

Certificate of Analysis GM501 VitriStore Thaw

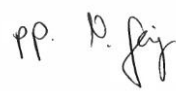
Batchnumber	VITRI-2511
Production date	11 April 2025
Expiry date	30 April 2026
Total batch size	40
Batchnumber HSA	B03H121903

Parameter	Results	Specifications
GM501 VitriStore Thaw 1		
pH	7,31	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	829	805-850 mOsm/kg
Concentration HSA	17	14,5-21,7 g/l
GM501 VitriStore Thaw 2		
pH	7,32	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Osmolality	546	535-565 mOsm/kg
Concentration HSA	17,7	15,2-22,8 g/l
GM501 VitriStore Thaw 3		
pH	7,34	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Osmolality	418	405-435 mOsm/kg
Concentration HSA	18,5	15,5-23,3 g/l
GM501 VitriStore Thaw 4		
pH	7,35	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,16	< 0,25 EU/mL
Osmolality	284	270-290 mOsm/kg
Concentration HSA	18,8	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	29 April 2025
Released by	Nicole Geiger
Signature	

REV 06_00 / 2023-09-15