

PRODUCT: Vit Kit-Freeze NX (Vitrification Kit for Freezing)
 Equilibration NX – ES (90186)
 Vitrification NX – VS (90187)
 Washing NX – WS (90181)

LOT #0000039028
 CATALOG #90188
 MFR DATE: 01/22/2025

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-Freeze NX (Vitrification Kit for Freezing) is intended for use in vitrification and storage of human 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 Freezing				
Assay	Specification	Lot #0000039022: Result	Lot #0000039024: Result	Lot #0000039020: Result
Sterility ¹	Pass	Pass	Pass	Pass
pH:				
90186	7.05 – 7.44	7.29		
90187	7.05 – 7.44		7.38	
90181	7.05 – 7.45			7.27
Osmolality:				
90186 1:1 dilution	1150 – 1550	1351 mOsm/Kg H ₂ O		
90187 1:3 dilution	1220 – 1620		1445 mOsm/Kg H ₂ O	
90181	265 – 300			276 mOsm/Kg H ₂ O
Endotoxin ²	≤0.60 EU/ml	<0.03 EU/mL	<0.12 EU/mL	<0.03 EU/mL
Albumin Recovery ³	≥85%	144%	158%	134%

Kit:

Mouse Embryo Test (One-Cell) ⁴	
-Control ⁵ :	
% of embryos developing	≥ 80% 100%
-This lot:	
% of embryos developing	≥ 80% 98%

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

²Utilizes 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: 

Date: 02/04/2025

Title: QA Product Release Coordinator

Rev. 3