



CERTIFICATE OF ANALYSIS
GemCell™ Plus Human Platelet Lysate
Irradiated
(Catalog Number 100-452)

Lot Number: H121008

Date of Manufacture: Apr2021

Product Expiry: Sep2023

Origin: United States

Storage Temperature: -20°C

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

Product description: *GemCell™ Plus 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			
	21CFR 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
Zika RNA		Nonreactive	Nonreactive
Physical Testing			
Osmolality		300 – 340 mOsm/kg	313 mOsm/kg
pH		6.80-8.15	7.69
Biochemistry			
Protein, Total		3.0-7.9 g/dL	5.6 g/dL
Cell Growth Verification		Pass	Pass
Irradiation		In Range	In Range



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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.

Megha Khakasi
Name

QC Supervisor
Title

07 FEB 2021
Date