



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Fujifilm Irvine Scientific Inc. Recalls Sperm Separation Media For Incorrect Labeling Pertaining to the Lower Label Component of the Kit.

Recall Date	Product Description	Recalling Firm	Recall Reason
2/14/2024	Sperm Separation Media Used to separate motile sperm from other constituents of semen.	FUJIFILM IRVINE SCIENTIFIC, INC. Santa Ana, California	The lower layer component of a sperm separation kit does not match the certificate of analysis. It contains the wrong lower layer.

Recall Class	Product Identification	Distribution	Affected Dates
II	Sperm Separation Media UDI-DI: 00857515006009, Lot 0000020693	21 Units in California California	February, 2024 and prior

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