

**Certificate of Analysis
GM501 VitriStore Thaw**

Batchnumber	VITRI-2504
Production date	06 February 2025
Expiry date	28 February 2026
Total batch size	110
Batchnumber HSA	B03H108433

Parameter	Results	Specifications
GM501 VitriStore Thaw 1		
pH	7,27	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	831	805-850 mOsm/kg
Concentration HSA	17,3	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	547	535-565 mOsm/kg
Concentration HSA	18,6	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	19,6	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	20,1	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 February 2025

Released by Joana Sturm

Signature



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