

## **CERTIFICATE OF ANALYSIS**

## BenchMark™ Human Platelet Lysate

## (Catalog Number 100-450)

Lot Number: H121007

Date of Manufacture: May2021

**Product Expiry: Oct2023** 

Origin:

**United States** 

Storage Temperature: -20°C

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

**Product description:** BenchMark<sup>™</sup> Human Platelet Lysate is a Research Grade cell culture supplement derived from human platelets manufactured for Gemini Bioproducts, LLC.

Test	Methodology	Specification	Analysis
Biological Testing	-	- 88 - 17400	
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

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 Kholasi	QC Supervisor
Name	Title
07FEB 2012	
Date	