

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-1906
Production date	26 March 2019
Expiry date	31 March 2020
Batchnumber HSA	B3ALC00323
Total volume (Kits)	149

	Results	Specifications
GM501 GentleVit Thaw 1		
pH	7,22	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
GM501 GentleVit Thaw 2		
pH	7,23	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
GM501 GentleVit Thaw 3		
pH	7,25	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,106	< 0,25 EU/mL
Osmolality	841	805-850 mOsm/kg
GM501 GentleVit Thaw 4		
pH	7,24	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	559	535-565 mOsm/kg
GM501 GentleVit Thaw 5		
pH	7,25	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	421	405-435 mOsm/kg
GM501 GentleVit Thaw 6		
pH	7,24	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	286	270-290 mOsm/kg
Mouse Embryo Assay (1-cell)	95,24	≥ 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	12. April 2019
Released by	Dr. Julia Heinzmann
Signature	