

Certificate of Analysis GM501 GentleVit Thaw

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| Batchnumber | GT-2006 |
| Production date | 17 June 2020 |
| Expiry date | 30 June 2021 |
| Batchnumber HSA | B3ALD01343 |
| Total volume (Kits) | 198 |

| | 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 | 7,25 | 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 | 840 | 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 | 557 | 535-565 mOsm/kg |
| GM501 GentleVit Thaw 5 | | |
| pH | 7,3 | 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 | 7,29 | 7,20-7,40 |
| Sterility test | PASSED | PASSED |
| Endotoxin | < 0,1 | < 0,25 EU/mL |
| Osmolality | 283 | 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.

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| Release date | 2. Juli 2020 |
| Released by | Dr. Julia Heinzmann |
| Signature |  |