

**Certificate of Analysis
GM501 VitriStore Thaw**

Batchnumber	VITRI-2508
Production date	05 March 2025
Expiry date	31 March 2026
Total batch size	B03H108433
Batchnumber HSA	101

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	824	805-850 mOsm/kg
Concentration HSA	17,6	14,5-21,7 g/l
GM501 VitriStore Thaw 2		
pH	7,23	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	552	535-565 mOsm/kg
Concentration HSA	18,7	15,2-22,8 g/l
GM501 VitriStore Thaw 3		
pH	7,28	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	414	405-435 mOsm/kg
Concentration HSA	19,4	15,5-23,3 g/l
GM501 VitriStore Thaw 4		
pH	7,28	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	281	270-290 mOsm/kg
Concentration HSA	19,7	16,0-24,0 g/l

Mouse Embryo Assay (1-cell) 100 ≥ 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	21 March 2025
Released by	Nicole Geiger
Signature	

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