

Certificate of Analysis
GM501 Cult with Gentamicin

Batchnumber	CULT-2608G
Production date	15 July 2026
Expiry date	31 January 2027
Batchnumber HSA	KP42A6872
Total volume (ml)	10400

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH (@37°C - 6% CO ₂)	7,26	7,20-7,45
Osmolality	280	270-290 mOsm/kg
Endotoxin level	< 0,05	< 0,25 EU/ml
Concentration HSA	9,8	8,0-12,0 g/l
Concentration gentamicin	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)	90	≥ 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	30 July 2026
Released by	Dr. René Richarz
Signature	

REV 09_00 / 2024-09-17