

**Certificate of Analysis
GM501 VitriStore Thaw**

Batchnumber	VITRI-2424
Production date	26 December 2024
Expiry date	31 December 2025
Total batch size	100
Batchnumber HSA	B03H108433

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	814	805-850 mOsm/kg
Concentration HSA	16,5	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	546	535-565 mOsm/kg
Concentration HSA	18,2	15,2-22,8 g/l
GM501 VitriStore Thaw 3		
pH	7,3	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	418	405-435 mOsm/kg
Concentration HSA	19,1	15,5-23,3 g/l
GM501 VitriStore Thaw 4		
pH	7,26	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	19,7	16,0-24,0 g/l

Mouse Embryo Assay (1-cell) 95 ≥ 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>)

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Released by Joana Sturm

Signature



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