



GEMINI
BIO-PRODUCTS

Certificate of Analysis

Created August 29, 2019

Product:

GemCell™ Human Serum AB
0.1µm sterile-filtered

Catalog #: 100-512

Lot #: H67X00K

Origin: United States (100%)

Manufacture Date: Jul 2019

Expiration Date: Jul 2024

TEST	METHODOLOGY	SPECIFICATION	RESULTS
Biological Testing			
Endotoxin	USP<85>	< 10 EU/mL	<0.500 EU/mL
Hemoglobin	Fleming, AF and Woolf, AJ (1965)	<20.0 mg/dL	7.0 mg/dL
Microbiological Testing			
Sterility	USP<71>		
Bacteria		Not Detected	Not Detected
Fungi		Not Detected	Not Detected
Mycoplasma	Barile, MF and Kern, J (1971)	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
HBV DNA		Not Detected	Not Detected
HIV-1 RNA		Not Detected	Not Detected
HCV RNA		Not Detected	Not Detected
Physical Testing			
Osmolality	USP<785>	260-350 mOsm/kg	326 mOsm/kg
pH	USP<791>	Report	7.89

