

Certificate of Analysis GM501 GentleVit Freeze

Batchnumber	GF-2119
Production date	09 November 2021
Expiry date	30 November 2022
Batchnumber HSA	B3ALE00033
Total volume (Kits)	199

	Results	Specifications
GM501 GentleVit Pre-Vitrification		
pH	7,33	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,167	< 0,25 EU/mL
Osmolality	281	270-290 mOsm/kg
GM501 GentleVit Freeze 1		
pH	7,34	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,149	< 0,25 EU/mL
GM501 GentleVit Freeze 2		
pH	7,34	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,129	< 0,25 EU/mL
GM501 GentleVit Freeze 3		
pH	7,34	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
GM501 GentleVit Freeze 4		
pH	7,29	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
GM501 GentleVit Freeze 5		
pH	7,29	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
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.

Release date	15 December 2021
Released by	Dr. Julia Heinzmann
Signature	

p.p. Julia Heinzmann