



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Immundiagnostik Recalls IDK Lactoferrin ELISA For Lack Of Approval

Recall Date	Product Description	Recalling Firm	Recall Reason
5/24/2023	Immundiagnostik Idk Lactoferrin Elisa In vitro enzyme immunoassay intended for the determination of lactoferrin in stool. P/N: K6870 Single Kit P/N: K6870.20.US.L 20 Plates	IMMUNDIAGNOSTIK, INC Manchester, New Hampshire	Marketed without a 510k

Recall Class	Product Identification	Distribution	Affected Dates
II	Immundiagnostik Idk Lactoferrin Elisa UDI: (01) 04050598000582 PN K6870/Lot Numbers: 220706 Exp. 05/04/2024; 221122 Exp. 06/07/2024. P/N:K6870.20.US.L Lot Numbers: 221124 Exp:07/29/2025, 230102 Exp: 10/24/2025	1 Unit in California	April 2023 - October 2025

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