

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-2607
Production date	11 March 2026
Expiry date	31 March 2027
Total batch size	199 Kits
Batchnumber HSA	B03J103333

Parameter	Results	Specifications
GM501 GentleVit Thaw 1		
pH	7,3	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,20	< 0,25 EU/mL
Concentration HSA	16,0	13,9-20,9 g/l
GM501 GentleVit Thaw 2		
pH	7,24	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,20	< 0,25 EU/mL
Concentration HSA	16,7	14,4-21,6 g/l
GM501 GentleVit Thaw 3		
pH	7,29	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,20	< 0,25 EU/mL
Osmolality	832	805-850 mOsm/kg
Concentration HSA	16,7	14,9-22,3 g/l
GM501 GentleVit Thaw 4		
pH	7,31	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,20	< 0,25 EU/mL
Osmolality	550	535-565 mOsm/kg
Concentration HSA	18,2	15,4-23,1 g/l
GM501 GentleVit Thaw 5		
pH	7,28	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,20	< 0,25 EU/mL
Osmolality	419	405-435 mOsm/kg
Concentration HSA	18,7	15,7-23,6 g/l
GM501 GentleVit Thaw 6		
pH	7,26	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,20	< 0,25 EU/mL
Osmolality	281	270-290 mOsm/kg
Concentration HSA	19,3	16,0-24,0 g/l
Mouse Embryo Assay (1-cell)	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.

¹Sterility test (according to the current PH. Eur. 2.6.1 / USP <71>)

Release date	27 March 2026
Released by	Dr. René Richarz
Signature	

REV 02_00 / 2023-09-15