



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Fujifilm Irvine Scientific Recalls Vit Kit-Freeze**

Recall Date	Product Description	Recalling Firm	Recall Reason
9/8/2021	<b>Vit Kit-Freeze</b> Intended for use in assisted reproductive procedures for vitrification and storage of human oocytes, zygotes, and embryos. Test results reported on C of A Vit Kit - Freeze (Vitrification Freeze Kit) with Gentamycin and DSS Contains 9 x 1 mL Equilibration Solution- ES; 9 X 1 mL Vitrification Solution- VS	<b>Fujifilm Irvine Scientific, Inc.</b> Santa Ana, California	Due to a component in kit being labeled with the incorrect Expiration Date
9/8/2021	<b>Vit Kit-Freeze</b> DSS Contains 2 x 1 mL Equilibration Solution- ES; 2 X 1 mL Vitrification Solution	<b>Fujifilm Irvine Scientific, Inc.</b> Santa Ana, California	Component in kit being labeled with the incorrect Expiration Date

Recall Class	Product Identification	Distribution	Affected Dates
II	<b>Vit Kit Freeze</b> Catalog number: 90133-DSOC Kit-Vitrification Freeze kit: Which contained VS Vitrification solution, Lot/Unit numbers: 90132210403; UDI # 00893727002811; 9 x1 mL Vitrification Solution, VS, Catalog #0132 and 9x1mL. Equilibration Solution, ES Catalog 90131	595 kits Nationwide including California	September 2021 and prior
II	<b>Vit Kit Freeze</b> Catalog number: 90133-SO Vitrification Freeze kit Lot/Unit numbers: 90132210403; UDI # 00893727002811 Product code MLQ	314 kits Nationwide including California	September 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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