PRODUCT: Vit Kit-Warm NX (Vitrification Kit for Warming)
Thawing NX - TS (90179)
Dilution NX - DS (90180)
Washing NX - WS (90181)

LOT #0000039026

CATALOG #90183

MFR DATE: 01/16/2025

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.

Vit Kit-Warm NX (Vitrification Kit for Warming) is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.
Caution: Federal law restricts this device to sale by or on the order of a physician.

Vitrification Kit for Warming

Assay	Specification	0000039014: Result	0000039018: Result	0000039020: Result
Sterility[1]	Pass	Pass	Pass	Pass
pH	7.05 – 7.45	7.23	7.27	7.27
Osmolality:				
90179	1550 – 1900	1632 mOsm/Kg H_2O		
90180	830 – 930		885 mOsm/Kg H_2O	
90181	265 – 300			276 mOsm/Kg H_2O
Endotoxin[2]	≤0.60 EU/ml	<0.03 EU/mL	<0.03 EU/mL	<0.03 EU/mL
Albumin Recovery[3]	≥85%	140%	137%	134%

Kit:

Mouse Embryo Test (One-Cell)[4]
-Control[5]:
% of embryos developing ≥80% 90%
-This lot:
% of embryos developing ≥80% 91%

[1]In accordance with the Current USP <71>; 21 CFR, Part 610.12.
[2]Utilizes a gel clot assay with a sensitivity of 0.03 EU/mL.
[3]Albumin concentration is determined by the BCG method.
[4]Fresh 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.
[5]Control embryos were cultured in growth medium only.

Released By: _____ Date: 01/27/2025

Title: QA Product Release Coordinator

Rev. 3