

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

HF Acquisition Co LLC Biological, Bio52 HealthFirst Mail In Monitoring System 52 and 12 Tests

Recall Date	Product Description	Recalling Firm	Recall Reason
02/11/2025	Biological, Bio52 HealthFirst Mail In Monitoring System, 52 Tests, Item: 1003600 Biological, Bio12 HealthFirst Mail In Monitoring System, 12 Tests, Item: 1003580	HF Acquisition Co LLC	Spore test strip monitoring system, designed for routine monitoring of sterilization processes, may have a printing error on the return envelope that may cause spore test results to be reported to the incorrect customer's account.

Recall Class	Product Identification	Distribution	Affected Dates
II	Item: 1003600 UDI-DI: 10850065007820 Lot(Expiration): 2301060(11/30/2024) 2302261(11/30/2024) 2307261(12/31/2024) 2312260(1/31/2025) 2313062(1/31/2025) 2331880(6/30/2025) 2401664(8/31/2025) 2414060(2/28/2026) 2414862(3/31/2026) 2414870(3/31/2026)	364 units in California	December and prior

	2416470(3/31/2026) 2416481(4/30/2026) 2416482(4/30/2026) Item: 1003580 UDI-DI: 10850065007813 Lot(Expiration): 2421181(5/31/2026)		
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For additional information, please visit the [FDA Website](#).