

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-2112
Production date	01 July 2021
Expiry date	31 July 2022
Batchnumber HSA	B3ALE00033
Total volume (Kits)	195

	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	7,29	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
GM501 GentleVit Thaw 3		
pH	7,27	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	839	805-850 mOsm/kg
GM501 GentleVit Thaw 4		
pH	7,3	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	558	535-565 mOsm/kg
GM501 GentleVit Thaw 5		
pH	7,3	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	0,137	< 0,25 EU/mL
Osmolality	415	405-435 mOsm/kg
GM501 GentleVit Thaw 6		
pH	7,28	7,20-7,40
Sterility test	PASSED	PASSED
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	281	270-290 mOsm/kg
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	12 August 2021
Released by	Dr. Julia Heinzmann
Signature	