



Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Life Technologies Corporation Recalls Torrent Suite Dx Software For System Vulnerability

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|---|--|---|
| 4/10/2024 | <p>Torrent Suite Dx Software Versions 5.14 and earlier used in connection with Ion PGM DX Systems-IVD intended for targeted sequencing of human genomic DNA (gDNA) from peripheral whole-blood samples and DNA and RNA extracted from formalin-fixed, paraffin-embedded (FFPE) samples. The Ion PGM Dx Instrument System is not intended for whole genome or de novo sequencing Product Name Installer /SKU /Updater SKU: (1) Torrent Suite Dx Software 5.14 -A52422/ A52417 (2) Torrent Suite Dx Software 5.12.5- A46166/ A46167 (3)Torrent Suite Dx Software 5.8- A36601/ A36602 (4)Torrent Suite Dx Software 5.6.4- A33178/ A33178 (5)Torrent Suite Dx Software 5.0- A29166/ A29166</p> | <p>LIFE TECHNOLOGIES CORPORATION Frederick, Maryland</p> | <p>Torrent Suite Dx Software versions 5.14 and earlier used in connection with Ion PGM DX Systems exploitation of the vulnerability by a threat actor may allow them to alter settings, configurations, software, or data on the instrument</p> |

| Recall Class | Product Identification | Distribution | Affected Dates |
|--------------|---|-----------------------|--------------------------|
| II | <p>Torrent Suite Dx Software UDI: 10190302017848;10190302016810 810 Torrent Suite Dx Software versions 5.14 and earlier</p> | 0 Units in California | February, 2024 and prior |

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

