

Certificate of Analysis GM501 VitriStore Thaw

Batchnumber	VITRI-2522
Production date	15 July 2025
Expiry date	31 July 2025
Total batch size	150
Batchnumber HSA	B03J094493

Parameter	Results	Specifications
GM501 VitriStore Thaw 1		
pH	7,21	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	836	805-850 mOsm/kg
Concentration HSA	17,9	14,5-21,7 g/l
GM501 VitriStore Thaw 2		
pH	7,22	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	18,8	15,2-22,8 g/l
GM501 VitriStore Thaw 3		
pH	7,23	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	420	405-435 mOsm/kg
Concentration HSA	20,3	15,5-23,3 g/l
GM501 VitriStore Thaw 4		
pH	7,25	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	284	270-290 mOsm/kg
Concentration HSA	20,3	16,0-24,0 g/l

Mouse Embryo Assay (1-cell)	100	≥ 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	31 July 2025
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Released by	Nicole Geiger
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Signature

pp. N. Geiger

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