

CERTIFICATE OF ANALYSIS

CELL CULTURE GRADE PROTEIN

Transferrin (Holo)

Code No.	T101-5
Grade	Highly pure
Lot No.	

RECEIVER INFORMATION

Expiry Date	Shelf life minimum 5 years from manufacture date
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
Country of Manufacture	UK
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.
Product Handling	Product must not be re-dispensed. Do not open containers until ready for use.

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 HAV 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 (All results below are to be reported with Post dispensing QC testing results)

TESTS	SPECIFICATIONS	RESULTS
<u>Dispensation Method Characterisation</u>	Dispensed by dry weight.	
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.	≥98% of total protein. 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 (equivalent to <100 cfu/g)	Pass/Fail.
Mycoplasma.	qPCR Analysis.	Positive/Negative.
	Cell Culture Test: No Mycoplasma growth for 4 weeks.	Positive/Negative.

TESTS	SPECIFICATIONS	RESULTS
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Iron Content

Iron estimated by ICP. 1100 - 1600 ppm. ppm.

Physical Appearance Salmon Pink to Reddish Crystalline Powder.

Purity Determined by coomassie blue stained SDS-PAGE and Cellulose Acetate Electrophoresis.

Name:		Position:	
Signed:		Date:	

CERTIFICATE OF ORIGIN

Product	Transferrin (Holo)
BBI Solutions Code No.	T101-5
Lot No.	
Starting Material	Pooled human serum/plasma. Sourced from FDA licensed plasma centres in the USA where informed consent is part of the donation process.
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:	