

**Certificate of Analysis
GM501 Cult with Gentamicin**

Batchnumber CULT-2408G
 Production date 22 November 2024
 Expiry date 31 May 2025
 Batchnumber HSA K331A687L
 Total volume (ml) 17100

Product was sterilized by aseptic processing techniques

| Parameter | Results | Specifications |
|---|----------------|-----------------------|
| pH | 7,27 | 7,20-7,45 |
| Osmolality | 281 | 270-290 mOsm/kg |
| Endotoxin level | < 0,05 | < 0,25 EU/ml |
| Concentration HSA | 10 | 8,0-12,0 g/l |
| Concentration gentamicin | 12,13 | 5-15 mg/l |
| Sterility test (performed according to the current Ph.Eur.2.6.1 / USP <71>) | No growth | No growth |
| Mouse Embryo Assay (1-cell to expanded blastocyst within 96 hours) | 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 09 December 2024
 Released by Joana Sturm
 Signature



REV 09_00 / 2024-09-17