

CERTIFICATE OF ANALYSIS

CELL CULTURE GRADE PROTEIN

Transferrin (Apo)

Code No.	T100-5
Grade	Highly pure
Lot No.	

RECEIVER INFORMATION

Expiry Date	Shelf life minimum 5 years* from manufacture date. (*shelf life is based on immunological potency of similar Transferrin preparations)
Manufacture Date	
Storage Temperature	Store at 2-8°C.
Storage Notes	Allow temperature to equilibrate to room temperature prior to use.
Shipping Notes	Cool pack.

PRODUCT INFORMATION

Source	Normal human serum/plasma.
Nominal Purity	>98%
Presentation	Single homogenous batch, heat treated at 62°C ± 2°C for 10 hours and lyophilised from approximately 0.020M NH ₄ HCO ₃ solution. May contain traces of buffer salts.

HEALTH AND SAFETY

Application	For Research and Manufacturing Only.
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Infectious Disease Tests

All donations of starting material tested using FDA approved tests for:	Result
HIV 1 & 2 antibodies	
Hepatitis B surface antigen	
Hepatitis C antibodies	
HAV (NAT)	
HBV (NAT)	
HCV (NAT)	
HIV (NAT)	
Parvovirus B19 (NAT)	
Starting material donor tested using FDA approved tests 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>Dispensation Method</u>	Dispensed by dry weight.	
<u>Characterisation</u>		
Moisture (when packed) by loss on drying.	≤ 5.0 %.	%.
Moisture by Karl Fisher.	≤ 5.0 %.	%.
Solubility.	Readily soluble at 1% in de-ionised water.	Pass/Fail.
pH (3% solution).	6.5-8.0	Report result.
<u>Purity, Identity, Sterility</u>		
Elemental Analysis – Nitrogen: after sample allowed to dry for 3hrs under vacuum at 60°C	Report Result	%.
Protein Analysis: calculation from Nitrogen elemental analysis value using a protein factor of 6.49	≥ 98 %.	%.
Cellulose Acetate Electrophoresis.	To show a major band indicating β ₁ electrophoretic mobility.	Pass/Fail.
SDS-Polyacrylamide Gel.	Major bands, corresponding to Transferrin with a molecular weight of approx. 77kDa.	Pass/Fail.
Optical density at 280nm using concentration of approx. 10mg/ml in water.	Report result.	Report result.
Endotoxin by LAL assay.	≤ 1 EU/mg.	EU/mg.
Bioburden using BBI SMP 1097	< 10 CFU/ml.	Pass/Fail.
Mycoplasma.	PCR Analysis.	Positive/Negative.
	Hoechst Stain.	Positive/Negative.
	Cell Culture Test: No Mycoplasma growth for 4 weeks.	Positive/Negative.

CERTIFICATE OF ORIGIN

Product	Transferrin (Apo)
BBI Solutions Code No.	T100-5
Lot No.	
Starting Material	Pooled human serum/plasma.
Donors Country of Origin	All donors are from US origin.
Clinical and Biological Selection	All donors were healthy at the time of collection. Each donation was tested individually and found negative for the viral disease described on the Certificate of Analysis by FDA approved methods.
Traceability	Donor centres are traceable and this information can be obtained if required.
Donor Status	In the USA, individuals who donate blood to be used for research and commercial applications can either receive payment or donate for free.

Name:		Position:	
Signed:		Date:	