

Thermo Fisher launches CE-IVD NGS test, software

October 2022—Thermo Fisher Scientific launched the CE-IVD Oncomine Dx Express test and Oncomine Reporter Dx for use in clinical labs.

The Oncomine Dx Express test delivers clinically relevant tumor mutation profiling using the Ion Torrent Genexus Dx Integrated Sequencer in as few as 24 hours. The qualitative in vitro diagnostic test detects deletions, insertions, substitutions, and copy number gain present in 42 genes and fusions or splicing variants in 18 genes from DNA and RNA in formalin-fixed, paraffin-embedded tumor tissue samples of solid malignant neoplasms. It also detects deletions, insertions, and substitutions in 42 genes and fusions or splicing variants in seven genes from cfTNA extracted from plasma samples of non-small cell lung cancer.

The Oncomine Reporter Dx software matches the variant data to relevant evidence, including approved therapies, guidelines, clinical trials, and peer-reviewed literature in a user-friendly and customizable report.

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