



## CERTIFICATE OF ANALYSIS

### **GemCell™ Human Platelet Lysate, cGMP** **(Catalog Number 100-451)**

Lot Number:

H019006

Date of Manufacture: Jan2019

Product Expiry: Jun2021

Origin: United States

Storage Temperature: -20°C

cGMP Grade. Not for Direct Therapeutic Use. Not for human or animal consumption.

**Product description:** *GemCell™ Human Platelet Lysate, cGMP, is a cell culture supplement derived from human platelets manufactured for Gemini Bioproducts, LLC.*

Test	Methodology	Specification	Analysis
<b>Biological Testing</b>			
Endotoxin	USP<85>	≤ 5.0 EU/ mL	<2.0 EU/mL
<b>Microbiological Testing</b>			
Sterility	USP<71>		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	USP<63>	Not Detected	Not Detected
<b>Viral Testing</b>			
	21 CFR Part 610		
Anti-HIV-I/II		Negative	Negative
Anti-HCV		Negative	Negative
Anti-HBc		Negative	Negative
Anti-HTLV- I/II		Negative	Negative
HBsAg		Nonreactive	Nonreactive
STS		Nonreactive	Nonreactive
WNV RNA		Nonreactive	Nonreactive
HCV RNA		Nonreactive	Nonreactive
HIV-1 RNA		Nonreactive	Nonreactive
HBV DNA		Nonreactive	Nonreactive
<b>Physical Testing</b>			
Osmolality		260 – 340 mOsm/kg	315 mOsm/kg
pH		6.8-8.1	7.6
<b>Biochemistry</b>			
Protein, Total		3.0-7.5 g/dL	5.6 g/dL
Cell Growth Verification		Pass	Pass



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The test results from testing performed as part of this lot release have been reviewed by Quality Assurance personnel who confirmed that the testing meets the specifications presented on this Certificate of Analysis.

Drashni B. Kumar

Name

QC Associate

Title

03 FEB 2021

Date