Certificate of Analysis

Product	Human Mesenchymal Stem Cells - Chorion Villi (hCHV-MSCs)
Passage Number	2
Cytion® Number	300646
Lot Number	300646-160822P2
Cell concentration; volume	1.0 million/vial
Date of manufacture	8/2022
Donor information	Normal female donor
Donor age	42 years old
Cell culture karyoptype	46,XY[7] / 46,XX[14]

The following test specifications have been met for this product lot:

Test description	Test Method	Test Specification	Result
Cell Viability post-thaw	Trypan Blue dye exclusion test, automated cell counter	>85-90% viable cells	Pass
Recommended cell plating density	Cell cultivation	1-3x10^3 cells/cm²	Pass
Morphology	Microscopic examination	Spindle-shaped, fibroblast-like for at least 5 passages	Pass
Sterility	Bacterial and fungal contamination: inoculation and culture in blood agar. Thioglycollate broth, trypticase soy broth and sabouraud dextrose agar plates	No microorganisms' growth observed	Pass
	Exogenous viruses and microorganisms contamination:	HBV, HCV, HSV1, HSV2, CMV, EBV, HHV6, Toxoplasma gondii, Treponema pallidum, Chlamydia trachomatis, Ureaplasma urealyticum, Ureaplasma parvum, all negative	Pass
Mycoplasma	Mycoplasma specific PCR	Negative	Pass
Cell line authentication	PCR	Unique profile	Pass
Interspecies contamination test	PCR	No interspecies contamination	Pass

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Donor infectious screening results; plasma	PCR	HBV	Pass
	PCR	HCV	
	PCR	EBV	
	IFA	HIV-1/2	
	IFA	CMV	
	WR	Treponema pallidum	
		all negative	
Cell type identity	FACS analysis	$CD73^+$, $CD90^+$, $CD105^+$, $HLA\text{-}DR^-$	Pass
		$CD14^-$, $CD34^-$, $CD45^-$	
		and combinations	
		$CD90^+73^+$; $CD90^+73^+105^+$; $CD45^-34^-$; $CD90hi73^-$; $CD90hi105^-$; $CD90^-/low73^+$; $CD90^-/low105^+$	
Multilineage differentiation capability	Differentiation media	Alizarin Red S positive	Pass
		Oil Red O positive	

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