

Certificate of Analysis and Release

Product: Embryo Freeze with propanediol

Batchnumber :		FP17EF03
Production date :	DD/MM/YYYY	19/09/2017
Expiry date :	DD/MM/YYYY	31/03/2019
Total batchsize:		17 Kits

Freezing medium	Results	Specifications
pH :	7,23	7.20-7.40
Bacterial screen :	PASSED	PASSED
Fungal screen	PASSED	PASSED
Endotoxine :	< 0,100 EU/mL	< 0.25EU/mL
Concentration HSA:	15,283	11,7 - 17,6 g/liter
Thawing medium 1		
pH :	7,23	7.20-7.40
Bacterial screen :	PASSED	PASSED
Fungal screen	PASSED	PASSED
Endotoxin :	< 0,100 EU/mL	< 0.25EU/mL
Concentration HSA:	14,634	11,4 - 17,1 g/liter
Thawing medium 2		
pH :	7,27	7.20-7.40
Bacterial screen :	PASSED	PASSED
Fungal screen :	PASSED	PASSED
Endotoxin :	< 0,100 EU/mL	< 0.25EU/mL
Concentration HSA:	16,325	11,4 - 17,1 g/liter
Thawing medium 3		
pH :	7,25	7.20-7.40
Osmolality:	549	530-560mOsm/kg
Bacterial screen :	PASSED	PASSED
Fungal screen :	PASSED	PASSED
Endotoxin :	< 0,100 EU/mL	< 0.25EU/mL
Concentration HSA:	14,836	11,4 - 17,1 g/liter
MEA (all media) :	100 %	≥ 80%

Product released by Eileen Vanderplancke on 04/10/2017 (DD/MM/YYYY)

Eileen Vanderplancke

*The plasma from Talecris (Grifols) which is the source for our human albumin is tested for anti-HIV 1, anti-HIV 2, anti-HCV and HBsAG.
The albumin responds to all the conditions for the FDA and the EMEA regarding safety.*