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ASIA EDITION

Thermo Fisher gets US FDA approval for NGS-based CDx for cancer

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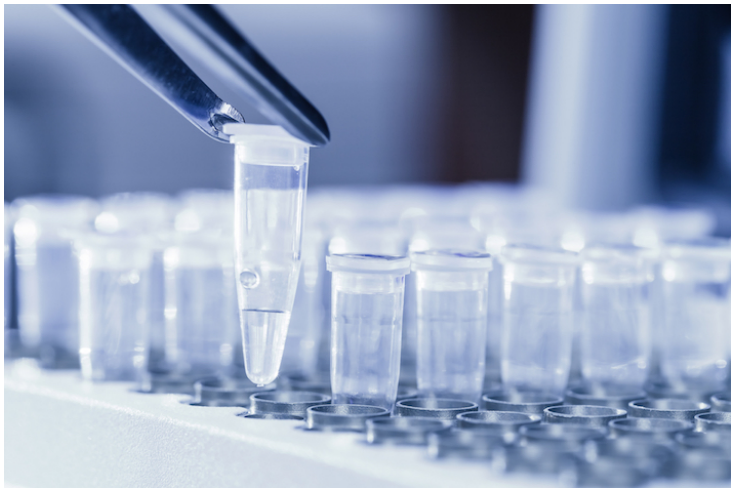
US FDA approval of Oncomine Dx Target test as the first NGS-based companion diagnostic to aid in therapy selection for patients with RET mutations/fusions in thyroid cancers



The US Food and Drug Administration (FDA) has granted approval to Thermo Fisher Scientific's Oncomine Dx Target Test as a companion diagnostic (CDx) to aid in selection of patients with *RET*-fusion positive locally advanced or metastatic non-small cell lung cancer (NSCLC), *RET*-fusion positive advanced or metastatic thyroid cancer and *RET*-mutation positive advanced or metastatic medullary thyroid cancer (MTC) who may be eligible for treatment with Lilly's Retevmo (selpercatinib).

This marks the Oncomine Dx Target Test's first approval as a CDx for a therapy targeting *RET*-positive thyroid cancer and second approval associated with *RET*-positive NSCLC.

Initially approved in 2020, Retevmo is a selective *RET* kinase inhibitor and was the first therapy approved for patients with advanced *RET*-driven lung and thyroid cancers. *RET* (rearranged during transfection) alterations are found in approximately 2% of patients with NSCLC, which is the leading cause of adult cancer death in the United States, 60% of patients with MTC and 20% in other thyroid cancers.

The Oncomine Dx Target test is a next-generation sequencing (NGS)-based test that can detect multiple alterations at once from a small sample size, helping to quickly match patients with the appropriate targeted therapy. It is also approved in Japan as a companion diagnostic for Retevmo in the same indications. The test is the only globally distributable NGS CDx solution that has received regulatory approval in 17 countries for 15 targeted therapies, covering more than 550 million lives globally.