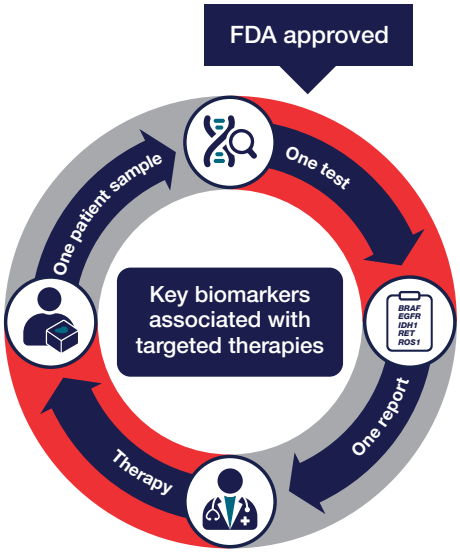
Ask your pathologist about the Oncomine Dx Target Test

A paradigm change in testing for targeted therapies in NSCLC, cholangiocarcinoma, and thyroid cancer



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), cholangiocarcinoma (CC), and thyroid cancer (TC), 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 a treatment decision

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

The Oncomine Dx Target Test is an FDA-approved, NGS companion diagnostic (CDx) test that can:

- Identify patients who are candidates for multiple therapies—one test indicated as a CDx device to aid in selecting NSCLC, CC, TC, and medullary thyroid cancer (MTC) patients for treatment with targeted therapies
- Accept small samples (10 ng DNA and 10 ng RNA) so that more patients can potentially access targeted therapies
- Generate results in a laboratory within 4 days, enabling faster treatment decisions

This test is reimbursed by Medicare and over 40 commercial payers, covering more than 200 million US enrollees.

Cancer type	Gene	Targeted therapies
NSCLC	*BRAF*	TAFINLAR® (dabrafenib) in combination with MEKINIST® (trametinib)
	EGFR L858R and exon 19 deletions	IRESSA® (gefitinib)
	EGFR exon 20 insertions	EXKIVITY™ (mobocertinib)
		RYBREVANT™ (amivantamab-vmjw)
	ERBB2/HER2 activating mutations (SNVs and exon 20 insertions)	ENHERTU® (fam-trastuzumab deruxtecan-nxki)
	RET	GAVRETO™ (pralsetinib) RETEVMO® (selpercatinib)
	ROS1	XALKORI® (crizotinib)
CC	*IDH1*	TIBSOVO® (ivosidenib)
MTC	*RET* mutations (SNVs, MNVs, and deletions)	RETEVMO® (selpercatinib)
TC	*RET* fusions	RETEVMO® (selpercatinib)

Figure 1. List of genes for therapeutic use.

For *In Vitro* Diagnostic Use.

Oncomine Dx Target Test—performance

Concordance with FDA-approved or validated reference methods based on FISH, PCR, Sanger sequencing, or NGS was established for all CDx biomarkers included in the test:

- 100% overall percent agreement (OPA), positive percent agreement (PPA) and negative percent agreement (NPA) for *BRAF* mutation, *EGFR* exon 20 insertions, and *ROS1* fusions
- 99% OPA, PPA, and NPA for *EGFR* exon 19 deletions and L858R
- 99% OPA, 100% PPA, and 99% NPA for *ERBB2/HER2* activating mutations (SNVs and exon 20 insertions)
- 92% OPA, 91% PPA, and 92% NPA in the first study and 95% OPA, 92% PPA, and 97% NPA in the second study for *RET* fusions in NSCLC
- 98% OPA, 99% PPA, and 97% NPA for *IDH1* mutations
- 99% OPA, 100% PPA, and 98% NPA for *RET* mutations in MTC and 100% OPA, PPA, and NPA for *RET* fusions in TC

Oncomine Dx Target Test—content

Gene targets for NSCLC				
Gene targets for therapeutic use				
BRAF: V600E	*EGFR*: L858R, exon 19 deletions, and exon 20 insertions	*ERBB2/HER2* activating mutations (SNVs and exon 20 insertions)	*RET*: fusions	*ROS1*: fusions
Analytically validated gene targets				
KRAS	*MET**	*PIK3CA*		
Additional gene targets**				
AKT1 *ALK** *CDK4* *DDR2*	*ERBB2* *ERBB3* *FGFR2* *FGFR3*	*HRAS* *KIT* *MAP2K1* *MAP2K2*	*MTOR* *NRAS* *PDGFRA* *RAF1*	*RET* *ROS1*

	Gene targets for CC	Gene targets for TC	Gene targets for MTC
Gene targets for therapeutic use	*IDH1*: mutations	*RET:* fusions	*RET:* fusions

Figure 2. Oncomine Dx Target Test complete gene list.

* The test reports fusion/translocation variants for *ROS1* and *RET* only. This test only reports mutations for *ALK* and *MET*.

** Performance for the additional gene target variants has been validated based on a representative method.

Oncomine Dx Target Test—report

Sequence variations to indicate therapeutic use for NSCLC (for illustrative purposes only; *EGFR*, *BRAF*, *ERBB2/HER2*, *ROS1*, and *RET* 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)
EGFR	*EGFR* exon 20 insertions	p.Ala767_Ser768 insSerValAsp	c.2311_2312ins GCGTGGACA	Positive	COSM13428	EXKIVITY™ (mobocertinib) RYBREVANT™ (amivantamab-vmjw)
BRAF	*BRAF* V600E	p.Val600Glu	c.1799T>A	Positive	COSM476	TAFINLAR® + MEKINIST® (dabrafenib in combination with trametinib)
ERBB2	*ERBB2* exon 20 insertions	p.Gly776delinsLeuCys	c.2326_2326delGinsCTTT	Positive	COSM12554	ENHERTU® (fam-trastuzumab deruxtecan-nxki)

Gene fusions (RNA)			
Gene	**Display name**	**Test result**	**Associated therapy**
ROS1	*ROS1* fusions	Positive	XALKORI® (crizotinib)
RET	*RET* fusions	Positive	GAVRETO™ (pralsetinib) RETEVMO® (selpercatinib)

Sequence variations to indicate therapeutic use for CC (for illustrative purposes only)

DNA sequence variants						
Gene	**Display name**	**Amino acid change**	**Nucleotide change**	**Test result**	**Hotspot ID**	**Associated therapy**
IDH1	*IDH1* R132G	p.Arg132Gly	c.394C>G	Positive	COSM28749	TIBSOVO® (ivosidenib)
RET	*RET* A883T	p.Ala883Thr	c.2647G>A	Positive	COSM100081	RETEVMO® (selpercatinib)

Figure 3. Example of the 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
NeoGenomics Laboratories, Inc.	866-776-5907	**neogenomics.com**
OncoCyte	615-639-0710	**oncocyte.com**

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