

**Certificate of Analysis
GM501 VitriStore Freeze**

Batchnumber	VITRI-2503
Production date	06 February 2025
Expiry date	28 February 2026
Batchnumber HSA	B03H108433
Total volume (Kits)	101

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
GM501 VitriStore Pre-Vitrification		
pH	7,28	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	281	270-290 mOsm/kg
Concentration HSA	20,1	16,0-24,0 g/l
GM501 VitriStore Freeze 1		
pH	7,27	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	17,3	12,8-19,2 g/l
GM501 VitriStore Freeze 2		
pH	7,27	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	11,2	8,3-12,4 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 21 February 2025

Released by Joana Sturm

Signature



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