

# CERTIFICATE OF ANALYSIS

## HUMAN SERUM PROTEIN

### Human Alpha-1-Antitrypsin ( $\alpha_1$ AT)

<b>Code No.</b>	<b>P165-5</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**                                      Pooled human serum/plasma.

**Nominal Purity**                          ≥96%.

**Presentation**                            Single homogenous batch, 0.2µm 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 tested using FDA approved tests for:	Result
HIV 1 & 2 antibodies	
Hepatitis B surface antigen	
Hepatitis C antibodies	
HIV-1/HBV/HCV NAT	
Syphilis	

**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>		
<b>Protein Concentration by Optical Density at 280nm Using</b> $E^{1cm}_{0.1\%} = 0.44$	<b>≥1 mg/ml</b>	<b>mg/ml</b>
SDS-Polyacrylamide Gel Electrophoresis	To show a band corresponding to α <sub>1</sub> AT molecular weight of 54kD	Pass/Fail
Radial Immunodiffusion (RID) Assay Using Siemens Standard	To confirm identity	Pass/Fail
Bioburden	<100 CFU/ml	Pass/Fail

**Physical Appearance** White to off white lyophilised solid.

**Purity** Defined by a major band on coomassie blue stained SDS-PAGE.

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