

**Oncomine Dx Target Test—
FDA approved**

Ask your pathologist about Oncomine Dx Target Test

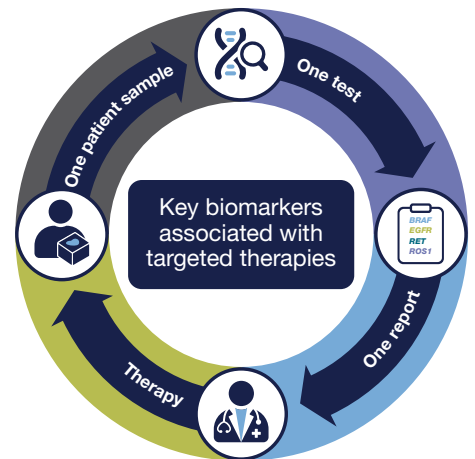
A new paradigm in testing for targeted therapies in NSCLC

This test is now reimbursed by Medicare and the top 40 commercial payers, covering over 200 million US lives.

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.

Did you know:

- Many biopsy samples are so small that they cannot be analyzed by some NGS tests, especially panels containing hundreds of genes, leading to tissue exhaustion
- It can take several weeks to get results with alternative NGS tests, potentially delaying treatment decision



Choosing the right NGS test can make a difference for your patient

The Oncomine Dx Target Test is an FDA-approved NGS CDx test that can:

- 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
- Accept small samples (10 ng DNA and RNA), for more patients to potentially access targeted therapies
- Generate results in a laboratory within four days, enabling faster treatment decisions

Cancer type	Gene	Targeted therapies
NSCLC	<i>BRAF</i>	TAFINLAR® (dabrafenib) in combination with MEKINIST® (trametinib)
	<i>EGFR</i>	IRESSA® (gefitinib)
	<i>RET</i>	GAVRETO™ (pralsetinib)
	<i>ROS1</i>	XALKORI® (crizotinib)

Figure 1. List of genes for therapeutic use.

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

Oncomine Dx Target Test—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 2. 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.

Oncomine Dx Target Test—report

NSCLC results for sequence variations for therapeutic use (for illustrative purposes only; *EGFR*, *BRAF*, *ROS1*, and *RET* are mutually exclusive)

DNA sequence variants						
Gene	Display name	Amino acid change	Nucleotide change	Test result	Hotspot ID	Associated therapy
<i>EGFR</i>	<i>EGFR</i> L858R	p.Leu858Arg	c.2573T>G	POSITIVE	COSM6224	IRESSA® (gefitinib)
<i>BRAF</i>	<i>BRAF</i> 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	
<i>ROS1</i>	<i>ROS1</i> fusions			POSITIVE	XALKORI® (crizotinib)	
<i>RET</i>	<i>RET</i> fusions			POSITIVE	GAVRETO™ (pralsetinib)	

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).

If your pathology laboratory does not perform the Oncomine Dx Target Test, you can send samples to one of these reference laboratories.

Reference lab	Telephone number	Website
Integrated Oncology (a division of LabCorp)	800-447-5816	integratedoncology.com
Quest Diagnostics, Inc.	866-697-8378	questdiagnostics.com
NeoGenomics Laboratories, Inc.	866-776-5907	neogenomics.com
Phenopath, a Quest Diagnostics Company	888-927-4366	phenopath.com

Find out more at thermofisher.com/oncomine-dxtarget