

**Certificate of Analysis
GM501 VitriStore Thaw**


Batchnumber	VITRI-2414
Production date	04 July 2024
Expiry date	31 July 2025
Total batch size	150
Batchnumber HSA	B03H100413

Parameter	Results	Specifications
GM501 VitriStore Thaw 1		
pH	7,25	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	827	805-850 mOsm/kg
Concentration HSA	15,8	14,5-21,7 g/l
GM501 VitriStore Thaw 2		
pH	7,26	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	553	535-565 mOsm/kg
Concentration HSA	17,4	15,2-22,8 g/l
GM501 VitriStore Thaw 3		
pH	7,29	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	17,4	15,5-23,3 g/l
GM501 VitriStore Thaw 4		
pH	7,32	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	280	270-290 mOsm/kg
Concentration HSA	18,1	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	23 July 2024
Released by	Nicole Geiger
Signature	

REV 06_00 / 2023-09-15