



GEMINI
BIO-PRODUCTS

Certificate of Analysis

Created July 24, 2019

Product: Human Albumin Solution—20%

Catalog #: 800-121

Lot #: H78X00K

Origin: United States (100%)

Manufacture Date: Jul 2019

Expiration Date: Jul 2022

TEST	METHODOLOGY	SPECIFICATION	RESULTS
Viral Testing	21 CFR 610.40		
HBsAg		Non-Reactive	Non-Reactive
Anti-HCV		Non-Reactive	Non-Reactive
Anti-HIV-1/HIV-2		Non-Reactive	Non-Reactive
Syphilis		Negative	Negative
HBV-NAT		Non-Reactive	Non-Reactive
HCV-NAT		Non-Reactive	Non-Reactive
HIV-1		Non-Reactive	Non-Reactive
Microbiological Testing			
Sterility	USP<71>		
Bacteria		Not Detected	Not Detected
Fungi		Not Detected	Not Detected
Physical Testing			
Protein		Test and Report	20.39g/dL
pH	USP<791>	Report	7.16
Endotoxin		Test and Report	<0.500 EU/mL

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.

Ali 24 JUL 2019

Created by/ date

Mark Weber 24 JUL 2019

Verified by/ date