State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Accriva Diagnostics recalls VerifyNow P2Y12 Test

Recall Date	Product Description	Recalling Firm	Recall Reason
3/30/2022	**VerifyNow P2Y12 Test** Designed to measure platelet P2Y12 receptor blockade. Substances known to specifically block the P2Y12 receptor include ticagrelor and the thienopyridine class of drugs, including clopidogrel and prasugrel. The test is based upon the ability of activated platelets to bind fibrinogen. Light transmittance increases as activated platelets bind and aggregate fibrinogen-coated beads. The instrument measures this change in optical signal.	**Accriva Diagnostics INC** San Diego, California	Two whole blood Platelet Reactivity tests exist that share the same reagent formulation. The test without US-FDA market clearance was distributed and it displays BASE results not displayed by the US-FDA market cleared device. A formula is being provided to health care personnel to calculate the percentage of platelet aggregation inhibition.

Recall Class	Product Identification	Distribution	Affected Dates
II	Lot Number: WL1060, Expiration: 2023-03-01	11 Tests in California	March 2022 – March 2023

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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