



CALIFORNIA DEVICE RECALL INFORMATION SHEET

QUIDEL CARDIOVASCULAR INC Quidel Triage Cardiac Panel for Troponin Signal Reduction

Recall Date	Product Description	Recalling Firm	Recall Reason
7/12/2023	Quidel Triage Cardiac Panel REF: 97000HS, 97021HS (Troponin I), 97022HS (CK-MB and Troponin I), 97000HSEU, 97000HSEUJP, 97000HZ01, 97000QIL. Lots T13664 - T14045.	QUIDEL CARDIOVASCULAR INC San Diego, CA	Raw material issue may cause cardiac panel products to have an average of 30% troponin signal reduction across measurement range 0.05 ng/mL to 30 ng/mL, QC testing won't detect anomaly, so an alternate method is recommended, if unavailable, use recommendations to mitigate potential patient impact, which could be missed/delayed myocardial infarction diagnosis.

Recall Class	Product Identification	Distribution	Affected Dates
I	Quidel Triage Cardiac Panel REF/UDI-DI/Lots(Expiration): 97000HS/30014613337911/T13666N(2023-06-26), T13667N(2023-07-03), T13669N(2023-07-08), T13706N(2023-07-21), T13826N(2023-09-03), T13944N(2023-10-14), T13948N(2023-10-20), T13949N(2023-10-22), T14019N(2023-11-05),	16,194 Units Nationwide	May 2023 and Prior

T14020N(2023-11-05),
T14023N(2023-11-11);
97021HS/30014613337935/T13
665RN(2023-06-25),
T13707RN(2023-06-28),
T13709RN(2023-08-11),
T13827RN(2023-09-04),
T13829RN(2023-09-18),
T13942RN(2023-10-09),
T13950RN(2023-10-23);
97022HS/30014613337942/T13
664RN(2023-06-20),
T13708RN(2023-08-03),
T13943RN(2023-10-10);
97000HSEU/30014613337928/
T13668RBN(2023-07-05),
T13705RN(2023-07-14),
T13765RBN(2023-08-26),
T13825RBN(2023-08-27),
T13828RBN(2023-09-18),
T13946RBN(2023-10-16);
97000HSEUJP/T13668RN(2023
-07-05), T13765RN(2023-08-
26), T13828RN(2023-09-18),
T13946RN(2023-10-16);
97000HZ01/T13763(2023-08-
19), T13764(2023-08-21),
T13830(2023-09-24),
T13831(2023-09-26),
T13940(2023-10-01),
T13941(2023-10-03),
T13947(2023-10-21),
T13951(2023-10-27),
T14021(2023-11-06),
T14022(2023-11-10),
T14024(2023-11-15),
T14025(2023-11-19),
T14041(2023-12-13),
T14042(2023-12-18),
T14043(2023-12-19),
T14044(2023-12-20),
T14045(2023-12-24);
T14024RN(2023-11-15);
T14025N, T14025RBN,
T14025RN(2023-11-19);
T14041N, T14041RBN,
T14041RN(2023-12-13);
T14042N, T14042RBN,
T14042RN(2023-12-18);
T14043N, T14043RBN,
T14043RN(2023-12-19);
T14044N, T14044RBN,
T14044RN(2023-12-20);
T14045N, T14045RBN.

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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