

# **CERTIFICATE OF ANALYSIS**

### Human holo-Transferrin

#### Powder

# (Catalog Number 800-131P)

Lot Number: H423026

Origin: United States Date of Manufacture: Feb2023

Storage Temperature: 2°C – 8°C Product Expiry: Feb2028

For Cell culture, Further Manufacturing or Research use Only. Not for Direct Therapeutic Use.

Test	Methodology	Specification	Analysis
<b>Biological Testing</b>			
Bioburden	BBI SMP 1097	<10 cfu/mL	<10 cfu/mL
Endotoxin	LAL	≤1 EU/mg	<0.05 EU/mg
Microbiological Testing			
Mycoplasma		Not Detected	Not Detected
Viral Testing			
HBsAg		Non-Reactive	Non-Reactive
Anti-HCV		Non-Reactive	Non-Reactive
Anti-HIV-1/HIV-2		Non-Reactive	Non-Reactive
ALT		Negative	Negative
Syphilis		Negative	Negative
HBV-NAT		Non-Reactive	Non-Reactive
HIV-NAT		Non-Reactive	Non-Reactive
HAV-NAT		Non-Reactive	Non-Reactive
HCV-NAT		Non-Reactive	Non-Reactive
Parvo B19-NAT		Non-Reactive	Non-Reactive
Physical Testing			
Appearance		Report	Salmon Pink to
			Reddish Powder
pH @ RT, 3% Solution		6.5 - 8.0	7.49
Moisture		≤5.0%	1.22%
Solubility		Readily Soluble at 1%	Pass
		in De-ionized water	
Optical density		Report	12.58
Biochemical Testing			
Purity	Cellulose Acetate Electrophoresis	≥98% of total protein	Pass
Protein Analysis		>98%	101.37%
SDS-Polyacrylamide Gel		Conforms	Pass
Iron Estimated by ICP		1200-1700 ppm	1214 ppm



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Results shown were obtained by carefully performed methods believed to be reliable. However, since some results may vary for specific tests depending on the methodology and other variables, it is suggested that tests for which results are particularly important to be repeated by the user of this product. All human blood products are collected from stringently screened donors at FDA-licensed collection centers in the United States. All donors are tested and found to be negative for Indirect Antiglobulin. Single homogenous batch, heat treated at  $62^{\circ}\text{C} \pm 2^{\circ}\text{C}$  for 10 hours and lyophilized from approximately 0.02M NH<sub>4</sub>HCO<sub>3</sub>. May contain traces of buffer salts. Dispensed by dry weight. Store at  $2^{\circ}\text{C} - 8^{\circ}\text{C}$ . Allow temperature to equilibrate to room temperature prior to use.

The testing that has been performed as part of this lot release has been reviewed by Quality Assurance personnel and it has been confirmed that the testing meets the specifications presented on this Certificate of Analysis.

Karen Zuniga	
Name	
QA Associate 11	
Title	
135EP2023	
Date	