

Certificate of Analysis GM501 SpermAIR

Batchnumber	AIR-2501
Production date	16 January 2025
Expiry date	31 July 2025
Batchnumber HSA	B03H108433
Total volume (ml)	22660

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,35	7,20-7,50
Osmolality	281	270-290 mOsm/kg
Endotoxin level	< 0,05	< 0,25 EU/ml
Concentration HSA	4,8	4,0-6,0 g/l
Sterility test (performed according to the current Ph. Eur. 2.6.1 / USP <71>)	No growth	No growth
MEA (1-cell to expanded blastocyst within 96 hours)	81	≥ 80 %

Source materials from which this product was derived was found negative when tested for antibodies against HIV-1/2 and HCV and nonreactive for HbsAg, HBV RNA, HIV-1 RNA and syphillis. 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

Released by

Signature

30/02/2025

Joana Sturm

REV 09_00 / 2024-08-16