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 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**—one test for detection of 369 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, helps save time**—laboratory results can be generated within 4 days, reducing the time required to get the complete NSCLC CDx biomarkers, compared to running several single-biomarker tests in a sequential manner

A new paradigm in testing for NSCLC-targeted therapies

What if one test could expedite your treatment selection decisions?

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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.
NSCLC biomarkers for selection of first-line therapies and currently used techniques

1. PCR
2. IHC
3. FISH
4. NGS
5. IHC

Oncomine Dx Target Test can detect 3 biomarkers and an additional 20 NSCLC-relevant genes from just one sample

**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 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.

*The test reports fusion/translocation variants for ROS1 only. The test only reports ALK, MET, and RET mutations and does not report ALK, MET, and RET fusions.*

**Results for Sequence Variations for Therapeutic Use**

<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.Val600Glu</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>XALKORI® (crizotinib)</td>
</tr>
</tbody>
</table>

**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. The 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 for 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 reports fusion/translocation variants for ROS1 only. The test only reports ALK, MET, and RET mutations and does not report ALK, MET, and RET fusions.

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

Find out more at thermofisher.com/oncomine-dxtarget