

MUSE CELLS Certificate of Analysis

Product:	Cord tissue derived mesenchymal stem cells		
Source:	Healthy donors (delivering mothers 18 – 44 years old)		
Intended use:	For clinical and ex vivo use		
Order number:	01/06/2025	Lot:	20250318VKLP520250626B (100)
Production:	06/2025	Expiry:	06/2028 at -196°C
Formulation:	Frozen in Cord blood plasma 80% and DMSO/DEX 20%		
Mass per vial:	Up to 100 mln per vial		

<u>Release Testing:</u>	<u>Specification</u>	<u>Lot Result</u>
CD73+	≥ 80%	100.0%
CD105+:	≥ 60%	99.3%
CD90+	≥ 80%	99.6%
SSEA3+	≥ 3%	92.2%

<u>Release Testing:</u>	<u>Specification</u>	<u>Lot Result</u>
Sterility:	Sterile	Complies
Viability when defrosted:	≥ 70%	88.6%
Endotoxin:	<5IU per sample	0,2IU

Sterility test of vial product was performed according to Eur.Pharm. (inoculation method).

Testing for HIV-1, HIV-2, hepatitis B, and hepatitis C, CMV and EBV, lime disease (*Borrelia burgdorferi*) is performed on a maternal blood sample and on a sample of the donated cord blood. Donors are not vaccinated with COVID19 vaccine. Endotoxin was performed according to Eur.Pharm. LAL method. Viability is evaluated by tripan blue exclusion assay or cytometrical dye exclusion assay.

Handling Instructions:

Reconstitution if frozen:	Thaw rapidly (< 1 minute) in 37°C water bath. Thawed samples must be used immediately.
Dilution for ex vivo procedures:	Recommended cultivation in DMEM high glucose media supplemented with 10% FCS.
Storage and stability:	Store cells in liquid nitrogen vapor phase for up to 3 years, do not thaw unless intended for ex vivo use. Short-term storage of cells (< 1 month) at -80°C is acceptable, but should be minimized to ensure maximum stability.

Quality Statement:

This product is manufactured, tested and realized in compliance with the relevant SOPs confirmed by National Transplant Bureau under the Ministry of Health under cGMP conditions.

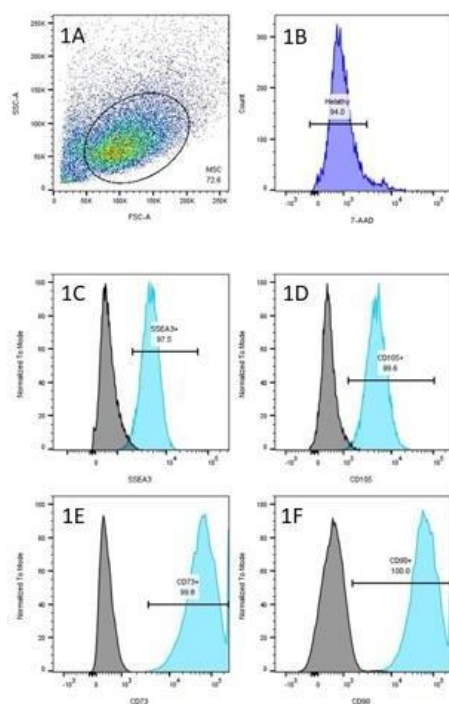


Image representative of LOT 20250318VKLP520250626B (100)

Cytometer: BD LSR II, BD, USA

Analytic software: FlowJo v10, BD, USA