

Certificate of Analysis GM501 SpermAIR

Batchnumber	AIR-2505
Production date	01 July 2025
Expiry date	31 January 2026
Batchnumber HSA	B03H121903
Total volume (ml)	32820

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,32	7,20-7,50
Osmolality	283	270-290 mOsm/kg
Endotoxin level	< 0,05	< 0,25 EU/ml
Concentration HSA	4,8	4,0-6,0 g/l
Concentration gentamicin	9,0	5,0-15,0 mg/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)	100	≥ 80 %
\mbox{HSSA} (% motility compared with control after 24h exposure to test medium)	90	≥ 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

REV 10_00 / 2025-03-19

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