

CERTIFICATE OF ANALYSIS

HUMAN SERUM PROTEIN

Thyroxine Binding Globulin (TBG)

Code No.	P125-2
Grade	Standard
Lot No.	

RECEIVER INFORMATION

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

PRODUCT INFORMATION

Source	Normal human serum/plasma.
Nominal Purity	>70% of the protein is TBG.
Presentation	Single homogenous batch, 0.2µm filtered, supplied lyophilised from 0.02M NH ₄ HCO ₃ 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.
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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.
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Material Safety	For further information and technical details, please download a Safety Data Sheet at www.bbisolutions.com or contact your BBI Account Manager.
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ANALYSIS

TESTS	SPECIFICATIONS	RESULTS
<u>Determination Method</u>		
Radial Immunodiffusion (RID) Vs. BBI Standard.	> 12.5 mg/ml.	mg/ml.
SDS-Polyacrylamide Gel Electrophoresis.	To show a major band corresponding to TBG molecular weight at 55kD.	Pass/Fail.
Cellulose Acetate Electrophoresis.	To show a major band with α electrophoretic mobility.	Pass/Fail.
Protein Concentration as Determined by Lowry Method.	Report result.	mg/ml.
Bioburden.	<100 CFU/ml.	Pass/Fail.
ANS mass/ mass	<1%	%
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Physical Appearance	White lyophilised solid.	
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Purity	Defined by TBG content as a percentage of total protein by Lowry.	

Name:		Position:	
Signed:		Date:	