

Certificate of Analysis

GM501 VitriStore Thaw

Batchnumber	VITRI-2321
Production date	05 September 2023
Expiry date	30 September 2024
Total batch size	100
Batchnumber HSA	B03H003853

Parameter	Results	Specifications
GM501 VitriStore Thaw 1		
pH	7,26	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	812	805-850 mOsm/kg
Concentration HSA	17,8	14,5-21,7 g/l
GM501 VitriStore Thaw 2		
pH	7,33	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	549	535-565 mOsm/kg
Concentration HSA	19,3	15,2-22,8 g/l
GM501 VitriStore Thaw 3		
pH	7,33	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,11	< 0,25 EU/mL
Osmolality	413	405-435 mOsm/kg
Concentration HSA	19,6	15,5-23,3 g/l
GM501 VitriStore Thaw 4		
pH	7,3	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,12	< 0,25 EU/mL
Osmolality	282	270-290 mOsm/kg
Concentration HSA	20,3	16,0-24,0 g/l

Mouse Embryo Assay (1-cell)	90,48	≥ 80 %
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Source materials from which this product was derived was found negative when tested for antibodies against HIV-1/2 and HCV and non-reactive for HbsAg, HBV RNA, HIV-1 RNA and syphilis. No known test method can offer assurance that products derived from human blood will not transmit infectious agents. Therefore, handle all specimens as if capable of transmitting HIV or hepatitis.

¹(according to the current Ph.Eur.2.6.1 / USP <71>)

Release date	20 September 2023
Released by	Nicole Geiger
Signature	pp. P. Geiger

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