

Certificate of Analysis GM501 VitriStore Freeze

Batchnumber	VITRI-2408
Production date	10 April 2024
Expiry date	30 April 2025
Batchnumber HSA	B03H003853
Total volume (Kits)	195

Parameter	Results	Specifications
GM501 VitriStore Pre-Vitrification		
pH	7,2	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	279	270-290 mOsm/kg
Concentration HSA	19,5	16,0-24,0 g/l
GM501 VitriStore Freeze 1		
pH	7,21	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	15,1	12,8-19,2 g/l
GM501 VitriStore Freeze 2		
pH	7,23	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	10	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 25 April 2024

Released by Nicole Geiger

Signature



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