GEMINI BIO-PRODUCTS

Certificate of Analysis

Created July 30, 2019

Product: **Human Albumin Solution—25%**

Catalog #: 800-120
Lot #: H79X00K
Origin: United States (100%)

Manufacture Date: Jul 2019
Expiration Date: Jul 2022

TEST	METHODOLOGY	SPECIFICATION	RESULTS
Microbiological Testing			
Sterility	USP<71>		
Bacteria		Not Detected	Not Detected
Fungi		Not Detected	Not Detected
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
HIV-1 NAT		Non-Reactive	Non-Reactive
HCV-NAT		Non-Reactive	Non-Reactive
HBV-NAT		Non-Reactive	Non-Reactive
Physical Testing			
Purity	SPE Gel Electrophoresis	Test and Report	96%
Protein		Test and Report	25.0 g/dL
Endotoxin		Test and Report	0.980 EU/mL
pH		Test and Report	6.98

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.

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Created by/ date

30/Jul/2019
Verified by/ date