

# CERTIFICATE OF ANALYSIS

## CELL CULTURE GRADE PROTEIN

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### Transferrin (Holo)

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<b>Code No.</b>	<b>T101-5</b>
<b>Grade</b>	<b>Highly pure</b>
<b>Lot No.</b>	

#### RECEIVER INFORMATION

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

#### PRODUCT INFORMATION

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

#### HEALTH AND SAFETY

<b>Application</b>	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	

<b>Precaution</b>	No test can guarantee the absence of an infectious agent. Please handle as potentially hazardous.
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<b>Material Safety</b>	For further information and technical details, please download a Safety Data Sheet at <a href="http://www.bbisolutions.com">www.bbisolutions.com</a> or contact your BBI Account Manager.
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## ANALYSIS

TESTS	SPECIFICATIONS	RESULTS
<b><u>Dispensation Method Characterisation</u></b>	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
<b><u>Purity, Identity, Sterility</u></b>		
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 <sub>1</sub> 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.

TESTS	SPECIFICATIONS	RESULTS
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**Iron Content**

Following review of Transferrin QC and Total Iron Analysis, it has been shown that the Cypress iron test is no longer suitable for purpose. The Cypress iron test shows lack of correlation with the more accurate ICP test and for this reason the Cypress iron test results will not be reported on BBI C of A's.

Iron estimated by ICP.	1200 - 1700 ppm.	ppm.
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<b>Physical Appearance</b>	Salmon Pink to Reddish Crystalline Powder.
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<b>Purity</b>	Determined by coomassie blue stained SDS-PAGE and Cellulose Acetate Electrophoresis.
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<b>Name:</b>		<b>Position:</b>	
<b>Signed:</b>		<b>Date:</b>	

## CERTIFICATE OF ORIGIN

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<b>Product</b>	Transferrin (Holo)
<b>BBI Solutions Code No.</b>	T101-5
<b>Lot No.</b>	
<b>Starting Material</b>	Pooled human serum/plasma. Sourced from FDA licensed plasma centres in the USA where informed consent is part of the donation process.
<b>Donors Country of Origin</b>	All donors are from US origin.
<b>Clinical and Biological Selection</b>	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.
<b>Traceability</b>	Donor centres are traceable and this information can be obtained if required.
<b>Donor Status</b>	In the USA, individuals who donate blood to be used for research and commercial applications can either receive payment or donate for free.

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