

Certificate of Analysis GM501 VitriStore Freeze

Batchnumber	VITRI-2601, VITRI-2601A
Production date	30 January 2026
Expiry date	31 January 2027
Batchnumber HSA	B03J103333
Total volume (Kits)	50

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
GM501 VitriStore Pre-Vitrification		
pH	7,25	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	18,6	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	15,2	12,8-19,2 g/l
GM501 VitriStore Freeze 2		
pH	7,25	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	10,2	8,3-12,4 g/l
Mouse Embryo Assay (1-cell)	90	≥ 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 18 February 2026

Released by Dr. René Richarz

Signature



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