



CERTIFICATE OF ANALYSIS

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

Lot Number:

H021033

Date of Manufacture: Feb2021

Product Expiry: Jul2023

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
Biological Testing			
Endotoxin	USP<85>	≤ 5.0 EU/ mL	<2.0 EU/mL
Microbiological Testing			
Sterility	USP<71>		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Mycoplasma	USP<63>	Not Detected	Not Detected
Viral Testing			
	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
Physical Testing			
Osmolality		260 – 340 mOsm/kg	317 mOsm/kg
pH		6.8-8.1	7.7
Biochemistry			
Protein, Total		3.0-7.5 g/dL	5.7 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.

Christy Francisco
Name

QC Associate
Title

11 MAY 2021
Date