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NEW
Oncomine Dx Target Test

A new paradigm in testing for NSCLC-targeted therapies

Accelerate results, from sample to report, and guide oncology treatment with the first IVD NGS-based test

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 4 days.

- **Multiple therapies**—one test indicated as a companion diagnostic (CDx) device to aid in selecting NSCLC patients for treatment with certain 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* fusions
- **Multiple biomarkers from one limited sample**—one test for detection of 369 variants in 23 cancer-associated genes that are clinically associated with NSCLC, minimizing the risk of depleting tissues and requiring additional biopsies. Based on Ion AmpliSeq™ technology, the required input is as low as 10 ng DNA and RNA
- **One workflow, helps save time**—laboratory results can be generated within 4 days
- **Established performance**—the concordance with 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*. For an additional 3 biomarkers, analytical performance was established. Remaining variants were validated based on a representative method

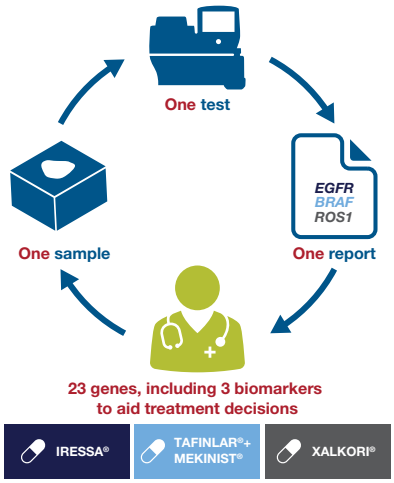

Figure 1. The Oncomine Dx Target Test enables multi-biomarker analysis of 23 gene targets, including 3 biomarkers to aid treatment decisions, in one test, from one sample, and in one report.

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For *In Vitro* Diagnostic Use.

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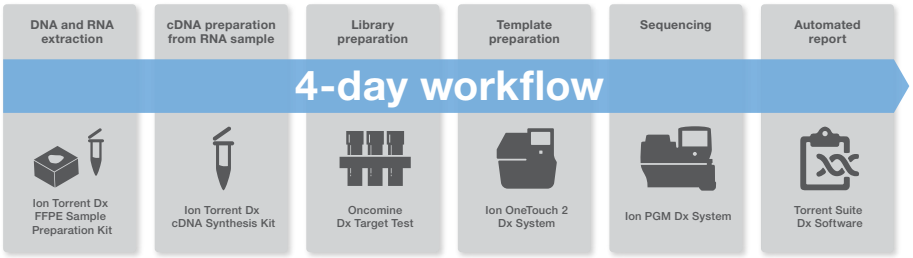

Figure 2. The Oncomine Dx Target Test utilizes a single streamlined NGS workflow for detecting cancer-associated biomarkers, incorporating reagents, instrument systems, and bioinformatics. The turnaround time from FFPE sample to report is 4 days.

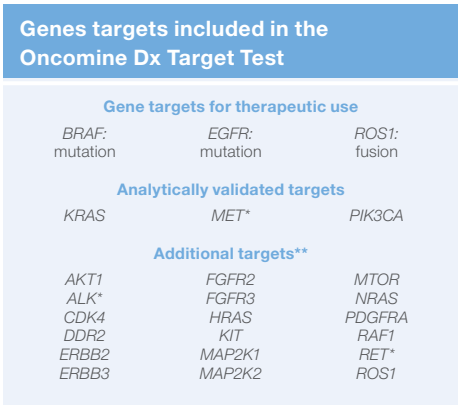

Figure 3. Cancer-associated gene targets included in the Oncomine Dx Target Test. * The test reports fusion/translocation variants for *ROS1* only. The test only reports *ALK*, *MET*, and *RET* mutations. ** Performance for the additional genes has been validated based on a a representative method.

A complete and flexible system

The Oncomine Dx Target Test is used in conjunction with the Ion PGM™ Dx System, which includes a complete NGS system of instruments, reagents, and software, now validated with the Oncomine Dx Target Test for somatic mutation reporting for FFPE NSCLC samples (see Figure 2 for workflow). The Ion PGM Dx sequencing system is a Class II 510K Medical Device and incorporates combined functionality, with both "IVD Mode" for molecular diagnostic tests and "Assay Development Mode" for clinical research. The system also facilitates 21 CFR Part 11 compliance, with role-based workflows, sample and reagent tracking, QC metrics, and audit trails.

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 being investigated in clinical trials and may be potentially actionable in the future as referenced in Figure 3.

Oncomine Dx Target Test—report

The Oncomine Dx Target Test report is automatically generated as a PDF and incorporates relevant patient, sample, and test information required to help ensure high performance standards, regulatory compliance, and quality control. The test results are presented in two parts: companion diagnostic biomarker results with associated therapy indication (Figure 4), and other analytically detected biomarker results in a separate section (not shown). The report is laboratory information management system (LIMS) compatible.

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 Fusions	POSITIVE	XALKORI® (crizotinib)

Figure 4. 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 separate section with the other biomarkers not validated for treatment selection (not shown).

Find out more at **thermofisher.com/oncomine-dxtarget**

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