

CERTIFICATE OF ANALYSIS

HUMAN SERUM PROTEIN

Human Prealbumin
(Also called Transthyretin)

Code No.	P171-1
Grade	Highly Pure
Lot No.	

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 >96%

Presentation Single homogenous batch, 0.2µm filtered, supplied lyophilised from 0.02M NH₄HCO₃ 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 or contact your BBI Account Manager.

ANALYSIS

TESTS	SPECIFICATIONS	RESULTS
<u>Determination Method</u>		
Optical Density at 280nm using $E^{1cm}_{0.1\%} = 1.40$	>1 mg/ml	mg/ml
SDS-Polyacrylamide Gel Electrophoresis	One major band corresponding to Prealbumin dimer molecular weight of 30kD. Under certain conditions monomer (15kD) and tetramer (60kD) forms can be observed	Pass/Fail
Radial Immunodifusion assay vs. Siemens standard	To confirm identity and verify the concentration of dispensing solution	Pass/Fail
Bioburden	<100 cfu/ml	Pass/Fail

Physical Appearance White lyophilised solid.

Purity Defined as a major band on coomassie stained SDS-PAGE.

Name:		Position:	
Signed:		Date:	