BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Thermo Fisher's NGS assay receives US FDA approval as companion diagnostic for ZEGFROVY

04 July 2025 | News

Oncomine Dx Express Test on the Ion Torrent Genexus Dx Integrated Sequencer generates results in as little as 24 hours

Thermo Fisher Scientific, the world leader in serving science, has announced that the US Food and Drug Administration (FDA) has approved the Oncomine™ Dx Express Test on the Ion Torrent™ Genexus™ Dx Integrated Sequencer as an in vitro diagnostic (IVD) assay for use as a companion diagnostic (CDx) for Dizal's ZEGFROVY® (sunvozertinib) and in tumour profiling.

This approval brings rapid next-generation sequencing (NGS) to decentralised clinical settings closer to where patients receive care. With the ability to deliver essential genomic insights in as little as 24 hours, this approval helps advance the accessibility of precision oncology tools and enables more timely decision making.

A patient's tumour profile has the potential to guide precision oncology care. However, delays in obtaining results can hinder clinicians' ability to make informed decisions, potentially causing patients to miss out on targeted therapies, which can impact treatment efficacy and patient outcomes. Furthermore, a significant number of patients miss out on targeted therapies due to inefficiencies or lack of access to testing, highlighting the critical role of timely genomic profiling. The Oncomine Dx Express Test was designed to simplify the NGS workflow and connect patients everywhere to precision oncology.

Now with the Oncomine Dx Express Test on the Ion Torrent Genexus Dx Integrated Sequencer, laboratories across a variety of clinical settings can deliver rapid genomic profiling with exceptional accuracy and ease, helping to ensure patients can benefit from the latest advancements in precision oncology.