

**Certificate of Analysis  
GM501 VitriStore Thaw**

Batchnumber	VITRI-2420
Production date	08 November 2024
Expiry date	30 November 2025
Total batch size	101
Batchnumber HSA	B03H100413

Parameter	Results	Specifications
<b>GM501 VitriStore Thaw 1</b>		
pH	7,28	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	822	805-850 mOsm/kg
Concentration HSA	15,7	14,5-21,7 g/l
<b>GM501 VitriStore Thaw 2</b>		
pH	7,29	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	553	535-565 mOsm/kg
Concentration HSA	16,6	15,2-22,8 g/l
<b>GM501 VitriStore Thaw 3</b>		
pH	7,3	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	414	405-435 mOsm/kg
Concentration HSA	17,3	15,5-23,3 g/l
<b>GM501 VitriStore Thaw 4</b>		
pH	7,29	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	280	270-290 mOsm/kg
Concentration HSA	17,7	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.*

<sup>1</sup>(according to the current Ph.Eur.2.6.1 / USP <71>)

Release date 26 November 2024

Released by Joana Sturm

Signature 

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