

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Terragene S.A. ASP BIOTRACE Auto Read 60 Steam BI Process Challenge Device

Recall Date	Product Description	Recalling Firm	Recall Reason
02/27/2025	ASP BIOTRACE Auto Read 60 Steam BI Process Challenge Device, REF 73135.	Terragene S.A.	Error in the IFU lists an incorrect incubation time on one occasion of 20 minutes rather than the correct incubation time of 60 minutes.

Recall Class	Product Identification	Distribution	Affected Dates
II	Lot numbers: F40062, F40064, F40072, F40074, F40101, F40116 UDI-DI - 07798375772624 (primary packaging), 07798375772877 (secondary packaging) containing IFU Rev.A R0.	2 units in California	January and prior

For additional information, please visit [FDA Website](https://www.fda.gov).