GEMINI BIO-PRODUCTS

Certificate of Analysis

Revised April 23, 2021

Product: **Human Serum Albumin**
Powder

Catalog #: 800-125P
Lot #: H62Y00L
Origin: United States (100%)

Manufacture Date: Oct 2020
Expiration Date: Feb 2022

TEST	METHODOLOGY	SPECIFICATION	RESULTS
Microbiological Testing			
Microbial Growth		<2.99 cfu/mL	No Growth
Endotoxin Testing			
Endotoxin		≤2 EU/mg	<1 EU/mg
Physical Testing			
pH @ RT			6.9
Biochemical Testing			
Purity	HPLC		99.7%

Each unit of plasma has been tested and found non-reactive for HBsAg, negative for anti-HCV and anti-HIV-1/2 by FDA approved tests. It is certified that all donations of plasma were individually tested and non-reactive to HBsAg, HIV-1/HIV-2 Ab, HCV Ab. Each plasma pool was tested and found negative for HBsAg, HIV-1/HIV-2 Ab by EIA and HCV-RNA by Polymerase Chain Reaction method (PCR). Each donor has been tested and found negative for syphilis according to FDA guidelines.

For Cell Culture, further Manufacturing and Research use only. Not for direct Therapeutic use. 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 plasma is 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.

23APR2021
Created By/ date

23 APR 2021
Verified By/ date

 Gemini Bioproducts, LLC. 930 Riverside Parkway, Suite 50, West Sacramento, CA, 95605