



CERTIFICATE OF ANALYSIS

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

Lot Number:

H423012

Date of Manufacture: Jan2023

Product Expiry: Jun2025

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	USP<785>	260 – 340 mOsm/kg	323 mOsm/kg
pH	USP<791>	6.8-8.1	7.8
Biochemistry			
Protein, Total	USP<1057>	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.

Jequeline Wilson
Name

QA Specialist
Title

26 JUL 2023
Date