

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-1916
Production date	01 October 2019
Expiry date	31 January 2020
Batchnumber HSA	B3ALD00533
Total volume (Kits)	196

	Results	Specifications
GM501 GentleVit Thaw 1		
pH	7,3	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
GM501 GentleVit Thaw 2		
pH	7,32	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
GM501 GentleVit Thaw 3		
pH	7,32	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	816	805-850 mOsm/kg
GM501 GentleVit Thaw 4		
pH	7,27	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	547	535-565 mOsm/kg
GM501 GentleVit Thaw 5		
pH	7,32	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	409	405-435 mOsm/kg
GM501 GentleVit Thaw 6		
pH	7,32	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	279	270-290 mOsm/kg
Mouse Embryo Assay (1-cell)	86	≥ 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	18. Oktober 2019
Released by	Dr. Julia Heinzmann
Signature	