

**Certificate of Analysis
GM501 VitriStore Freeze**

Batchnumber	VITRI-2419
Production date	08 November 2024
Expiry date	30 November 2025
Batchnumber HSA	B03H100413
Total volume (Kits)	100

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
GM501 VitriStore Pre-Vitrification		
pH	7,29	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	17,7	16,0-24,0 g/l
GM501 VitriStore Freeze 1		
pH	7,28	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	14,4	12,8-19,2 g/l
GM501 VitriStore Freeze 2		
pH	7,31	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	9,1	8,3-12,4 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 26 November 2024

Released by Joana Sturm

Signature



REV 06_00 / 2023-09-15