



DCO00044

ART70001TPL Rev3

Certificate of Analysis

PLUS™ GMP Grade Human Platelet Lysate

Lot Number: 04201801G **Manufacture Date:** 2018-04-20 **Expiration:** 2023-04-20

Product Specifications: PLUS™ is a serum media supplement derived from human platelet rich plasma collected at U.S. blood and plasma centers. PLUS™ supports the *in vitro* propagation and maintenance of human cells. Each donor is tested by FDA approved methods and is negative for Hepatitis B, Hepatitis C, Human Immunodeficiency Virus type 1 & 2, Human T-Lymphotropic Virus type 1&2, and Syphilis.

QC Test	Method	Specification	Results
1Infectious Disease	Human Immunodeficiency Virus	Non-reactive	Non-reactive
	-HIV I/II Ab	Non-reactive	Non-reactive
	-HIV-NAT		
	Human T-Lymphotropic Virus	Non-reactive	Non-reactive
	-HTLV I/II Ab		
	Hepatitis B Virus	Non-reactive	Non-reactive
	-HBs Ag	Non-reactive	Non-reactive
	-HBc Ab	Non-reactive	Non-reactive
	-HBV-NAT	Non-reactive	Non-reactive
	Hepatitis C Virus	Non-reactive	Non-reactive
	-HCV Ab	Non-reactive	Non-reactive
	-HCV-NAT	Non-reactive	Non-reactive
	Syphilis	Non-reactive	Non-reactive
	-RPR or FTA-ABS	Non-reactive	Non-reactive
West Nile Virus	Non-reactive	Non-reactive	
-WNV-NAT	Non-reactive	Non-reactive	
Trypanosoma cruzi	Non-reactive	Non-reactive	
-T. cruzi Ab	Non-reactive	Non-reactive	
Sterility: Bacterial and Fungal	21 CFR Part 610.12 14-Day Sterility Test	No Growth	No Growth
Endotoxin	Endosafe® PTS™	<10 EU/mL	≤0.500 EU/mL
Mycoplasma	Cultivable Mycoplasma Isolation	Not Detected	Not Detected
pH	pH Electrode	6.4 – 8.0	7.1
Osmolality	Freezing Point	260 – 355 mOsm/kg	318 mOsm/kg
Total Protein	Quantitative Spectrophotometry	4.0 – 9.0 g/dL	5.4 g/dL
Performance Testing	² hMSC Outgrowth	Supports hMSC expansion	PASS

Biochemical Analysis	
Sodium	159 mmol/L
Potassium	4.8 mmol/L
Chloride	99 mmol/L
Creatinine	0.76 mg/dL
Glucose	135 mg/dL
Calcium	59.4 mg/dL
Hemoglobin	1.5 mg/dL

¹Infectious disease testing was done on each donor by Blood Bank facility at time of collection using FDA approved methods for Platelet Apheresis Products and was negative for Hepatitis B, Hepatitis C, Human Immunodeficiency Virus type 1&2, Human T-Lymphotropic Virus type 1&2, and Syphilis.

²hMSC outgrowth with platelet lysate shown to be equal to, or greater than, outgrowth with Fetal Bovine Serum, hMSC outgrowth determined by MTT (3-(4, 5-Dimethylthiazol-2-yl)-2, 5-Diphenyltetrazolium Bromide) assay.

Joyce Howard 22 JUN 2018
 Verified by Date