

Certificate of Analysis

GM501 VitriStore Freeze

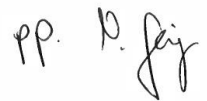
Batchnumber	VITRI-2513
Production date	16 May 2025
Expiry date	31 May 2026
Batchnumber HSA	B03H121903
Total volume (Kits)	150

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
GM501 VitriStore Pre-Vitrification		
pH	7,23	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	20,4	16,0-24,0 g/l
GM501 VitriStore Freeze 1		
pH	7,24	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	16,0	12,8-19,2 g/l
GM501 VitriStore Freeze 2		
pH	7,21	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	10,4	8,3-12,4 g/l
Mouse Embryo Assay (1-cell)	95,24	≥ 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	13 June 2025
Released by	Nicole Geiger
Signature	

REV 06_00 / 2023-09-15