

PRODUCT: Sperm Washing Medium
Modified HTF Medium
With Human Serum Albumin

LOT #0000039041

CATALOG #9983

MFR DATE: 12/26/2024

STORAGE: 2° - 8°C

EXPIRES: 12/31/2026

CERTIFICATE OF ANALYSIS

Products manufactured by FUJIFILM Irvine Scientific, Inc. are produced in accordance with the Good Manufacturing Practices (GMP's) for Medical Devices. FUJIFILM Irvine Scientific, Inc. is licensed by both Federal and State agencies and is inspected regularly for compliance.

All donors used to obtain human albumin were tested and found to be non-reactive for Hepatitis B Surface Antigen (HB_sAg), antibodies to Human Immunodeficiency Virus (HIV), and Hepatitis C Virus (HCV) by approved testing methods.


Assay	Specification	Result
Sterility ¹	Pass	Pass
pH	7.3 - 7.5	7.5
Osmolality	272 - 288 mOsm/Kg H ₂ O	277 mOsm/Kg H ₂ O
Endotoxin ²	≤6 EU/ml	<0.05 EU/ml
Albumin Recovery ³	≥85%	122%
Mouse Embryo Test (One-cell) ⁴		
-Control:		
% of embryos developing	≥80%	97% (90/93)
-This lot:		
% of embryos developing	≥80%	97% (90/93)

¹In accordance with the Current USP <71>; 21 CFR, Part 610.12.

²Utilizes a Chromogenic assay with a sensitivity of 0.005 EU/ml.

³Albumin concentration is determined by the BCG method.

⁴One cell mouse embryo testing is performed using mouse embryos. Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 96 hours in culture following a 2 hour exposure to Sperm Washing Medium. Control was for growth media only.

Released By: 

Date: 01/22/2025

Title: QA Product Release Coordinator

Rev. 4