UCM SAFETY TESTING

Measures are taken throughout production to protect against the presence of pathogenic viruses or microbial contamination.

*** Note: Results shown are actual data pertaining to Product Lot UCM-190604-TS, the cell line used for its production, and the single donor of its source tissue.**

Umbilical Cord Tissue Donor Screening and Testing (GTP) -- Specification: No infectious disease or risk factor for infectious disease.

Maternal blood samples were collected within 7 days of umbilical cord collection and tested at CLIA-certified lab on FDA approved tests.

Test Name	Result *	Method	Detection Target
Hepatitis B Virus (HBV)			
HEPATITIS Bs Ag	NONREACTIVE	EIA	HBV Surface Antigen
HEPATITIS Bc (Total) Ab	NONREACTIVE	ELISA	Antibodies to HBV Core Antigen
HBV ULTRIO	NONREACTIVE	Nucleic Acid Test (TMA)	HBV DNA
Hepatitis C Virus (HCV)			
HEPATITIS C Ab	NONREACTIVE	ELISA	Antibodies to HCV
HCV ULTRIO	NONREACTIVE	Nucleic Acid Test (TMA)	HCV RNA
Human Immunodeficiency Virus (HIV)			
HIV 1&2 Ab	NONREACTIVE	EIA	Antibodies to HIV-1 and/or HIV-2
HIV ULTRIO	NONREACTIVE	Nucleic Acid Test (TMA)	HIV-1 RNA
Human T-Lymphotropic Virus (HTLV)			
HTLV I/II Ab - AVIOQ	NONREACTIVE	Microelisa	Antibodies to HTLV I/II
Cytomegalovirus (CMV)			
CMV TOTAL Ab	NONREACTIVE	Solid phase red-cell adherence	IgG and IgM Antibodies to CMV
Treponema pallidum (Syphilis)			
SYPHILIS - NON-TREPONEMAL	NONREACTIVE	Rapid Plasma Reagin (RPR) Test	Reagin Antibodies (Syphilis screen)
West Nile Virus (WNV)			
WNV TMA:SINGLET RESULT	NONREACTIVE	Nucleic Acid Test (TMA)	WNV RNA
Trypanosoma cruzi (Chagas)			
CHAGAS ORTHO	NONREACTIVE	ELISA	Antibodies to T. cruzi (Chagas)

Cell Line Safety Testing for Biologics (GMP) -- Specification: No microbial (bacterial/fungal), mycoplasma, aventitious agent or viral contaminant.

Cells were expanded in culture, submitted to a third-party FDA-registered laboratory, and tested in accordance with GMP.

Test Name	Result *	Method	Detection Target
Sterility			
Sterility Testing for Final and Biological Products	PASS; No Growth	Direct Method: Inoculation into Test Microbial Media (FTM and SCDM/TSB) Incubated for 14 days per USP <71>	Bacteria and Fungi
and Baceriostasis/Fungistasis Test	No Inhibition		
Mycoplasma			
Cultivable and Non-cultivable Mycoplasmas	PASS; Not Detected	Cultivation for 28 days (Agar Cultivable) and Fluorescent Detection (Non-Cultivable) per USP <63> , EP <2.6.7>	Mycoplasmas
and Mycoplasmastasis Test	No Inhbition		
In Vitro Adventitious Virus/Agent Assay			
Tissue Culture Safety Testing	PASS; Not Detected	Cultures for 28 days on Indicator Cell Lines (MRC-5, Vero 76, HeLa) for hemadsorption, hemagglutination, and cytopathogenicity	Adventitious Viruses or Agents
Pathogenic Human Viruses			
Detection and Quantitation of Virus DNA or RNA:			
Hepatitis A Virus (HAV)	PASS; Not Detected	PCR Amplification of Nucleic Acid Sequences, Quantitation with Copy Number Standard, and Detection by Fluorescent Probe	HAV RNA
Hepatitis B Virus (HBV)	PASS; Not Detected		HBV DNA
Hepatitis C Virus (HCV)	PASS; Not Detected		HCV RNA
Human Cytomegalovirus (HCMV)	PASS; Not Detected		HCMV DNA
Epstein-Barr Virus (EBV)	PASS; Not Detected		EBV DNA
Human Parvovirus B19 (B19)	PASS; Not Detected		B19 DNA
Human Polyomavirus JCV (JC)	PASS; Not Detected		JC DNA
Human Polyomavirus BKV (BK)	PASS; Not Detected		BK DNA
Herpesvirus 6 (HHV-6)	PASS; Not Detected		HH-6 DNA
Herpesvirus 7 (HHV-7)	PASS; Not Detected		HH-7 DNA
Herpesvirus 8 (HHV-8)	PASS; Not Detected		HH-8 DNA
Human Papillomavirus types 16, 18 (HPV-16, HPV-18)	PASS; Not Detected		HPV-16, HPV-18 DNA
Endotoxin			
Determination of Endotoxin	PASS; 0.2 EU/mL (<0.3 EU/ml)	Kinetic-Chromogenic LAL Assay per USP <85>	Endotoxin
and Spike Recovery Test	PASS; 99% (>60%)		

UCM Lot Release Safety Testing (GMP) -- Specifications: No microbial or mycoplasma contaminant; Low endotoxin; Evidence of container closure integrity.

UCM product material and filled vials were submitted to a third-party FDA-registered laboratory and tested in accordance with GMP.

Test Name	Result *	Method	Detection Target
Sterility			
Sterility Testing for Final and Biological Products	PASS; No Growth	Direct Method: Inoculation into Test Microbial Media (FTM and SCDM/TSB) Incubated for 14 days per USP <71>	Bacteria and Fungi
and Baceriostasis/Fungistasis Test	No Inhibition		
Mycoplasma			
Cultivable and Non-cultivable Mycoplasmas	PASS; Not Detected	Cultivation for 28 days (Agar Cultivable) and Fluorescent Detection (Non-Cultivable) per USP <63> , EP <2.6.7>	Mycoplasmas
and Mycoplasmastasis Test	No Inhbition		
Endotoxin			
Determination of Endotoxin	PASS; 0.2 EU/mL (<0.3 EU/ml)	Kinetic-Chromogenic LAL per USP <85> Assay	Endotoxin
and Spike Recovery Test	PASS; 106% (>60%)		
Container Closure Integrity (CCI)			
CCI Test (CCIT) of UCM Container Closure System (CCS)	PASS; No Dye Ingress	Dye ingress under Vacuum with Detection/ Quantitation by UV-Vis spectrophotometry	Container closure system integrity breech or leak
and Qualification of CCIT for UCM CCS with Controls	PASS		