

# CERTIFICATE OF ANALYSIS

## HUMAN URINE PROTEIN

### Human Alpha-1-Microglobulin ( $\alpha_1M$ )

|                 |                    |
|-----------------|--------------------|
| <b>Code No.</b> | <b>P121-1</b>      |
| <b>Grade</b>    | <b>Highly Pure</b> |
| <b>Lot No.</b>  |                    |

#### RECEIVER INFORMATION

**Expiry Date**  
**Manufacture Date**  
**Storage Temperature**      Store at 2-8°C.  
**Storage Notes**                      Do not freeze.  
**Shipping Notes**                      Cool pack.

#### PRODUCT INFORMATION

**Source**                                      Human urine from patients with chronic renal tubular proteinuria.

**Nominal purity**                          >96%.

**Presentation**                            Single homogenous batch, 0.2 $\mu$ m filtered, supplied lyophilised from 0.02M NH<sub>4</sub>HCO<sub>3</sub> solution. May contain traces of buffer salts.

**Reconstitution advice**                Use of phosphate buffer, pH >7.0 containing 0.15M NaCl is recommended.  
 To ensure full product recovery, it is advised that reconstitution is performed directly into supplied vial incorporating further washings with the reconstitution buffer.

**Recovery**                                    In order to meet our customer needs, it should be noted that there is normally a dispensing overage allowance and the product recovery may, therefore, be greater than expected.

#### HEALTH AND SAFETY

**Application**                                For Research and Manufacturing Only.

#### Infectious Disease Tests

| Starting material donor tested using FDA approved tests for: | Result |
|--|--------|
| HIV 1 & 2 antibodies   |        |
| Hepatitis B Surface Antigen                                  |        |
| Hepatitis C virus antibodies                                 |        |

**Precaution**                                No test can guarantee the absence of an infectious agent. Please handle as potentially hazardous.

**Material Safety**                          For further information and technical details, please download a Safety Data Sheet at [www.bbisolutions.com](http://www.bbisolutions.com) or contact your BBI Account Manager.

**ANALYSIS**

| TESTS   | SPECIFICATIONS   | RESULTS   |
|---|--|-----------|
| <b><u>Determination Method</u></b>  |  |           |
| Protein concentration by optical density at 280nm using<br>$E^{1cm}_{0.1\%} = 1.58$ | > 1 mg/ml  | mg/ml     |
| SDS-Polyacrylamide Gel Electrophoresis  | To show one band corresponding to $\alpha_1M$ molecular weight of 27kD. Under certain conditions dimer (54kD) sub unit can be observed | Pass/Fail |
| Radial immunodifusion vs. BBI Solutions SPRS standard                               | To confirm identity and verify the dispensing concentration  | Pass/Fail |
| Bioburden   | < 100 CFU/ml   | Pass/Fail |
| <b>Physical appearance</b>  | Off-white/light brown freeze dried solid.  |           |
| <b>Purity</b>   | Defined as a major band on coomassie stained SDS-PAGE.   |           |

|                |  |                  |  |
|----------------|--|------------------|--|
| <b>Name:</b>   |  | <b>Position:</b> |  |
| <b>Signed:</b> |  | <b>Date:</b>     |  |