



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Beckman Coulter, Inc. Hybritech p2PSA Reagent for Insufficient Concentration of Blocking Reagent

Recall Date	Product Description	Recalling Firm	Recall Reason
7/5/2023	Access Hybritech p2PSA Reagent REF B03704 and REF A49752	Beckman Coulter, Inc. Chaska, MN	Reagent lot numbers include an insufficient concentration of blocking reagent.

Recall Class	Product Identification	Distribution	Affected Dates
II	Access Hybritech p2PSA reagent Lot #234320, exp. 7/31/2023, UDI (01)15099590211325(17)230731(11)220731(10)234320; Lot #234134, exp. 6/30/2023, UDI (01)15099590211325(17)230630(11)220630(10)234134; and Lot #234133, exp. 6/30/2023, UDI (01)15099590204112(17)230630(11)220630(10)234133.	16 Units in California	May 2023 and Prior

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