

Certificate of Analysis and Release

Product: VitriThaw ES media

Batchnumber :		FP18VTE14
Production date :	DD/MM/YYYY	22/08/2018
Expiry date :	DD/MM/YYYY	31/08/2019
Total batchsize:		199 Kits

VitriThaw ES medium 5

	Result	Specification
pH :	7,31	7.2 - 7.4
Osmolality :	283	270-295mOsm/kg
Sterility test :	PASSED	PASSED
Endotoxin :	<0,1 EU/ml	< 0,25EU/mL
Concentration HSA:	20	16,0 - 24,0 g/liter

VitriThaw ES medium 4

pH :	7,34	7.2 - 7.4
Sterility test :	PASSED	PASSED
Endotoxin :	<0,1 EU/ml	< 0,25EU/mL
Osmolality :	417	405-435mOsm/kg
Concentration HSA:	19,608	15.5 - 23.3 g/liter

VitriThaw ES medium 3

pH :	7,45*	7.2 - 7.4
Sterility test :	PASSED	PASSED
Endotoxin :	<0,1 EU/ml	< 0,25EU/mL
Osmolality :	559	535-565mOsm/kg
Concentration HSA :	19,237	15.2 - 22.8 g/liter

VitriThaw ES medium 2

pH :	7,31	7.2 - 7.4
Sterility test :	PASSED	PASSED
Endotoxin :	<0,1 EU/ml	< 0,25EU/mL
Osmolality :	823	805-850mOsm/kg
Concentration HSA :	17,268	14.5 - 21.7 g/liter

VitriThaw ES medium 1

pH :	7,32	7.2-7.4
Sterility test :	PASSED	PASSED
Endotoxin :	<0,1 EU/ml	< 0,25EU/mL
Concentration HSA :	16,595	13.2 - 19.8 g/liter

MEA (1-cell to expanded blastocyst within 96 hours):	90,48%	≥ 80%
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* The slightly higher pH value of VitriThaw ES medium 3 has been accepted based on the output of the performed risk analysis. Therefore, this batch is released under concession.
More information on this matter is available upon request.

Product released by Lenie Bocklandt on 06/09/2018 (DD/MM/YYYY)



Bocklandt lenie

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HbC, HCV, and non-reactive for HbsAg, HCV RNS and HIV-1 RNA and syphilis. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.