.10 Analyze fresh, or store as indicated below. Avoid collection of specimens within 24 hours of intense exercise since this can falsely elevate protein excretion.  Cerebrospinal Fluid: Centrifuge specimen before analysis. Analyze fresh or store as indicated below. Specimen should not contain blood.  Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing. |

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| **Specimen Limitations**  *Do not use the following:* | None |  |

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| **Reagents** | Reagent Kit 7D79 Urine/CSF Protein is supplied as a liquid, ready-to-use, two-reagent kit which contains R1 and R2. Refer to Package Insert for chemical composition.  Unopened reagents are stable until the expiration date when stored at 15 to 30°C. Reagent stability is 41 days if the reagent is uncapped and onboard. Do not use components beyond the expiration date. Do not mix materials from different kit lot numbers. |

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| **Calibration** | Calibration is stable for approximately 41 days (984 hours) and is required with each change in reagent lot number. Verify calibration with at least two levels of controls according to the established quality control requirements for your laboratory. Refer to CH03-100 Appendix A for Calibrator material. |
| **Quality Control** | A minimum of two levels of controls spanning the medical decision range are to be run once every 24 hours of assay use. Refer to Chemistry QA Manual Quality Control Procedure CHQA01-002 and Appendix CHQA01-002 Appendix A, CHQA01-002 Appendix B, CHQA01-002 Appendix C for detailed instructions, materials in use and LIS QC accession numbers. |

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| **Procedure** | For a detailed description of how to run an assay, refer to Section 5 of the instrument-specific operations manual. |

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| **Limitations of Procedure** | Refer to Package Insert for limitations of the procedure. |

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| **Sensitivity** | The Limit of Quantitation (LOQ) for Urine/CSF Protein is 6.75 mg/dL. |

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| **Analyte Specs:**   * **Specificity** * **Precision** * **Interfering Substances** | Refer to Package Insert for Specific Performance Characteristics. |

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| **Dilution** | Urine and CSF: Specimens with protein values exceeding 200.0 mg/dL are flagged and may be diluted using the Automated Dilution Protocol or the Manual Dilution Procedure.  If using the Automated Dilution Protocol, the system performs a 1:2 or 1:10 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.  Manual dilutions should be performed as follows: Use saline (0.85% to 0.90% NaCl) to dilute the sample. The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor. If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.  NOTE: If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution. |

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| **Unit of Measure** | mg/dL |

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| **Analytical Measurement Range** | The AMR for Urine/CSF Protein is 6.8 to 200.0 mg/dL. |

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| **Results** |  |  |  |
| **Reference Range** | CSF Protein:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Age From | Age To | Sex | Normal Low | Normal High | Unit of Measure | | 0 minutes | 30 days | All | 20 | 45 | mg/dL | | 31 days | 150 years | All | 15 | 45 | mg/dL |   Urine Protein, Random: 1 – 14 mg/dL  24 Hour Urine Protein: 50 – 300 mg/24hr |  |
| **Alert Values** | None |  |

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| **Reporting Results** | Results are interfaced to the LIS and verified by the tech or auto-verified by the LIS as appropriate.  Urine/CSF Protein results lower than 6.8 mg/dL are reported as <6.8 mg/dL.  CSF Protein results higher than 2,000.0 mg/dL are reported as > 2,000.0 mg/dL. |

**Approval Signatures:**

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| **Date** | **Printed Name** | **Signature** |
|  | Vanessa Rawlings, MHA, MT  Elkins Park Supervisor |  |
| 3/17/2014 | Jennifer Lore, MFS, MT  Chemistry Supervisor |  |
|  | Nancy A. Young, M.D., FCAP Medical Director | N/A – New Leadership |

**History Review**

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| **Date Reviewed** | **Reviewed By** | **Revisions** |
| 3/17/2014 | J. Lore | New Leadership Change  Updated QC Material Appendix |
| 10/6/2014 | J. Lore  T. Cameron | No Changes |
| 1/30/2015 | J. Lore | Added Calibrator CH03-100 Appendix A. |
| 10/15/02015 | J. Lore | No Changes |
| 10/31/2016 | J. Lore V. Rawlings | No Changes |
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