Tell your oncologist about Oncomine Dx Target Test
A new paradigm in testing for targeted therapies in NSCLC

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.

- **Identify patients for multiple therapies**—one test indicated as a companion diagnostic (CDx) device to aid in selecting NSCLC patients for treatment with targeted therapies.

- **Multiple biomarkers from one limited sample**—one test for detection of 23 genes, minimizing the risk of depleting tissues and requiring additional biopsies. Based on Ion AmpliSeq™ technology, the required input is as low as 10 ng of DNA and RNA.

- **One workflow, helps save time**—laboratory results can be generated within four days.

- **Established performance**—concordance with FDA approved or validated reference methods based on FISH, PCR, or NGS was established for all CDx biomarkers: overall percent agreement (OPA) of 100% for BRAF, 99% for EGFR, 100% for ROS1, and 92% for RET.

**Figure 1**. List of genes for therapeutic use.

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For In Vitro Diagnostic Use.
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 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—gene content
The Oncomine Dx Target Test includes targets for cancer-associated genes. Four of them are companion diagnostics to aid in selecting patients for approved targeted therapies in NSCLC, while remaining genes 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.

DNA sequence variants

<table>
<thead>
<tr>
<th>Gene</th>
<th>Display name</th>
<th>Amino acid change</th>
<th>Nucleotide change</th>
<th>Test result</th>
<th>Hotspot ID</th>
<th>Associated therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGFR</td>
<td>EGFR L858R</td>
<td>p.Leu858Arg</td>
<td>c.2573T&gt;G</td>
<td>POSITIVE</td>
<td>COSM6224</td>
<td>IRESSA® (gefitinib)</td>
</tr>
<tr>
<td>BRAF</td>
<td>BRAF V600E</td>
<td>p.Glu600Val</td>
<td>c.1799T&gt;A</td>
<td>POSITIVE</td>
<td>COSM476</td>
<td>TAFINLAR® + MEKINIST® (dabrafenib in combination with trametinib)</td>
</tr>
</tbody>
</table>

Gene fusions (RNA)

<table>
<thead>
<tr>
<th>Gene</th>
<th>Display name</th>
<th>Test result</th>
<th>Associated therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROS1</td>
<td>ROS1 fusions</td>
<td>POSITIVE</td>
<td>XALKOR® (crizotinib)</td>
</tr>
<tr>
<td>RET</td>
<td>RET fusions</td>
<td>POSITIVE</td>
<td>GAVRETO® (pralsetinib)</td>
</tr>
</tbody>
</table>

Figure 3. Complete gene list. * The test reports fusion/translocation variants for ROS1 and RET only. The test only reports ALK and MET mutations. ** Performance for the additional gene target variants has been validated based on a representative method.

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