

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-1816
Production date	04 December 2018
Expiry date	31 December 2019
Batchnumber HSA	B3AKC00053
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	7,21	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
GM501 GentleVit Thaw 3		
pH	7,23	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	831	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	549	535-565 mOsm/kg
GM501 GentleVit Thaw 5		
pH	7,28	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	418	405-435 mOsm/kg
GM501 GentleVit Thaw 6		
pH	7,21	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,104	< 0,25 EU/mL
Osmolality	280	270-290 mOsm/kg
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.

Release date	11. Februar 2019
Released by	Dr. Julia Heinzmann
Signature	