

# Oncomine Dx Target Test—enable your laboratory for the future of cancer care

The Ion Torrent<sup>™</sup> Oncomine<sup>™</sup> 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<sup>®</sup> (gefitinib) for *EGFR* L858R and exon 19 deletions, or TAFINLAR<sup>™</sup> + MEKINIST<sup>™</sup> (dabrafenib in combination with trametinib) for *BRAF* V600E, or XALKORI<sup>™</sup> (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<sup>™</sup> technology, the required input is as low as 10 ng of DNA or 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 CDxs (see Figure 1).



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.



## *ion*torrent



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.

#### A complete and flexible system

The Oncomine Dx Target Test is used in conjunction with the Ion PGM<sup>™</sup> Dx System, which includes a complete NGS system of instruments, reagents, and software, and is 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 an *in vitro* diagnostic instrument 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**

Gene fusions (RNA)

The cancer-associated gene targets included in the Oncomine Dx Target Test all play an important role in

#### Genes targets included in the Oncomine Dx Target Test

Gene targets for therapeutic use							
BRAF: mutation	EGFR: mutation	ROS1: fusion					
Analytically validated targets							
KRAS	MET*	PIK3CA					
Additional targets**							
AKT1 ALK* CDK4 DDR2 ERBB2 ERBB3	FGFR2 FGFR3 HRAS KIT MAP2K1 MAP2K2	MTOR NRAS PDGFRA RAF1 RET* ROS1					

Figure 3. Cancer-associated gene targets included in the Oncomine Dx Target Test.

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 research 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	Display name	Test tesult	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).

\* 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.

### Find out more at oncomine.com/dx/testing-methods

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