State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Helena Laboratories, Corp. Serrated Blade Applicator Kit for Wrong Packaging and Samples

Recall Date	Product Description	Recalling Firm	Recall Reason
6/28/2023	**Serrated Blade Applicator Kit** REF: 552687, For use with the Spife Nexus system, Contents: 30 Blade Applicators. used in invitro diagnostics	**Helena Laboratories, Corp.** Beaumont, Texas	Packaging for a serrated blade applicator kit (12 Sample) may contain a serrated blade applicator (18 sample). This results in a characteristic pattern of missed or light samples on the gel, leading to incorrect or no result, or delay in result.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Serrated Blade Applicator Kit** Lot # 3-22, UDI-DI: M5255526870	4 Units in California	May 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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