

## **Certificate of Analysis**

Created March 22, 2019

**Product:** 

apo-Transferrin

**Human** Powder

Catalog #: 800-130P

Lot #: H69S13H Origin: United States (100%) Manufacture Date: Nov 2016 Expiration Date: Nov 2021

<b>T</b> EST	<b>M</b> ETHODOLOGY	SPECIFICATION	RESULTS
Biological Testing			
Endotoxin	LAL	≤1 EU/mg	0.231 EU/mL
Bioburden		<10 cfu/mL	Pass
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		Pass	Pass
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	White Crystalline Powder
pH, 3% Solution		6.5-8.0	6.91
Moisture		≤5.0 %	0.82 %
Solubility		Readily soluble at 1% in de-ionized water	Pass
Optical Density		Report	10.74



## **Biochemical Testing**

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TEST	METHODOLOGY	SPECIFICATION	RESULTS
Purity	Cellulose Acetate Electrophoresis	≥98 %	Pass
Protein analysis		>98 %	103.4 %
SDS-Polyacrylamide Gel		Conforms	Pass
Iron estimated ICP	<del>1</del>	<50 ppm	4 ppm

Results shown were obtained by carefully performed methods believed to be reliable. However, since some results may vary for specific tests depending upon methodology and other variables, it is suggested that tests for which results are particularly important 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°±2°C for 10 hours and lyophilised from approximatley 0.02M NH4HCO3. May contain traces of buffer salts. Dispensed by dry weight.

Store at 2-8°C. Allow temperature to equilibrate to room temperature prior to use.

Created by/ date

Verified by/ date