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NEW: Oncomine Dx Target Test

A new paradigm in testing for NSCLC-targeted therapies

What if one test could expedite your treatment selection decisions?

The Ion Torrent™ Oncomine™ Dx Target Test is the first targeted next-generation sequencing (NGS) *in vitro* diagnostic test for non-small cell lung cancer (NSCLC), simultaneously delivering multiple biomarker results for multiple targeted therapies from one sample within four days.

- **Multiple therapies**—one test indicated as a companion diagnostic (CDx) device to aid in selecting NSCLC patients for treatment with targeted therapies, including IRESSA® (gefitinib) for *EGFR* L858R and exon 19 deletions, or TAFINLAR + MEKINIST® (dabrafenib in combination with trametinib) for *BRAF* V600E, or XALKORI® (crizotinib) for *ROS1* fusion
- **Multiple biomarkers**—one test for detection of 368 variants in 23 cancer-associated genes that are clinically associated with NSCLC
- **One sample**—one sample is used to deliver multiple biomarker results, minimizing the risk of depleting tissues and requiring additional biopsies
- **One workflow, saving time**—laboratory results can be generated within four days, reducing the time required to get the complete NSCLC CDx biomarkers, compared to running several single-biomarker tests in a sequential manner

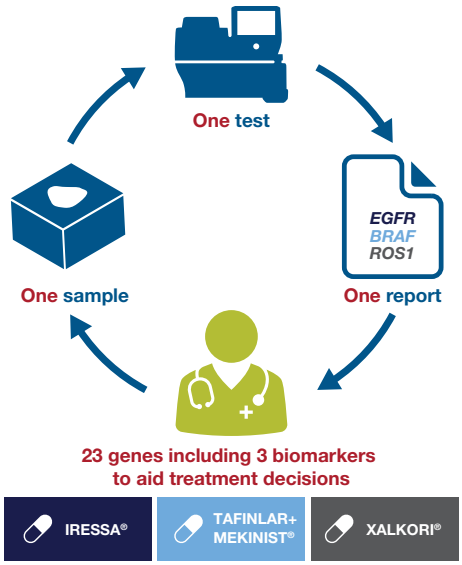

Figure 1. The Oncomine Dx Target Test enables multi-biomarker analysis of 23 gene targets, including 3 biomarkers to aid treatment decisions, in one test, from one sample, and in one report.

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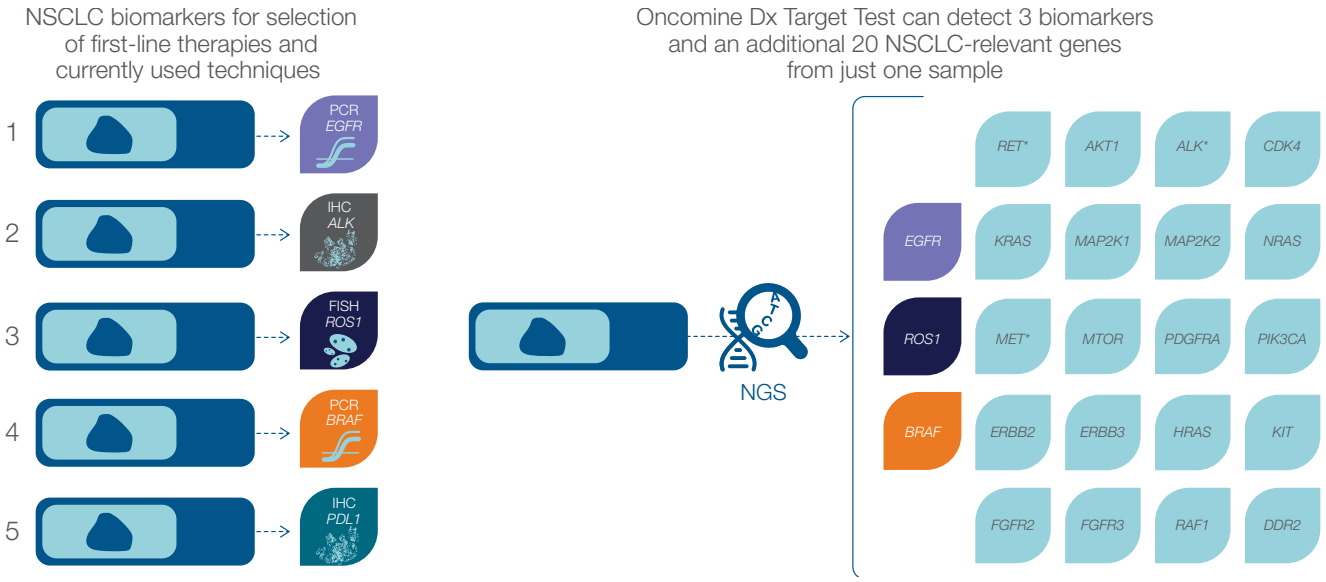

Figure 2. There are several biomarkers associated with NSCLC. Currently, five are targeted based on treatment (on the left side). Additional biomarkers have been recommended by scientific guidelines for adding potential value in the patient stratification process. Oncomine Dx Target Test is the only available diagnostic test delivering identification of multiple biomarkers at once (on the right side). The test includes 3 biomarkers, validated by selection of relevant targeted therapies (*EGFR* or *ROS1* or *BRAF*) and 20 additional genes, relevant for NSCLC pathogenesis analytically validated for variant detection from NSCLC tissue.

*The test does not report *ALK, MET,* and *RET* translocation/fusion variants, only.

Oncomine Dx Target Test—content

The cancer-associated gene targets included in the Oncomine Dx Target Test all play an important role in NSCLC pathogenesis. Three of them are companion diagnostics to aid in selecting patients for approved targeted therapies, while others are currently investigated in clinicial trials and are potentially actionable in the future as referenced in Figure 2.

Oncomine Dx Target Test—performance

The concordance with approved validated comparator methods based on FISH or PCR was established for all CDx biomarkers: 99% for *EGFR*, 100% for *BRAF*, and 96.5% for *ROS1*.

Results for Sequence Variations for Therapeutic Use (For illustrative purposes only. *EGFR*, *BRAF* and *ROS1* are mutually exclusive.)

DNA Sequence Variants

Gene	Display Name	Amino Acid Change	Nucleotide Change	Test Result	Hotspot ID	Associated Therapy
EGFR	EGFR L858R	p.Leu858Arg	c.2573T>G	POSITIVE	COSM6224	IRESSA® (gefitinib)
BRAF	BRAF V600E	p.Val600Glu	c.1799T>A	POSITIVE	COSM476	TAFINLAR+MEKINIST® (dabrafenib in combination with trametinib)

Gene Fusions (RNA)

Gene	Display Name	Test Result	Associated Therapy
ROS1	ROS1 Fusion	POSITIVE	XALKORI® (crizotinib)

Figure 3. Example of Oncomine Dx Target Test report format. The report includes a section with results of the validated biomarkers and information about relevant treatment indication, as well as a section with the other biomarkers, not validated for treatment selection.

Find out more at **thermofisher.com/oncominedx**

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