

Certificate of Analysis and Release

Product: Embryo Freeze with propanediol

Batchnumber :		FP18EF01
Production date :	DD/MM/YYYY	1/02/2018
Expiry date :	DD/MM/YYYY	31/08/2019
Total batchsize:		26 Kits

Freezing medium	Results	Specifications
pH :	7,22	7.20-7.40
Bacterial screen :	PASSED	PASSED
Fungal screen	PASSED	PASSED
Endotoxine :	<0,1 EU/ml	< 0.25EU/mL
Concentration HSA:	15,989	11,7 - 17,6 g/liter
Thawing medium 1		
pH :	7,28	7.20-7.40
Bacterial screen :	PASSED	PASSED
Fungal screen	PASSED	PASSED
Endotoxin :	<0,1 EU/ml	< 0.25EU/mL
Concentration HSA:	15,124	11,4 - 17,1 g/liter
Thawing medium 2		
pH :	7,25	7.20-7.40
Bacterial screen :	PASSED	PASSED
Fungal screen :	PASSED	PASSED
Endotoxin :	<0,1 EU/ml	< 0.25EU/mL
Concentration HSA:	15,068	11,4 - 17,1 g/liter
Thawing medium 3		
pH :	7,30	7.20-7.40
Osmolality:	546	530-560mOsm/kg
Bacterial screen :	PASSED	PASSED
Fungal screen :	PASSED	PASSED
Endotoxin :	<0,1 EU/ml	< 0.25EU/mL
Concentration HSA:	14,78	11,4 - 17,1 g/liter
MEA (all media) :	90%	≥ 80%

Product released by Justine Van Renterghem on 16/02/2018 (DD/MM/YYYY)



*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.*