

Certificate of Analysis
GM501 Hyaluronidase

Batchnumber	HYA-2408
Production date	26 February 2024
Expiry date	28 February 2025
Total volume (ml)	3600
Batchnumber HSA	B03H025323
Batchnumber HYA	S1047H40

Parameter	Results	Specifications
pH	7,41	7,30-7,60
Osmolality	280	270-290 mOsm/kg
Endotoxin	< 0,23	<0,5 EU/ml
Concentration HSA	3,9	3,2-4,8 g/l
Enzyme activity	93-137	40-160 IU/ml
Sterility test (according to the current Ph.Eur.2.6.1 /USP<71>)	No growth	No growth
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.

Release date	12 March 2024
Released by	Nicole Geiger
Signature	

REV 09_00 /2023-09-15