

**Certificate of Analysis
GM501 VitriStore Thaw**

Batchnumber	VITRI-2412
Production date	24 May 2024
Expiry date	31 May 2025
Total batch size	151
Batchnumber HSA	B03H100413

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	816	805-850 mOsm/kg
Concentration HSA	18,7	14,5-21,7 g/l
GM501 VitriStore Thaw 2		
pH	7,29	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	543	535-565 mOsm/kg
Concentration HSA	20,0	15,2-22,8 g/l
GM501 VitriStore Thaw 3		
pH	7,28	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	419	405-435 mOsm/kg
Concentration HSA	20,6	15,5-23,3 g/l
GM501 VitriStore Thaw 4		
pH	7,31	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	282	270-290 mOsm/kg
Concentration HSA	21,7	16,0-24,0 g/l

Mouse Embryo Assay (1-cell) 80,95 ≥ 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>)

Release date	11 June 2024
Released by	 Nicole Geiger
Signature	