

PRODUCT: Vitrifaction Thaw Kit (Vit Kit-Thaw)
Thawing Solution-TS (90134)
Dilution Solution-DS (90135)
Washing Solution-WS (90136)

LOT #0000037954
CATALOG #90137-DSOC
MFR DATE: 02/19/2025

STORAGE: 2° - 8°C

EXPIRES: 09/30/2025

CERTIFICATE OF ANALYSIS

Products manufactured by FUJIFILM Irvine Scientific, Inc. are produced in accordance with the Guideline for Manufacture of In Vitro Diagnostic Products and 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 the human albumin were tested and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), antibodies to Human Immunodeficiency Virus (HIV), and Hepatitis C virus (HCV) by approved testing methods.

Vitrification Thaw Media				
Assay	Specification	0000037939: Result	0000037942: Result	0000037945: Result
Sterility ¹	Pass	Pass	Pass	Pass
pH	7.1 - 7.4	7.24	7.26	7.26
Osmolality:				
90134	1732 - 1912	1802 mOsm/Kg H ₂ O		
90135	857 - 910		884 mOsm/Kg H ₂ O	
90136	268 - 292			279 mOsm/Kg H ₂ O
Endotoxin ²	≤0.6 EU/mL	<0.05 EU/mL	<0.05 EU/mL	<0.05 EU/mL
Albumin Recovery ³	≥85%	149%	135%	137%

Kit:

Mouse Embryo Test (One-Cell)⁴
-Control⁵:
% of embryos developing ≥80% 97%
-This lot:
% of embryos developing ≥80% 88%

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.

⁴Fresh one-cell mouse embryos (n=31) were exposed to each medium for a limited time then washed and cultured in growth medium (HTF+0.4%BSA). Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 96 hours in culture.

⁵Control embryos were cultured in growth medium only.

Released By: Julia Nakagawa

Date: 02/28/2025

Title: QA Product Release Lead

Rev 4