State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Abbott Laboratories Recalls Abbott Cell-Dyn Ruby And Abbott Cell-Dyn Sapphire For Failing To Disclose In The Labels That The Devices Contain A Dry Natural Rubber (Latex) Subcomponent.

Recall Date	Product Description	Recalling Firm	Recall Reason
10/19/2023	**Abbott Cell-Dyn Ruby** Model CD-Ruby, List Number 08H67-01.	**ABBOTT LABORATORIES** Abbott Park, Illinois	The devices contain a dry natural rubber (latex) subcomponent, which are not labeled as containing dry natural rubber(latex).
10/19/2023	**Abbott Cell- Dyn Sapphire** Model CD-Sapphire, List Number 08H00-01. Multi parameter, automated hematology analyzer.	**ABBOTT LABORATORIES** Abbott Park, Illinois	The devices contain a dry natural rubber (latex) subcomponent, which are not labeled as containing dry natural rubber(latex).

Recall Class	Product Identification	Distribution	Affected Dates
II	**Abbott CELL-DYN Ruby** All serial numbers are involved. CELL-DYN Ruby - UDI/DI 00380740017170	13 Units in California California	October, 2023 and prior

II	**Abbott CELL-DYN Sapphire** All serial numbers are involved. CELL-DYN Sapphire - UDI/DI 00380740016616	2 Units in California California	October, 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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