

PRODUCT: Vitrification Freeze Kit (Vit Kit-Freeze)
Equilibration Solution-ES (90131)
Vitrification Solution-VS (90132)

LOT # 0000037119
CATALOG #90133-DSOC

MFR DATE: 01/27/2025

STORAGE: 2°- 8°C

EXPIRES: 10/31/2025

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 Freeze Media			
Assay	Specification	Lot #0000037115: Result	Lot #0000037113: Result
Sterility ¹	Pass	Pass	Pass
pH	7.1 - 7.5	7.4	7.4
Osmolality: of 90131 1:1 dilution	1055 – 1445	1292 mOsm/Kg H ₂ O	
of 90132 1:3 dilution	1100 – 1588		1419 mOsm/Kg H ₂ O
Endotoxin ²	≤0.6 EU/mL	<0.05 EU/mL	<0.24 EU/mL
Albumin Recovery ³	≥85%	153%	128%

Kit:

Mouse Embryo Test (One-Cell) ⁴	
-Control ⁵ :	
% of embryos developing ≥ 80%	87%
-This lot:	
% of embryos developing ≥ 80%	85%

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

²Utilizes a Chromogenic assay with a sensitivity of 0.005 EU/mL and a gel clot assay with a sensitivity of 0.03 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: Dalia Ramirez

Date: 02/05/2025

Title: QA Product Release Coordinator