

Certificate of Analysis
GM501 Cult with Gentamicin

Batchnumber	CULT-2501G
Production date	14 January 2025
Expiry date	31 July 2025
Batchnumber HSA	M424A6871
Total volume (ml)	15700

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,3	7,20-7,45
Osmolality	281	270-290 mOsm/kg
Endotoxin level	< 0,05	< 0,25 EU/ml
Concentration HSA	9,3	8,0-12,0 g/l
Concentration gentamicin	7,46	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	29 January 2025
Released by	Joana Sturm
Signature	

REV 09_00 / 2024-09-17