

# CERTIFICATE OF ANALYSIS

## HUMAN SERUM PROTEIN

Human Prealbumin  
(Also called Transthyretin)

<b>Code No.</b>	<b>P171-2</b>
<b>Grade</b>	<b>Standard</b>
<b>Lot No.</b>	

### RECEIVER INFORMATION

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

### PRODUCT INFORMATION

**Source** Normal human serum/plasma.

**Nominal Purity** >40%

**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

All donations of starting material are tested using FDA approved methods for:	Result
HIV 1 & 2 antibodies	
Hepatitis B surface antigen	
Hepatitis C antibodies	
HIV / HBV / HCV NAT	
Parvovirus B19	
Starting material donor tested using FDA approved methods for:	Result
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**


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TESTS	SPECIFICATIONS	RESULTS
<b><u>Determination Method</u></b>		
<b>Radial Immunodiffusion Assay Vs. Siemens Standard</b>	<b>&gt;1 mg/ml</b>	<b>mg/ml</b>
SDS-Polyacrylamide Gel Electrophoresis	To show a major band corresponding to tetramer Prealbumin molecular weight of predominately 30kD. Under certain conditions monomer (15kD) and tetramer (60kD) subunits can be observed. Contaminants not identified	Pass/Fail
Cellulose Acetate Electrophoresis	To show a band with Prealbumin electrophoretic mobility	Pass/Fail
Total Protein Concentration as Determined by Lowry Method	>2.5 mg/ml	mg/ml
Purity	>40%	%
Bioburden	<100 cfu/ml	Pass/Fail

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**Physical Appearance**                      Off white, lyophilised solid.

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**Purity**    Defined as Prealbumin content by RID, as a percentage of protein by Lowry.

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