California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Hologic, Inc. Panther Fusion GBS Assay containing Panther Fusion GBS Reagent Cartridge IVD

Recall Date	Product Description	Recalling Firm	Recall Reason
01/14/2025	Panther Fusion GBS Assay REF PRD-04484 Kit containing Panther Fusion GBS Reagent Cartridge IVD	Hologic, Inc.	Potential weak pouch seal on Panther Fusion GBS assay cartridge, causing potential for invalid or incorrect results leading to a possible delay of treatment.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 15420045510890 Kit Lot 715927, containing Cartridge Lot 624907 Exp. Date 2025-08-15	10 units in California	December and prior

For additional information, please visit the FDA Website.