



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Diasorin Molecular recalls subset of Simplexa Direct Amplification Disc Kit for Leakage and Risk of Cross-contamination

Recall Date	Product Description	Recalling Firm	Recall Reason
11/19/2021	Simplexa Direct Amplification Disc Kit Product Kit Code MOL1455	DiaSorin Molecular LLC Cypress, California	A subset of affected discs are at risk of leakage when it is used more than one time with Simplexa COVID-19 Direct and/or Simplexa Flu A/B & RSV Direct Gen II. Leakage from a well that had a positive sample may cause further cross-contamination in areas of the lab if not properly cleaned.

Recall Class	Product Identification	Distribution	Affected Dates
II	Lot numbers: 12410N-14463N	2,322 in California	November 2021 and Prior

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