

**Certificate of Analysis
GM501 VitriStore Thaw**

Batchnumber	VITRI-2407
Production date	15 March 2024
Expiry date	31 March 2024
Total batch size	100
Batchnumber HSA	B03H025323

Parameter	Results	Specifications
GM501 VitriStore Thaw 1		
pH	7,32	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	839	805-850 mOsm/kg
Concentration HSA	17,3	14,5-21,7 g/l
GM501 VitriStore Thaw 2		
pH	7,28	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	557	535-565 mOsm/kg
Concentration HSA	18,7	15,2-22,8 g/l
GM501 VitriStore Thaw 3		
pH	7,27	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	415	405-435 mOsm/kg
Concentration HSA	19,3	15,5-23,3 g/l
GM501 VitriStore Thaw 4		
pH	7,29	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	283	270-290 mOsm/kg
Concentration HSA	19,6	16,0-24,0 g/l

Mouse Embryo Assay (1-cell) 95,24 ≥ 80 %

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	08 April 2024
Released by	Nicole Geiger
Signature	

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