



Connecting patients everywhere to precision oncology

Oncomine Dx Express Test

Precision oncology, now from minimal tumor tissue

A patient's tumor profile has the potential to guide precision oncology care. However, delays in obtaining results can hinder the clinicians' ability to make informed decisions, potentially causing patients to miss out on targeted therapies, which can impact treatment efficacy and patient outcomes. In real-world oncology care, tissue is often the issue—limited quantity, quality, and accessibility can delay or prevent molecular profiling.

The Ion Torrent™ Oncomine™ Dx Express Test was designed to simplify the next-generation sequencing (NGS) workflow and enable laboratories, even those without NGS expertise, to deliver genomic profiles efficiently. Now, laboratories can bring precision oncology to more patients, delivering genomic profiles from FFPE tissue, even when tissue is limited.

The Oncomine Dx Express Test offers:



Rapid results

Generate results in as little as **24 hours**,* supporting timely and informed therapy decisions.



Minimal sample input requirements

Utilize only 10 ng DNA and 10 ng RNA from as little as two 5 µm formalin-fixed, paraffin-embedded (FFPE) slides, **enabling analysis of small biopsies and limited samples**.



Highly automated workflow

Perform testing with as little as **20 minutes of hands-on time**,* helping reduce the risk of human error and enhance efficiency and scalability of genomic testing in your laboratory.



FFPE tissue biopsy compatibility

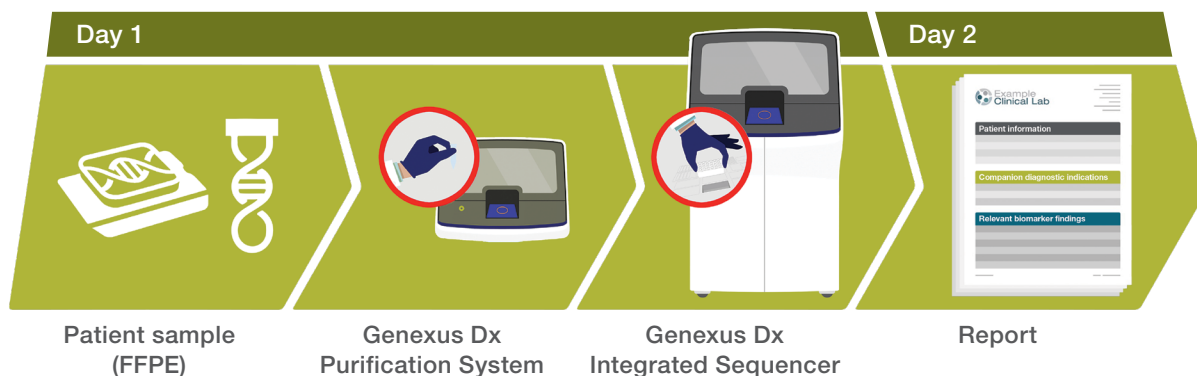
Accommodate minimal FFPE **tissue biopsies**, increasing the likelihood of obtaining results even when tissue is limited.

A true end-to-end IVD solution from one supplier

An end-to-end in vitro diagnostic (IVD) solution for all aspects of the NGS workflow offers seamless integration, facilitating compatibility and efficiency across the entire process. This eliminates the complexities of managing multiple vendors,

streamlining procurement and support.

This comprehensive approach helps simplify integration, operation, troubleshooting, and maintenance, supporting consistent performance and optimal system uptime.



* Timing varies by number of samples and type of run.

Rapid results for CDx and tumor profiling biomarkers

The Oncomine Dx Express Test is indicated as a companion diagnostic (CDx) to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling. The test also detects tumor profiling biomarkers recommended in professional guidelines for multiple solid tumors (Table 2). This includes substitutions, insertions, and deletions in 42 genes,

copy number variants (CNVs) in 10 genes, and fusions or splice variants in 18 genes from DNA and RNA extracted from FFPE tumor tissue (relevant in non-small cell lung cancer (NSCLC), colorectal cancer, cholangiocarcinoma, melanoma, and others).

Table 1. Companion diagnostics indications.

Specimen type	Tissue type	Gene	Variant	Targeted therapy
Tissue	NSCLC	EGFR	EGFR exon 20 insertions	ZEGFROVY™ (sunvozertinib)
		ERBB2/HER2	ERBB2/HER2 activating mutations (SNVs in exons 18-21 within the tyrosine kinase domain and exon 20 insertions)	HYRNUO® (sevabertinib)

Table 2. The Oncomine Dx Express Test panel FFPE gene list.

DNA						RNA				
Substitutions, insertions, and deletions						Copy number variants		Fusions and splice variants		
AKT1	CDK4	ESR1	HRAS	MAP2K2	PIK3CA	AR	FGFR2	ALK	FGFR2	NTRK3
AKT2	CHEK2	FGFR1	IDH1	MET	PTEN	EGFR	FGFR3	AR	FGFR3	NUTM1
AKT3	CTNNB1	FGFR2	IDH2	NRAS	RAF1	ERBB2	KRAS	BRAF	MET	RET
ALK	EGFR	FGFR3	KEAP1	NTRK1	RET	ERBB3	MET	EGFR	NRG1	ROS1
AR	ERBB2	FGFR4	KIT	NTRK2	ROS1	FGFR1	PIK3CA	ESR1	NTRK1	RSPO2
ARAF	ERBB3	FLT3	KRAS	NTRK3	STK11			FGFR1	NTRK2	RSPO3
BRAF	ERBB4	GNAS	MAP2K1	PDGFRA	TP53					



Experience efficiency with walkaway automation of the Genexus Dx System



Genexus Dx Purification System

The Ion Torrent™ Genexus™ Dx System automates the NGS workflow from patient samples to reports with only two user touchpoints and as little as 20 minutes of hands-on time.

Pre-treated FFPE tissue sections samples are loaded onto the Ion Torrent™ Genexus™ Dx Purification System and the instrument performs automated purification and quantification of DNA and RNA.



Genexus Dx Integrated Sequencer

Library preparation, template preparation, sequencing, analysis, and reporting are performed by the Ion Torrent™ Genexus™ Dx Integrated Sequencer. Throughout this procedure, sample and reagent information is recorded and tracked by the software.

This highly automated workflow helps reduce laboratory staff burden and the potential for human errors, and alleviates the need for specialized bioinformatics expertise.



Analysis and reporting

The Ion Torrent™ Genexus™ Dx Software directs the progress of the sample from creation of a run plan through automated sample preparation, library preparation, template preparation, sequencing, and analysis. The Genexus Dx Software generates the following results and reports for each sequenced sample and its associated controls:

- Quality control, key findings, and variant screens
- Run report
- Clinical test report
- Clinical laboratory report

Quality control specifications throughout the NGS workflow are automatically applied to streamline interpretation and help ensure reportable results are accurate.

For FFPE samples, positive calls are classified into three biomarker levels:

- Level 1: Companion Diagnostics (CDx) Biomarkers noted in Table 1 of the “Intended use”.
- Level 2: Cancer Mutations with Evidence of Clinical Significance
- Level 3: Cancer Mutations with Potential Clinical Significance

<

Tumor Mutation Profiling Results: Summary

The results below provide tumor mutation profiling information to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with solid malignant neoplasms. Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product.

Cancer Mutations with Evidence of Clinical Significance (Level 2)

SNVs/Indels

Gene	Variant Name	AA Change	Nuc Change	Test Result	Variant ID	Variant Type
MET	MET exon 14 skipping (DNA)	p.T	c.3072_3082+7delTTTTCACAGAGGTATATT	POSITIVE	COSM937267	del

Fusions

Variant Name	Genes (Exons)	Variant Type	Test Result
CCDC6-MET fusion	CCDC6(1)-MET(12)	Fusion	POSITIVE

ⓘ Fusions include gene fusions and splice variants.

CNVs

None Detected

For In Vitro Diagnostic Use | Rx Only
Ion Torrent Genexus Dx Software 6.8.2.1

Page 1 of 152

er Point Blvd
San Francisco

JUN 2025

ed

EGFR	EGFR exon 20 insertion	p.H773dup	c.2319_2320insAAC	POSITIVE	COSM12377	ZIGROVY™ (sunitinib)
Tumor Mutation Profiling Results: Summary						
The results below provide tumor mutation profiling information to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with solid malignant neoplasms. Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product.						
Cancer Mutations with Evidence of Clinical Significance (Level 2)						
SNVs/Indels						
None Detected						
Fusions						
None Detected						
① Fusions include gene fusions and splice variants.						
CNVs						
None Detected						
Cancer Mutations with Potential Clinical Significance (Level 3)						
SNVs/Indels						
For In Vitro Diagnostic Use Rx Only Ion Torrent Genexus Dx Software 6.8.2.1						
						Page 1 of 152

Performance characteristics—FFPE

Extensive performance studies were conducted to establish performance characteristics of the Oncomine Dx Express Test for FFPE tumor samples. A summary of selected studies is provided below. For complete studies and results, refer to the Oncomine Dx Express Test User Guide.

Limit of blank

- Per-position false positive rate: 0% across 24 blank samples representing 10 tissue types for all variant categories, except for Level 3 SNVs. For Level 3 SNVs, the per-position false positive rate was 0.00004% after masking certain Level 3 SNVs with variant allele frequencies below 5% to prevent false positives.
- Per-sample false positive rate: 0% across the same 24 blank samples and 10 tissue types for all variant categories, except for Level 3 SNVs. For Level 3 SNVs, the per-sample false positive rate was 0.52% after masking certain Level 3 SNVs with variant allele frequencies below 5% to prevent false positives.

Limit of detection—CDx variants

- 3.24% to 4.38% allelic frequency for *EGFR* exon 20 insertion CDx variants with insertion lengths of 3, 6, 9, and 12 bp
- 2.98% to 4.07% allelic frequency for *ERBB2/HER2* exon 20 insertion variants with insertion lengths of 3, 6, 9, and 12 bp
- 3.60% to 6.42% allelic frequency for *ERBB2/HER2* SNVs

Limit of detection—tumor profiling variants

- 3.24% to 7.34% allelic frequency for SNVs
- 2.98% to 5.24% allelic frequency for insertions
- 3.08% to 4.67% allelic frequency for deletions
- 4.56 to 5.78 copies for CNVs
- 5.0 to 15.5 molecular counts for RNA fusion variants
- 1.5 to 4.93 imbalance scores for RNA fusions by expression imbalance





Panel reproducibility study—CDx variants

The panel reproducibility study was conducted at multiple test sites to evaluate the repeatability and reproducibility of the Oncomine Dx Express Test for detection of CDx variants starting from extracted nucleic acid.

EGFR exon 20 insertions

- **Reproducibility:** The positive call rate was 100% for all *EGFR* exon 20 insertion variants, with no instances of no calls observed. The negative call rate was estimated using two wild-type (WT) NSCLC samples and was calculated for hotspots within the scope of the study. For WT samples, the negative call rate was 100.0%, excluding no calls.
- **Repeatability:** Repeatability for the detection of *EGFR* exon 20 insertion variants was evaluated by assessing within-run variability. When including or excluding no call results, within-run repeatability was 100%. For WT samples, when including or excluding no call results, within-run repeatability was 100%.

ERBB2/HER2 exon 20 insertions

- **Reproducibility:** The positive call rate was 100% for all *ERBB2/HER2* exon 20 insertion variants, with no instances of no calls observed. The negative call rate, estimated using two WT NSCLC samples, was 100.0%, excluding no calls.
- **Repeatability:** When including or excluding no call results, within-run repeatability for the detection of *ERBB2/HER2* exon 20 insertion variants was 100%. For WT samples, when including or excluding no call results, within-run repeatability was also 100%.

ERBB2/HER2 SNVs

- **Reproducibility:** The positive call rate was 100% for both *ERBB2/HER2* SNVs (G776V and R896H) at both LoD levels tested (1.2–3.0X LoD), with no instances of no calls observed in variant-positive samples. The negative call rate, evaluated using WT NSCLC samples and calculated for relevant hotspots, was $\geq 99.3\%$, excluding no calls (100% in one WT sample and 99.3% in the other).
- **Repeatability:** Repeatability for detection of *ERBB2/HER2* SNVs was evaluated by assessing within-run variability. When excluding no call results, within-run repeatability was $\geq 97.2\%$ across all samples. For variant-positive samples, repeatability was 100%. For WT samples, repeatability ranged from 97.2% to 100% when excluding no calls, and 94.4% to 100% when including no calls.

Panel reproducibility study—tumor profiling variants

The variability across sites, operators, and instruments (reproducibility) and within-run precision performance (repeatability) were evaluated starting with the extracted nucleic acid.

Three test sites, with two operators and four instruments per site, were used for the study.

The results are summarized in Tables 3 and 4.

Table 3. Panel reproducibility positive call rate for tumor profiling variants by variant class.

Variant type	Fold LoD level	Total calls	Observed positive calls	Observed negative calls	Observed no calls	Positive call rate (95% CI)—no calls included	Positive call rate (95% CI)—no calls excluded
SNV	1–1.5x	1,368	1,329	26	13	97.15% (96.13%, 97.91%)	98.08% (97.20%, 98.69%)
SNV	2–3x	576	575	0	1	99.83% (99.02%, 99.97%)	100% (99.34%, 100%)
Insertion	1–1.5x	504	503	0	1	99.80% (98.88%, 99.96%)	100% (99.24%, 100%)
Insertion	2–3x	144	144	0	0	100% (97.40%, 100%)	100% (97.40%, 100%)
Deletion	1–1.5x	576	561	9	6	97.40% (95.75%, 98.42%)	98.42% (97.03%, 99.17%)
Deletion	2–3x	216	216	0	0	100% (98.25%, 100%)	100% (98.25%, 100%)
CNV	1–1.5x	792	789	3	0	99.62% (98.89%, 99.87%)	99.62% (98.89%, 99.87%)
Fusion	1–1.5x	1,584	1,555	29	0	98.17% (97.38%, 98.72%)	98.17% (97.38%, 98.72%)
Fusion	2–3x	432	432	0	0	100% (99.12%, 100%)	100% (99.12%, 100%)
Fusion imbalance	1–1.5x	72	72	0	0	100% (94.93%, 100%)	100% (94.93%, 100%)
Splice variant	1–1.5x	288	287	1	0	99.65% (98.06%, 99.94%)	99.65% (98.06%, 99.94%)
Splice variant	2–3x	144	144	0	0	100% (97.40%, 100%)	100% (97.40%, 100%)

Table 4. Panel reproducibility negative call rate for tumor profiling variants by variant class.

Variant type	Fold LoD level	Total calls	Observed positive calls	Observed negative calls	Observed no calls	Negative call rate (95% CI)—no calls included	Positive call rate (95% CI)—no calls excluded
SNV	1–1.5x	2,964,168	1,319	2,945,554	17,295	99.37% (99.36%, 99.38%)	99.96% (99.95%, 99.96%)
SNV	2–3x	1,164,456	455	1,160,937	3,064	99.70% (99.69%, 99.71%)	99.96% (99.95%, 99.96%)
Insertion	1–1.5x	593,064	1	589,125	3,938	99.34% (99.31%, 99.36%)	100.00% (100.0%, 100%)
Insertion	2–3x	233,424	0	232,810	614	99.74% (99.72%, 99.76%)	100.00% (100.0%, 100%)
Deletion	1–1.5x	783,648	0	746,619	37,029	95.27% (95.23%, 95.32%)	100.00% (100.0%, 100%)
Deletion	2–3x	307,872	0	300,911	6,961	97.74% (97.69%, 97.79%)	100.00% (100.0%, 100%)
CNV	1–1.5x	6,408	0	6,408	0	100% (99.94%, 100%)	100% (99.94%, 100%)
Fusion	1–1.5x	1,825,056	50	1,821,714	3,292	99.82% (99.81%, 99.82%)	100.00% (100.0%, 100%)
Fusion	2–3x	564,984	88	561,681	3,215	99.42% (99.40%, 99.43%)	99.98% (99.98%, 99.99%)
Fusion imbalance	1–1.5x	2,880	0	1,414	1,466	49.10% (47.27%, 50.92%)	100% (99.73%, 100%)
Splice variant	1–1.5x	7,200	101	7,099	0	98.60% (98.30%, 98.84%)	98.60% (98.30%, 98.84%)
Splice variant	2–3x	2,160	0	2,160	0	100% (99.82%, 100%)	100% (99.82%, 100%)

Repeatability—tumor profiling variants

A variance component analysis was performed for target variants tested near or above the LoD, using the appropriate quantitative metric for each variant type (i.e., variant allele frequency [VAF] for SNVs and indels, copy number for CNVs, and molecular counts for RNA variants). The results show a coefficient of variation (CV) of less than 10% between operators and instruments for all variants, except for one *ALK* fusion, one *ROS1* fusion, and one *MET* splice variant, which had CVs of 20.95%, 14.59%, and 11.65%, respectively. The CV for between-run variability was below 20% for all variants except for one *ALK* fusion and one *ROS1* fusion, which had CVs of 20.95% and 17.12%, respectively. Percent CVs for reagent lot ranged from 0.0% to 34.15% across all variants. Percent CVs for within-run and within-laboratory variability varied by variant type, with the highest CVs observed for RNA variants.

Analytical accuracy—CDx variants

Study I—*EGFR* exon 20 insertions

The ability to identify *EGFR* exon 20 insertion variants was evaluated with FFPE NSCLC tumor specimens as compared to the reference assay. The accuracy of the Oncomine Dx Express Test for detecting *EGFR* exon 20 insertions in patients with NSCLC was evaluated by comparing results of the Oncomine Dx Express Test with those of a validated NGS-based reference method. Positive percent agreement (PPA), negative percent agreement (NPA), and overall percent agreement (OPA) estimates, along with their respective 95% confidence intervals (CI), were calculated using the orthogonal test results as the reference and summarized in Table 5.

Table 5. Agreement between the Oncomine Dx Express Test and an orthogonal method for detection of *EGFR* exon 20 insertion.

Parameter	Agreed (N)	Excluding Oncomine Dx Express Test unknowns [1]			Including Oncomine Dx Express Test unknowns [1]		
		Total (N)	Percent agreement	95% CI	Total (N)	Percent agreement	95% CI
PPA	84	84	100%	(95.6%, 100%)	84	100%	(95.6%, 100%)
NPA	105	110	95.5%	(89.8%, 98.0%)	111	94.6%	(88.7%, 97.5%)
OPA	189	194	97.4%	(94.1%, 98.9%)	195	96.9%	(93.5%, 98.6%)

[1] Unknowns are defined as values due to insufficient sample, or sample quality control (QC) sequencing failure resulting in an invalid result or no call for the variant.

Study II—*ERBB2/HER2* SNVs and exon 20 insertion biomarkers

The accuracy of the Oncomine™ Dx Express Test for detecting *ERBB2/HER2* tyrosine kinase domain (TKD) activating mutations (SNVs and exon 20 insertions) in patients with NSCLC was evaluated by comparing the test results of the Oncomine™ Dx Express Test with those of a validated NGS-based reference method. The analytical concordance is summarized in Table 6.

Table 6. Agreement between the Oncomine Dx Express Test and reference method for detection of *ERBB2/HER2* activating mutations.

Parameter	Agreed (N)	Excluding Oncomine Dx Express Test unknowns [1]			Including Oncomine Dx Express Test unknowns [1]		
		Total (N)	Percent agreement	95% CI	Total (N)	Percent agreement	95% CI
PPA	58	58	100.0%	(93.8%, 100.0%)	58	100.0%	(93.8%, 100.0%)
NPA	125	128	97.7%	(93.8%, 99.2%)	128	97.7%	(93.3%, 99.2%)
OPA	183	186	98.4%	(95.4%, 99.4%)	186	98.4%	(95.4%, 99.4%)

[1] Unknowns are defined as values due to insufficient sample, or sample quality control (QC) sequencing failure resulting in an invalid result or no call for the variant.

Analytical accuracy—tumor profiling variants

The accuracy of the Oncomine Dx Express Test for detecting SNVs, indels, CNVs, fusions, and RNA splice variants was evaluated by comparing its results with those obtained from validated orthogonal methods across three separate studies.

Accuracy study I

The accuracy study I evaluated the accuracy of the Oncomine Dx Express Test in detecting various tumor profiling variants, including SNV/multi-nucleotide variants (MNVs), indels, CNVs, and RNA splice variants in FFPE clinical samples using a representative approach, comparing its results with the validated

NGS orthogonal test. PPA and NPA estimates and the respective 95% confidence interval (CI) between Oncomine Dx Express Test and the orthogonal test were calculated using the orthogonal test result as reference and are summarized in Table 7.

Table 7. Agreement summary for SNV, insertion, deletion, CNV, and RNA tumor profiling variants.

Variant type	Oncomine Dx Express Test+, orth* test+	Oncomine Dx Express Test+, orth test–	Oncomine Dx Express Test–, orth test+	Oncomine Dx Express Test–, orth test–	PPA (n/N) [95% CI]	NPA (n/N) [95% CI]
All variants	586	112	11	800,035	98.2% (586/597) [96.7%, 99.0%]	100.0% (800,035/800,147) [100.0%, 100.0%]
All SNVs	397	47	2	387,643	99.5% (397/399) [98.2%, 99.9%]	100.0% (387,634/387,690) [100.0%, 100.0%]
All insertions	5	1	0	61,874	100.0% (5/5) [56.6%, 100.0%]	100.0% (61,874/61,875) [100.0%, 100.0%]
All deletions	23	2	0	78,635	100.0% (23/23) [85.7%, 100.0%]	100.0% (78,635/78,637) [100.0%, 100.0%]
All CNVs	114	32	7	4,294	94.2% (114/121) [88.5%, 97.2%]	99.3% (4,294/4,326) [99.0%, 99.5%]
All RNA variants	47	30	2	261,123	95.9% (47/49) [86.3%, 98.9%]	100.0% (261,123/261,153) [100.0%, 100.0%]

* orth = orthogonal

Accuracy study II

The accuracy study II evaluated the accuracy of the Oncomine Dx Express Test in detecting *ERBB2* CNVs, *ALK* fusions, and *RET* fusions by comparing its results with validated orthogonal assays, as summarized in Table 8.

Table 8. Agreement summary for *ERBB2* CNV, *ALK* fusion, and *RET* fusion tumor profiling variants.

Variant type	Oncomine Dx Express Test+, orth* test+	Oncomine Dx Express Test+, orth test–	Oncomine Dx Express Test–, orth test+	Oncomine Dx Express Test–, orth test–	PPA (n/N) [95% CI]	NPA (n/N) [95% CI]
Level 2 <i>ERBB2</i> CNVs	29	4	0	37	100.0% (29/29) [88.3%, 100.0%]	90.2% (37/41) [77.5%, 96.1%]
Level 2 <i>ALK</i>	26	1	0	41	100.0% (26/26) [87.1%, 100.0%]	97.6% (41/42) [87.7%, 99.6%]
Level 2 <i>RET</i>	17	1	0	34	100.0% (17/17) [81.6%, 100.0%]	97.1% (34/35) [85.5%, 99.5%]

* orth = orthogonal

Accuracy study III

The accuracy study III evaluated the accuracy of the Oncomine Dx Express Test in detecting *EGFR* T790M and *EGFR* L858R SNVs, and *EGFR* exon 19 deletions, by comparing its results with an orthogonal PCR method, as summarized in Table 9.

Table 9. Agreement summary for *EGFR* exon 19 deletions, L858R, and T790M tumor profiling variants.

Variant type/ gene	Oncomine Dx Express Test+, orth* test+	Oncomine Dx Express Test+, orth test–	Oncomine Dx Express Test–, orth test+	Oncomine Dx Express Test–, orth test–	PPA (n/N) [95% CI]	NPA (n/N) [95% CI]
All <i>EGFR</i>	23	1	0	45	100.0% (23/23) [85.7%, 100.0%]	97.8% (45/46) [88.7%, 99.6%]
Level 2 <i>EGFR</i>	23	1	0	45	100.0% (23/23) [85.7%, 100.0%]	97.8% (45/46) [88.7%, 99.6%]
<i>EGFR</i> SNVs	11	1	0	45	100.0% (11/11) [74.1%, 100.0%]	97.8% (45/46) [88.7%, 99.6%]
<i>EGFR</i> deletions	12	0	0	45	100.0% (12/12) [75.8%, 100.0%]	100.0% (45/45) [92.1%, 100.0%]

* orth = orthogonal

Clinical accuracy—*ERBB2/HER2* activating mutations

The ability of the Oncomine Dx Express Test in detecting *ERBB2/HER2* TKD activating mutations from FFPE tumor specimens of patients with NSCLC was also evaluated by comparing results of the Oncomine Dx Express Test to results obtained with the enrolling clinical trial assays (CTAs). All 80 mutation-positive specimens were correctly identified, and 129 of 130 mutation-negative specimens were confirmed negative by the Oncomine Dx Express Test. The PPA, NPA, and OPA were 100.0%, 99.2%, and 99.5%, respectively.

Oncomine Dx Express Test

The following reagents and supplies are available for order as needed. For detailed contents and storage information, see the Oncomine Dx Express Test Part II: Sequencing and Results Reports User Guide (Pub. No. MAN0024908).

Ordering information

Product	Cat. No.
Oncomine Dx Express Test Panel	A54103
Oncomine Dx Express Test FFPE DNA and RNA Control Kit	A52167
Genexus Dx FFPE DNA and RNA Purification	A51076
Genexus Dx Purification Supplies 2	A51081
Genexus Dx Nucleic Acid Quantitation	A51078
Genexus Dx Purification Supplies 1	A51080
Genexus Dx Library Strips 1 and 2-HD	A50430
Genexus Dx Templating Strips 3-GX5 and 4	A50431
Genexus Dx Sequencing Kit	A50432
Genexus Dx Barcodes 1-32 HD	A54104
Genexus Dx GX5 Chip and Genexus Coupler	A54106
Genexus Dx Pipette Tips	A54105
Genexus Dx Filter	A50868
Genexus Dx Conical Bottles	A50869
MicroAmp EnduraPlate Optical 96-Well Clear GPLE Reaction Plates with Barcode	4483348
Adhesive PCR Plate Foils	AB0626

Learn more at thermofisher.com/oncomine-express-test

Oncomine Dx Express Test

Connecting patients everywhere to precision oncology

Delays in genomic testing can prevent patients from receiving timely, targeted therapies.

The Ion Torrent™ Oncomine™ Dx Express Test on the Ion Torrent Genexus™ Dx System enables rapid, accurate genomic profiling—empowering clinicians to make informed decisions and help patients benefit from the latest in precision oncology.

Minimal sample input requirements mean **more sample types can be profiled, including small and challenging samples, core-needle biopsies, and fine-needle aspirates.**



Automated nucleic acid purification, quantification, library preparation, template preparation, sequencing, analysis, and reporting **reduce manual pipetting steps and the potential for human errors, minimizing the need for specialized expertise.**

24
hours

Results are delivered in as little as 24 hours* **from sample to report, to enable timely therapy decisions.**

20
minutes

Results are generated with only two user touchpoints and as little as 20 minutes of hands-on time*—**simplifying every step of the NGS** workflow.**

46
genes, FFPE

Detects key biomarkers recommended in **professional guidelines across multiple solid tumors—from DNA and RNA in FFPE**.**

1
vendor

One vendor for the end-to-end *in vitro* diagnostic (IVD) workflow simplifies integration, operation, troubleshooting, and maintenance, **supporting consistent performance and optimal system uptime.**

Learn more at thermofisher.com/oncomine-express-test

For In Vitro Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **FLY-13610831 0826**

* Timing varies by number of samples and type of run.

** NGS = next-generation sequencing; FFPE = formalin-fixed paraffin-embedded



AKT1, ALK, ESR1, RET are tumor profiling biomarkers.

NGS biomarker reports in 24 hours from your in-house lab*

Make treatment decisions without waiting weeks for NGS results

In the rapidly advancing field of precision oncology, the growing number of targeted treatments brings new hope to your patients. However, waiting weeks for next-generation sequencing (NGS) results, and then possibly not receiving them due to quantity not sufficient (QNS), can diminish this hope.

Now, with the Ion Torrent™ Oncomine™ Dx Express Test, that timeline is changing. With its rapid turnaround time, the Oncomine Dx Express Test helps accelerate treatment initiation, which may contribute to improved patient outcomes.

It is an *in vitro* diagnostic (IVD)-validated and highly automated NGS solution that has been designed to enable labs, even those with no previous NGS experience to generate reliable results quickly and efficiently.

Ask your local pathology lab to implement the Oncomine Dx Express Test and empower you with rapid NGS results.

* Timing varies by number of samples and type of run.

 Learn more at thermofisher.com/oncomine-express-test

For *In Vitro* Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **PTA-13611650 0826**



AKT1, BRAF, PTEN, RET are tumor profiling biomarkers.

Ask for rapid NGS results from tissue in mere days, not weeks

With the Oncomine Dx Express Test, your local lab can now generate results in as little as 24 hours

In the rapidly advancing field of precision oncology, the growing number of targeted treatments brings new hope to your patients. However, waiting weeks for next-generation sequencing (NGS) results can diminish this hope.

The Ion Torrent™ Oncomine™ Dx Express Test transforms this process by delivering NGS results in as little as 24 hours,* from tissue sample to report.

It is a validated *in vitro* diagnostic (IVD) solution developed to address barriers to NGS implementation and enable a broad spectrum of labs—close to you and your patients—to deliver results quickly and efficiently.

Request the Oncomine Dx Express Test from your lab to eliminate the lengthy wait for a complete biomarker picture and enable you to make rapid, informed treatment decisions that help minimize delays in patient care.

* Timing varies by number of samples and type of run.

Learn more at thermofisher.com/oncomine-express-test

For In Vitro Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. PTA-13611650 0826



AKT1, ALK, ESR1, RET are tumor profiling biomarkers.

Ask for rapid NGS results from tissue in mere days, not weeks

With the Oncomine Dx Express Test, your local lab can now generate results in as little as 24 hours

In the rapidly advancing field of precision oncology, the growing number of targeted treatments brings new hope to your patients. However, waiting weeks for next-generation sequencing (NGS) results can diminish this hope.

The Ion Torrent™ Oncomine™ Dx Express Test transforms this process by delivering NGS results in as little as 24 hours,* from tissue sample to report.

It is a validated *in vitro* diagnostic (IVD) solution developed to address barriers to NGS implementation and enable a broad spectrum of labs—close to you and your patients—to deliver results quickly and efficiently.

Request the Oncomine Dx Express Test from your lab to eliminate the lengthy wait for a complete biomarker picture and enable you to make rapid, informed treatment decisions that help minimize delays in patient care.

* Timing varies by number of samples and type of run.

 Learn more at thermofisher.com/oncomine-express-test

For *In Vitro* Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. PTA-13611650 0826



ALK, BRAF, IDH1, RET are tumor profiling biomarkers.

Accelerate your treatment decisions with rapid NGS from FFPE tissue

Oncomine Dx Express Test delivers results in 24 hours—faster than ever before

In the rapidly advancing field of precision oncology, the growing number of targeted treatments brings new hope to your patients. However, waiting weeks for next-generation sequencing (NGS) results, and then possibly not receiving them due to quantity not sufficient (QNS) can diminish this hope. The Ion Torrent™ Oncomine™ Dx Express Test transforms this process by delivering NGS results in as little as 24 hours*, from formalin-fixed paraffin-embedded (FFPE) tissue to report.

With its rapid turnaround time, the Oncomine Dx Express Test helps accelerate treatment initiation, which may contribute to improved patient outcomes.

Request the Oncomine Dx Express Test from your lab to make the best-informed treatment decisions and minimize delays in patient care.

The Oncomine Dx Express Test provides:

- **Rapid results**—Receive results in as little as 24 hours, supporting timely and informed therapy decisions.
- **Minimal sample input requirements**—Use as little as two 5 µm FFPE slides, increasing the likelihood of obtaining results even when tissue is limited.
- **Facilitation of MDT collaboration**—Streamline the testing workflow with in-house testing while preserving specimen integrity and enhancing communication across multidisciplinary teams (MDT).
- **An automated NGS workflow**—Implement in laboratories, even those without NGS expertise, enabling consistent and high-quality results.

Request Oncomine Dx Express Test from your pathology lab, so you and your patients don't have to wait weeks for NGS results.

*Timing varies by number of samples and type of run.



Guideline-recommended companion diagnostics and tumor profiling biomarkers

The Oncomine Dx Express Test is indicated as a companion diagnostic (CDx) biomarker to identify patients who may benefit from personalized treatment, as listed in Table 1 in accordance with the approved therapeutic product labeling.

The test also detects tumor profiling biomarkers recommended in professional guidelines for multiple solid tumors (Table 2). This includes substitutions, insertions, and deletions in 42 genes, copy number variants in 10 genes, and fusions or splice variants in 18 genes from DNA and RNA extracted from FFPE tumor

tissue (relevant in non-small cell lung cancer (NSCLC), colorectal cancer, cholangiocarcinoma, melanoma, and others).

Gene panel content of the Oncomine Dx Express Test covers key genes associated with approved therapies, professional guidelines, and ongoing clinical trials (Table 3).

Table 1. Companion diagnostics indications.

Specimen type	Tissue type	Gene	Variant	Targeted therapy
Tissue	NSCLC	EGFR	EGFR exon 20 insertions	ZEGFROVY™ (sunvozertinib)
		ERBB2/HER2	ERBB2/HER2 activating mutations (SNVs in exons 18-21 within the tyrosine kinase domain and exon 20 insertions)	HYRNUO® (sevabertinib)

Table 2. The Oncomine Dx Express Test panel gene list.*

DNA						RNA				
Substitutions, insertions, and deletions						Copy number variants		Fusions and splice variants		
AKT1	CDK4	ESR1	HRAS	MAP2K2	PIK3CA	AR	FGFR2	ALK	FGFR2	NTRK3
AKT2	CHEK2	FGFR1	IDH1	MET	PTEN	EGFR	FGFR3	AR	FGFR3	NUTM1
AKT3	CTNNB1	FGFR2	IDH2	NRAS	RAF1	ERBB2	KRAS	BRAF	MET	RET
ALK	EGFR	FGFR3	KEAP1	NTRK1	RET	ERBB3	MET	EGFR	NRG1	ROS1
AR	ERBB2	FGFR4	KIT	NTRK2	ROS1	FGFR1	PIK3CA	ESR1	NTRK1	RSPO2
ARAF	ERBB3	FLT3	KRAS	NTRK3	STK11			FGFR1	NTRK2	RSPO3
BRAF	ERBB4	GNAS	MAP2K1	PDGFRA	TP53					

Table 3. Oncomine Dx Express Test content clinical relevance.**

134 therapy labels
26 clinical guidelines
1.573 clinical trials

** Analysis based on Oncomine Knowledgebase (v 03.2026).

Why rapid NGS biomarker results are critical for first-line therapy choice

Immunotherapy has shown limited efficacy in *EGFR*-mutant and *ALK*-rearranged NSCLC, as demonstrated in clinical trials and supported by real-world evidence showing lower response rates in driver-positive disease (Figure 1)¹. High PD-L1 expression does not reliably negate the need for matched targeted therapy; therefore targeted therapy should generally be prioritized when an actionable driver alteration is identified.²

In addition, data suggest that giving immunotherapy before targeted therapy can increase toxicity in oncogene-driven NSCLC, particularly when the targeted agent is started soon after.³

That's why even in PD-L1-high advanced NSCLC, treatment initiation should ideally wait for complete molecular or NGS biomarker results, because high PD-L1 expression does not exclude actionable oncogenic drivers and may lead to suboptimal first-line immunotherapy choice.² In particular, pembrolizumab-based regimens are currently only indicated for the first-line treatment of metastatic nonsquamous NSCLC, without *EGFR* or *ALK* genomic tumor alterations.⁴

A complete report when you need it

Results from the Oncomine Dx Express Test are generated in as little as 24 hours, helping you to make well informed therapy decisions in time. Rapid access to NGS biomarker results helps confirm actionable drivers, potentially avoid ineffective immunotherapy in driver-positive disease, and reduce the risks associated with improper treatment sequencing.

Retrospective real-world data: lower response to IO in driver-positive disease

Response to PD-1/PD-L1 inhibitors by genomic subtype¹

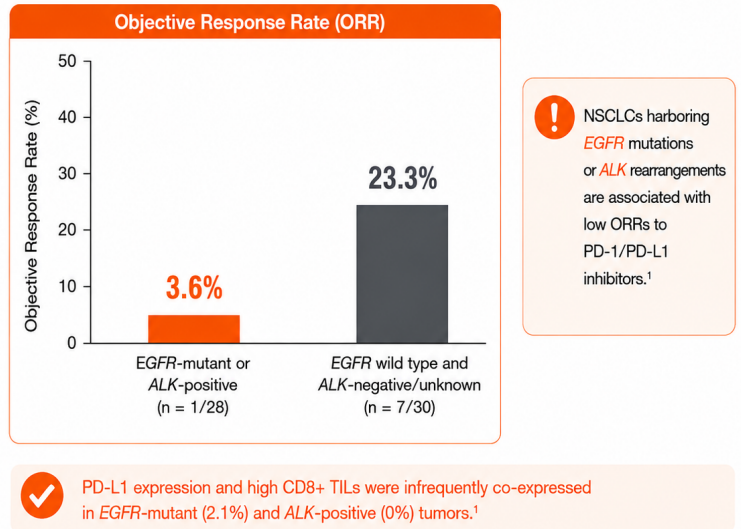


Figure 1. IO response by genomic subtype



References

1. Gainor JF, et al. *Clin Cancer Res*. 2016;22(18):4585–4593.
2. Shimoda Y, Yoshida T, Miyakoshi J, et al. *Cancer Immunol Immunother*. 2023;72:2613–2620.
3. Hirsch FR, Kim C. *Oncol Ther*. 2024;PMCID: PMC11187040.
4. Pembrolizumab [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; 2026. Accessed May 1, 2026.

 Learn more at thermofisher.com/oncomine-express-test

For In Vitro Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. ZEGFROVY is a trademark of Dizal (Jiangsu) Pharmaceutical Co., Ltd. HYRNUO is a registered trademark of Bayer. **FLY-13612114 0826**



BRAF, FGFR, NTRK, RET are tumor profiling biomarkers.

NGS biomarker reports from tissue biopsy in 24 hours

Elevate your oncology biomarker testing capabilities

The Oncomine Dx Express Test: an end-to-end solution for any lab

The Ion Torrent™ Oncomine™ Dx Express Test on the Ion Torrent™ Genexus™ Dx System automates the next-generation sequencing (NGS) workflow, from specimen to report, with as little as 20 minutes of hands-on time.* This reduces the risk of human error and helps enhance laboratory efficiency.

It is an *in vitro* diagnostic (IVD)-validated solution that can deliver companion diagnostics (CDx) and tumor profiling results in as fast as 24 hours.*

With the Oncomine Dx Express Test, your lab can provide rapid NGS results and facilitate timely treatment decisions.

* Timing varies by number of samples and type of run.

 Learn more at thermofisher.com/oncomine-express-test

For In Vitro Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **PTA-13611441 0826**



BRAF, FGFR, NTRK, RET are tumor profiling biomarkers.

The time to embrace NGS is now

The Oncomine Dx Express Test—from extraction to report, with as little as 20 minutes of hands-on time

The Ion Torrent™ Oncomine™ Dx Express Test on the Ion Torrent™ Genexus™ Dx System automates the next-generation sequencing (NGS) workflow, from specimen to report, with as little as 20 minutes of hands-on time.* This reduces the risk of human error and helps enhance laboratory efficiency.

As a validated *in vitro* diagnostic (IVD) solution, it is significantly easier to implement than other NGS tests, and delivers results in as little as 24 hours,* enabling you to deliver timely reports and facilitate treatment decisions.

Embrace this opportunity to elevate your capabilities and enhance precision oncology in your hospital.

* Timing varies by number of samples and type of run.

 Learn more at thermofisher.com/oncomine-express-test

For In Vitro Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **PTA-13611441 0826**



BRAF, KRAS, MET, RET are tumor profiling biomarkers.

Oncomine Dx Express Test

Connecting patients everywhere to precision oncology

A patient's tumor profile has the potential to guide precision oncology care. However, delays in obtaining results can hinder clinicians' ability to make informed decisions, potentially causing patients to miss out on targeted therapies, which may impact treatment efficacy and patient outcomes. In real-world oncology care, tissue is often the issue—limited quantity, quality, and accessibility can delay or prevent molecular profiling.

The Ion Torrent™ Oncomine™ Dx Express Test was designed to simplify the next-generation sequencing (NGS) workflow and enable laboratories, even those without NGS expertise, to deliver genomic profiles efficiently. Now, laboratories can bring precision oncology to more patients, delivering genomic profiles from minimal FFPE tissue, even when tissue is limited.

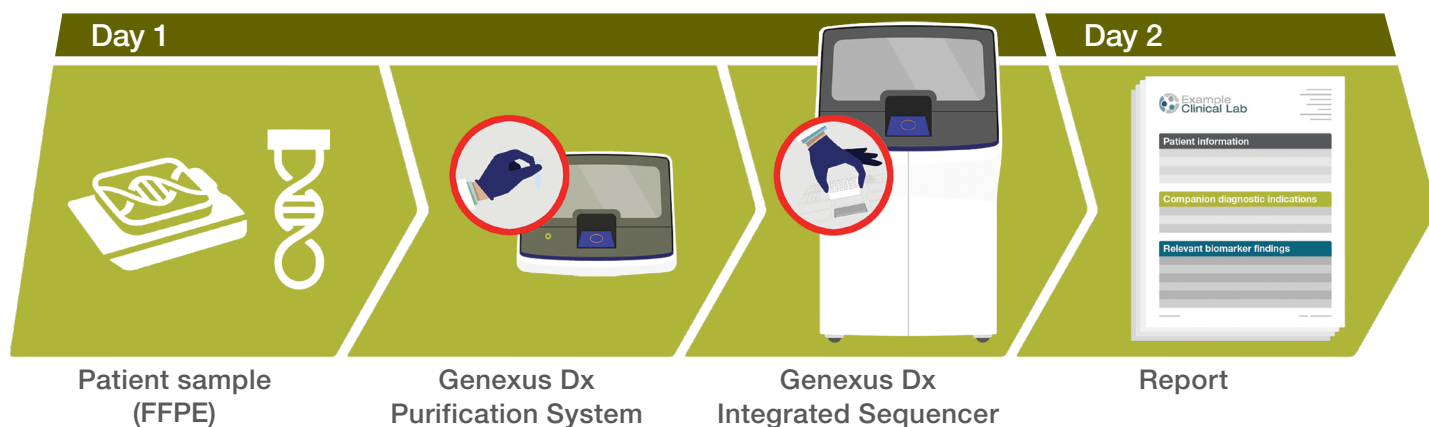
The Ion Torrent™ Genexus™ Dx System automates the NGS workflow, from specimen to report in as little as 24 hours* with as little as 20 minutes of hands-on time.* This easy-to-use, end-to-end solution reduces manual steps and has low sample input requirements. With the Oncomine Dx Express Test, you'll be able to deliver results for more patients in a short time, while using fewer resources in your laboratory.

The Oncomine Dx Express Test offers:

- **Rapid results**—Generate results in as little as 24 hours, supporting timely and informed therapy decisions.
- **Highly automated workflow**—Perform testing with as little as 20 minutes of hands-on time; this helps reduce the risk of human error and enhances efficiency and scalability of genomic testing in your laboratory.
- **Minimal sample input requirements**—Utilize only 10 ng DNA and 10 ng RNA from as little as two 5 µm formalin-fixed, paraffin-embedded (FFPE) slides, enabling analysis of small biopsies and limited samples.
- **FFPE tissue compatibility**—Accommodate minimal FFPE tissue biopsies, increasing the likelihood of obtaining results even when tissue is limited.

Delivering results in as little as 24 hours

The Genexus Dx System automates the NGS workflow from patient sample to report with only two user touchpoints. DNA and RNA are purified and quantified on the Ion Torrent™ Genexus™ Dx Purification System, followed by library preparation, template preparation, sequencing, analysis, and reporting on the Ion Torrent™ Genexus™ Dx Integrated Sequencer. The entire workflow requires as little as 20 minutes of hands-on time, which helps reduce burden for laboratory staff and the potential for human error, and alleviates the need for specialized bioinformatics expertise.



* Timing varies by number of sample and type of run.

CDx and guideline recommended biomarkers for tumor profiling across solid tumors

The Oncomine Dx Express Test is indicated as a companion diagnostic (CDx) to identify patients who may benefit from personalized treatments, as listed in Table 1 in accordance with the approved therapeutic product labeling.

The test also detects tumor profiling biomarkers recommended in professional guidelines for multiple solid tumors (Table 2). This includes substitutions, insertions, and deletions in 42 genes, copy number variants in 10 genes, and fusions or splice variants in 18 genes from DNA and RNA extracted from FFPE tumor tissue—relevant in non–small cell lung cancer (NSCLC), colorectal cancer, cholangiocarcinoma, melanoma, and others.

Table 1. Companion diagnostics indications.

Specimen type	Tissue type	Gene	Variant	Targeted therapy
Tissue	NSCLC	EGFR	EGFR exon 20 insertions	ZEGFROVY™ (sunitinib)
Tissue	NSCLC	ERBB2/HER2	ERBB2/HER2 activating mutations (SNVs in exons 18-21 within the tyrosine kinase domain and exon 20 insertions)	HYRNUO® (sevabertinib)

Table 2. The Oncomine Dx Express Test FFPE panel gene list.

DNA						RNA				
Substitutions, insertions, and deletions						Copy number variants		Fusions and splice variants		
AKT1	CDK4	ESR1	HRAS	MAP2K2	PIK3CA	AR	FGFR2	ALK	FGFR2	NTRK3
AKT2	CHEK2	FGFR1	IDH1	MET	PTEN	EGFR	FGFR3	AR	FGFR3	NUTM1
AKT3	CTNNB1	FGFR2	IDH2	NRAS	RAF1	ERBB2	KRAS	BRAF	MET	RET
ALK	EGFR	FGFR3	KEAP1	NTRK1	RET	ERBB3	MET	EGFR	NRG1	ROS1
AR	ERBB2	FGFR4	KIT	NTRK2	ROS1	FGFR1	PIK3CA	ESR1	NTRK1	RSPO2
ARAF	ERBB3	FLT3	KRAS	NTRK3	STK11			FGFR1	NTRK2	RSPO3
BRAF	ERBB4	GNAS	MAP2K1	PDGFRA	TP53					



Comparison with other NGS technologies

Compared to other NGS technologies, the Oncomine Dx Express Test helps to shorten time-to-results, minimizes the number of manual steps in the NGS workflow, and requires less sample input (Figure 1). Faster results enable timely decision-making. Minimizing manual steps of the NGS workflow reduces the risk of human error, enabling more accurate and reliable results, and helps ensure patients everywhere have access to genomic testing.

	Oncomine Dx Express Test		Other NGS technologies	
 Time to report	1 day		4–5 days	
 Hands-on time	20 minutes			>10 hours (FFPE)
 Sample input		10 ng (FFPE)		40 ng (FFPE)

Figure 1. Comparison of NGS workflows.

 Learn more at thermofisher.com/oncomine-express-test



Oncomine Dx Express Test

Epidemiology of lung cancer

Lung cancer is the leading cause of cancer-related deaths in the United States. In 2025, an estimated 226,650 new cases (110,680 in men and 115,970 in women) of lung and bronchial cancer are projected to be diagnosed, and 124,730 deaths are projected (64,190 in men and 60,540 in women) [1]. Only 28.1% of all patients with lung cancer live five years or more after diagnosis [2].

Molecular diagnostic testing for therapy selection in NSCLC

Numerous gene alterations have been identified that influence therapy selection. Testing lung cancer specimens, particularly non-small cell lung cancer (NSCLC), for these alterations is crucial for identifying potentially effective targeted therapies and avoiding those unlikely to provide clinical benefit. To obtain comprehensive molecular biomarker profiling from limited biopsy tissue, multiplex technology such as next-generation sequencing (NGS) is preferred over single-gene tests, according to an expert consensus guideline from the College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP) [3]. Testing for circulating cell-free DNA (cfDNA) in lung cancer allows noninvasive detection of tumor-derived alterations, which may be particularly useful when tissue samples are limited or unavailable.

For the most current information regarding the essential biomarkers for lung cancer and their association with therapeutic outcomes, refer to the therapeutic labels available at [Drugs@FDA](#).

For the most current information regarding cleared or approved companion diagnostic devices, refer to [List of Cleared or Approved Companion Diagnostic Devices \(In Vitro and Imaging Tools\)](#).

EGFR: epidermal growth factor receptor gene. *EGFR* encodes the epidermal growth factor receptor tyrosine kinase, a member of the ERBB/human epidermal growth factor receptor (HER) family. It is typically presented on the surface of epithelial cells and can be either mutated or overexpressed in various human malignancies.

Besides the common *EGFR* mutations (e.g., exon19del, L858R), exon 20 insertion mutations are less frequent and represent a heterogeneous group of mutations. Most *EGFR* exon 20 alterations are in-frame duplication or insertions,

and patients harboring *EGFR* exon 20 insertions generally do not respond to first-, second-, and third- generation *EGFR* tyrosine kinase inhibitor (TKI) therapy. However, more recently developed *EGFR* TKIs have demonstrated meaningful clinical activity in tumors harboring *EGFR* exon 20 insertions, making accurate identification of these alterations a clinical need. Due to the heterogeneity of *EGFR* exon 20 insertions, NGS-based approaches are preferred, as targeted PCR-based approaches may under-detect *EGFR* exon 20 insertions.

ERBB2/HER2: erb-b2 receptor tyrosine kinase 2. *ERBB2* encodes the erb-b2 receptor tyrosine kinase 2, a member of the human epidermal growth factor receptor (HER) family, which is frequently overexpressed in various cancer types. *ERBB2* alterations include mutations and amplifications, with exon 20 insertions/duplications being the most common. Activating *ERBB2* mutations are associated with responsiveness to anti-*HER2* targeted therapies, however, not all mutations are activating. NGS is preferred for its ability to capture the diverse range of *ERBB2* alterations, though Sanger sequencing and targeted PCR can also be used.

Test intended uses

FFPE samples

The Oncomine™ Dx Express Test is a qualitative *in vitro* diagnostic (IVD) test that uses targeted NGS technology to detect substitutions, insertions, and deletions in 42 genes from DNA, copy number variants (CNVs) in 10 genes from DNA, and fusions or splice variants in 18 genes from RNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor samples using the Genexus™ Dx Integrated Sequencer.

The test is intended to be used as a companion diagnostic (CDx) to identify patients who may benefit from treatment with the targeted therapies listed in Table 1, in accordance with the approved therapeutic product labeling.

Table 1. Companion diagnostics indications–FFPE samples.

Tissue type	Gene	Variant	Targeted therapy
NSCLC	<i>EGFR</i>	<i>EGFR</i> exon 20 insertions	ZEGFROVY™ (sunvozertinib)
	<i>ERBB2/HER2</i>	<i>ERBB2/HER2</i> activating mutations (SNVs in exons 18–21 within the tyrosine kinase domain and exon 20 insertions)	HYRNUO® (sevabertinib)

Additionally, the test is intended to provide tumor mutation profiling information to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with solid malignant neoplasms. Genomic findings other than those listed in Table 1 are not prescriptive or conclusive for labeled use of any specific therapeutic product.

Test performance and characteristics

FFPE samples

The OncoPrint Dx Express Test targets key regions of 46 cancer-related genes for FFPE solid tumor samples.

Substitutions, and insertions and deletions (indels), from DNA for the following 42 genes are reported for FFPE solid tumor samples: *AKT1*, *AKT2*, *AKT3*, *ALK*, *AR*, *ARAF*, *BRAF*, *CDK4*, *CHEK2*, *CTNNB1*, *EGFR*, *ERBB2*, *ERBB3*, *ERBB4*, *ESR1*, *FGFR1*, *FGFR2*, *FGFR3*, *FGFR4*, *FLT3*, *GNAS*, *HRAS*, *IDH1*, *IDH2*, *KEAP1*, *KIT*, *KRAS*, *MAP2K1*, *MAP2K2*, *MET*, *NRAS*, *NTRK1*, *NTRK2*, *NTRK3*, *PDGFRA*, *PIK3CA*, *PTEN*, *RAF1*, *RET*, *ROS1*, *STK11*, and *TP53*.

Copy number variants (CNVs) from DNA for the following 10 genes are reported for FFPE solid tumor samples: *AR*, *EGFR*, *ERBB2*, *ERBB3*, *FGFR1*, *FGFR2*, *FGFR3*, *KRAS*, *MET*, and *PIK3CA*.

Fusions and splice variants from RNA for the following 18 genes are reported for FFPE solid tumor samples: *ALK*, *AR*, *BRAF*, *EGFR*, *ESR1*, *FGFR1*, *FGFR2*, *FGFR3*, *MET*, *NRG1*, *NTRK1*, *NTRK2*, *NTRK3*, *NUTM1*, *RET*, *ROS1*, *RSPO2*, and *RSPO3*.

The performance characteristics of the OncoPrint Dx Express Test were determined using DNA and RNA derived from a variety of FFPE tissue types. These FFPE tissue samples were analyzed for substitutions, insertions, deletions, and CNVs in DNA, as well as fusions and splice variants in RNA, including CDx and tumor profiling variants. The primary evidence supporting the OncoPrint

Dx Express Test's performance in detecting CDx variants was obtained from data generated using intended-use specimens and sample blends throughout all validation studies.

A summary of selected studies is provided below. For complete studies and results, refer to the OncoPrint Dx Express Test User Guide [4].

Based on the data observed, the test demonstrated 0% per-position false positive rates across 24 blank samples representing 10 tissue types for all variant type categories except for Level 3 SNVs. For Level 3 single nucleotide variants (SNVs), the per-position false positive rate was 0.00004% after masking certain Level 3 SNVs with variant allele frequencies below 5% to prevent false positives. The per-sample false positive rates across 24 blank samples representing 10 tissue types was 0% for all variant type categories except for Level 3 SNVs. For Level 3 SNVs, the per-sample false positive rate was 0.52% after masking certain Level 3 SNVs with variant allele frequencies below 5% to prevent false positives.

EGFR exon 20 insertion CDx variants demonstrated a limit of detection ranging from 3.24% to 4.38% allelic frequency, with insertion lengths of 3, 6, 9, and 12 bp.

ERBB2/HER2 exon 20 insertion CDx variants demonstrated a limit of detection ranging from 2.98% to 4.07% allelic frequency, with insertion lengths of 3, 6, 9, and 12 bp. *ERBB2/HER2* SNVs demonstrated a limit of detection ranging from 3.60% to 6.42% allelic frequency.

For *EGFR* exon 20 insertions, three test sites, with two operators and two instruments per site, were used. The positive call rate for reproducibility was 100.0% for all *EGFR* exon 20 insertion variants, with no instances of no calls observed. The negative call rate, estimated using two wild-type (WT) NSCLC samples across relevant hotspots, was 100%. Within-run repeatability was 100% both including and excluding no-call results.

For *ERBB2/HER2* exon 20 insertions, reproducibility testing demonstrated a positive call rate of 100% across all evaluated insertion variants, with no no-call results observed. The negative call rate, estimated using two WT NSCLC samples, was 100.0% when excluding no-call results. Within-run repeatability for the detection of *ERBB2/HER2* exon 20 insertion variants was 100% when including or excluding no-call results. For WT samples, within-run repeatability was also 100% under both conditions.

For *ERBB2/HER2* SNVs, reproducibility testing showed a positive call rate of 100% for all variants evaluated, with no no-call results observed. The negative call rate, estimated using two WT NSCLC samples, was $\geq 99.3\%$ when excluding no-call results. Within-run repeatability for the detection of *ERBB2/HER2* SNVs was 100% when excluding no-call results. For WT samples, within-run repeatability was $\geq 97.2\%$ when excluding no-call results.

For tumor profiling variants, the variability across sites, operators, and instruments (reproducibility) and within-run precision performance (repeatability) were evaluated starting with the extracted nucleic acid. Three test sites, with two operators and four instruments per site, were used for the study. The positive call rates, excluding no calls, were between 98.08% and 100%, and negative call rates, excluding no calls, were between 98.60% and 100%. For repeatability, the results show a coefficient of variation (CV) of less than 10% between operators/instruments for all variants, except for one *ALK* fusion, one *ROS1* fusion, one *MET* splice variant, which had CVs of 20.95%, 14.59%, and 11.65%, respectively. The CV for between-run variability was below 20% for all variants, except for one *ALK* fusion and one *ROS1* fusion, which had CVs of 20.95% and 17.12%, respectively. Percent CVs for reagent lot ranged from 0.0% to 34.15% across all variants. Percent CVs for within-run and within-laboratory variability varied by variant type, with the highest CVs observed for RNA variants.

The accuracy of the Oncomine Dx Express Test for detecting CDx variants in patients with NSCLC was evaluated by comparing results of the Oncomine Dx Express Test with those of validated NGS-based orthogonal methods. Positive percent agreement (PPA), negative percent agreement (NPA), and overall percent agreement (OPA) estimates, along with their respective 95% confidence intervals (CI), were calculated using the orthogonal test results as the reference. The concordance analysis for *EGFR* exon 20 insertions showed a PPA of 100%, NPA of 95.5%, and OPA of 97.4% when excluding unknowns*, and PPA of 100%, NPA of 94.6%, and OPA of 96.9% when including unknowns. The concordance analysis for *ERBB2/HER2* activating mutations showed a PPA of 100%, NPA of 97.7%, and OPA of 98.4%, when excluding or including unknowns.

Accuracy of the Oncomine Dx Express Test for detecting tumor profiling SNVs, indels, CNVs, fusions, and RNA splice variants was evaluated by comparing its results with those obtained from validated orthogonal methods across three separate studies.

In the accuracy study I, the aggregated PPA was 98.2% across all variants (including SNVs, insertions, deletions, CNVs, fusions, and splice variants), and the aggregated NPA was 100.0% across all variants for tumor profiling variants.

In the accuracy study II, the concordance analysis showed an aggregated PPA of 100% and an aggregated NPA of 90.2%, PPA of 100% and NPA of 97.6%, and PPA of 97.1% and NPA of 97.1% for *ERBB2* CNVs, *ALK* fusions, and *RET* fusions, respectively.

In the accuracy study III, the concordance analysis for *EGFR* T790M and *EGFR* L858R SNV, and *EGFR* exon 19 deletion variants showed an aggregated PPA of 100.0% and an aggregated NPA of 97.8%.

To evaluate the ability of the Oncomine Dx Express Test to identify *EGFR* exon 20 insertion mutations in FFPE NSCLC tumor specimens, 424 samples (192 positive specimens from patients enrolled in a clinical trial and 232 commercially-sourced biomarker-negative samples) were analyzed by comparing results of the Oncomine Dx Express Test to results obtained with the enrolling clinical trial assays (CTAs). The PPA, NPA, and OPA were 97.9%, 100%, and 98.9%, respectively when excluding unknowns.

For *ERBB2/HER2* TKD activating mutations in FFPE NSCLC tumor specimens, 210 samples (80 *ERBB2/HER2* TKD activating mutation-positive and 130 commercially-sourced biomarker-negative samples) were analyzed by comparing results of the Oncomine Dx Express Test to results obtained with the enrolling CTAs. The PPA, NPA, and OPA were 100.0%, 99.2%, and 99.5%, respectively.

*Unknowns are defined as invalid due to insufficient sample, or sample QC sequencing failure resulting in an invalid result or no call for the variant.

The molecular profile of a tumor can vary between primary and metastatic sites, as well as change over time in response to treatment, leading to the development of mutations that could confer resistance to therapeutic agents.

Contraindications

There are no known contraindications.

Assay warnings and limitations

FFPE samples

1. Use of this product must be limited to personnel trained in the techniques of PCR, NGS, and the use of the Oncomine Dx Express Test, the Genexus Dx Purification System, when applicable, and the Genexus Dx Integrated Sequencer.
2. Users are cautioned that DNA variant-positive calls in a small number of genomic regions have been observed to generate multiple variant calls with overlapping alleles, even when only one variant is present. For details on these observed cases, see Appendix B, “Variants targeted by the Oncomine Dx Express Test”.
3. Due to the nature of hotspot variant calling, when several variants are located in the same genomic region in close proximity to each other, the presence of a positive variant can result in a “No Call” for the neighboring variants instead of a negative call.
4. Genomic findings listed in the Oncomine Dx Express Test results report under Cancer Mutations with Evidence of Clinical Significance (Level 2) and Cancer Mutations with Potential Clinical Significance (Level 3) are not prescriptive or conclusive for labeled use of any specific therapeutic product, and clinical validation has not been performed. Confirmation of tumor mutation status using an FDA-approved CDx test is needed for therapeutic use.
5. Decisions on patient care and treatment must be based on the independent medical judgment of the treating physician, taking into consideration all applicable information concerning the patient’s condition, such as patient and family history, physical examinations, information from other diagnostic tests, and patient preferences, in accordance with the standard of care in a given community.
6. The Oncomine Dx Express Test is for use with the Genexus Dx Integrated Sequencer and the Genexus Dx Purification System (for integrated workflows), or other IVD-labeled extraction chemistries.
7. The Oncomine Dx Express Test is for detecting the following somatic mutations in FFPE samples: single-nucleotide variants (SNVs), insertions, deletions, and copy number variants (CNVs) in DNA, and fusions and splice variants in RNA.
8. The Oncomine Dx Express Test has been validated to detect and report only the variants listed in Appendix B, “Variants targeted by the Oncomine Dx Express Test”, and has not been validated for novel variant detection.

Guide to interpreting results

For FFPE samples, the test output classifies variants into the following levels according to the cancer indication.

- Level 1: Companion Diagnostics (CDx) Biomarkers (noted in Table 1 of the Intended Use)
- Level 2: Cancer Mutations with Evidence of Clinical Significance
- Level 3: Cancer Mutations with Potential Clinical Significance

Test results should be interpreted in the context of pathological evaluation of tumors, treatment history, clinical findings, and other laboratory data.

All clinical interpretations of the variants detected should be made by a board-certified pathologist or equivalent. It is recommended that the physician ordering the test consult with a board-certified pathologist. Patients are advised to seek information from their oncologist or certified health care provider. Additional information may be obtained from NCCN Guidelines™ and IASLC/AMP NSCLC testing guidelines.

9. The Oncomine Dx Express Test is for use with 10 ng each of DNA and RNA per sample for FFPE samples. Input levels less than or greater than this amount are not recommended.
10. Although the Genexus Dx Integrated Sequencer can perform on-board dilution of samples up to 1,024-fold, the use of samples at the upper limit of supported concentrations (512 ng/μL for FFPE DNA and RNA) has not been validated.
11. Results for samples with DNA or RNA concentration failure are reported for Nucleic Acid to Result runs. A warning message appears in the run planning screen and the run summary screen to indicate to the user that a sample does not meet the minimum concentration requirement of the assay.
12. The Oncomine Dx Express Test is for use with FFPE tumor specimens.
13. Core needle biopsy (CNB) and fine needle aspirate (FNA) cell block specimen types have not been analytically validated for the detection of tumor profiling variants targeted by Oncomine Dx Express Test.
14. The effects of potential variations in FFPE specimen fixation have not been evaluated.
15. A potential source of contamination in the procedure is nucleic acid from previous sample extraction steps. Follow good laboratory practices and all precautions and guidelines in these user guides to avoid cross-contamination between samples.
16. The Oncomine Dx Express Test is a qualitative test. The test is not for quantitative measurements of percent mutation.
17. The test is not indicated to be used for standalone diagnostic purposes, screening, monitoring, risk assessment, or prognosis.
18. For prescription use only. The test must be ordered by a qualified medical professional in accordance with clinical laboratory regulations.
19. The performance of the Oncomine Dx Express Test in samples obtained from patients that have had organ or tissue transplantation has not been evaluated.
20. A negative result does not rule out the presence of a mutation below the Limits of Detection (LoD) of the assay in the patient's tumor and should be followed by additional confirmatory testing.
21. Alterations at allele frequencies below the LoD of the assay may not be detected consistently.
22. The minimum tumor content thresholds for Oncomine Dx Express Test are ≥20% for resection and fine needle aspirate (FNA) cell block samples and ≥10% for core needle biopsy (CNB) samples, regardless of variant type.
23. For optimal CNV results with FFPE samples that have a tumor content of <40%, macrodissect and enrich the samples for tumor content. For resection or surgical biopsies, macrodissect and enrich the sample for tumor content if the tumor content is <20% and the tumor content in the region of interest is ≥10%. For core needle biopsies and fine needle aspirates, macrodissection is not recommended due to the limiting tissue section surface areas.
24. The *ERBB2* copy number alteration call may not be accurate when tumor content is between 20–39%. Additional confirmatory testing with a clinically validated test is strongly recommended.
25. The presence of >70% necrotic tissue may yield unreliable sequencing results for the detection of *EGFR* exon 20 insertion mutations and *ERBB2* exon 20 insertion mutations.
26. For fusion variants detected by expression imbalance alone (RNA exon tile fusion imbalance), confirmatory testing using a clinically validated assay is recommended.
27. The accuracy of Oncomine Dx Express Test for detecting gene fusions in *FGFR1*, *NTRK2*, *NUTM1*, *RSPO2*, and *RSPO3* genes has not been evaluated.
28. When panel reproducibility was evaluated using extracted RNA samples, the *ALK* fusion imbalance in NSCLC demonstrated a low negative percent agreement of 28.57% (144/504).
29. When panel reproducibility was evaluated using extracted DNA samples, the *BRAF* V600E variant in colorectal cancer demonstrated a low positive percent agreement of 86.11% (62/72).
30. For *MET* Exon 14 skipping results for cancer types other than non-small cell lung cancer, confirmatory testing using a clinically validated assay is recommended.
31. For NSCLC, the Oncomine Dx Express Test assay definition file includes prevalent but not all rare or newly identified *EGFR* exon 20 insertions, *ERBB2/HER2* exon 20 insertions, and *ERBB2/HER2* SNVs in exons 18-21 within the tyrosine kinase domain. The Oncomine Dx Express Test may miss rare or newly identified:
 - a. *EGFR* exon 20 insertions carried by a subset of patients who may derive benefit from sunvozertinib
 - b. *ERBB2/HER2* activating mutations (SNVs in exons 18-21 within the tyrosine kinase domain and exon 20 insertions) carried by a subset of patients who may derive benefit from sevabertinib

References

1. Siegel RL, Kratzer TB, Giaquinto AN et al. (2025) Cancer statistics, 2025. *CA Cancer J Clin* 75(1):10–45.
2. Cancer Stat Facts: Lung and Bronchus Cancer. National Cancer Institute, seer.cancer.gov/statfacts/html/lungb.html, accessed on July 7, 2025.
3. Lindeman NI, Cagle PT, Aisner DL et al. (2018) Updated molecular testing guideline for the selection of lung cancer patients for treatment with targeted tyrosine kinase inhibitors: guideline from the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology. *Arch Pathol Lab Med* 142(3):321–346.
4. Oncomine Dx Express Test User Guide.

 Learn more at thermofisher.com/oncomine-express-test

For In Vitro Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. ZEGFROVY® is a trademark of Dical (Jiangsu) Pharmaceutical Co., Ltd. HYRNUO is a registered trademark of Bayer. **BROC-13613026 0826**

Oncology Diagnostics > Oncomine Dx Express Test - US

Oncomine Dx Express Test

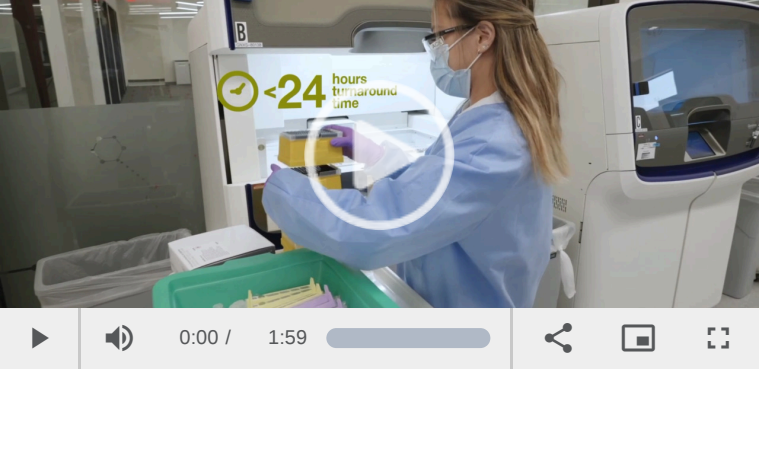
Request information

OverviewPathologistsOncologists

Connecting patients everywhere to precision oncology

In the rapidly evolving field of precision oncology, the increasing availability of targeted treatments offers renewed hope to patients. Unfortunately, the lengthy wait for next-generation sequencing (NGS) results—often weeks—and the risk of insufficient sample quantity (QNS) can diminish this hope. The FDA-approved Oncomine™ Dx Express Test is set to transform this process. Designed for implementation in laboratories without prior NGS expertise and close to patients, it delivers results in as little as 24 hours*—from tissue sample to report.

*Timing varies by number of samples and type of run.

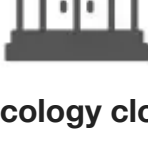


What can Oncomine Dx Express Test enable you to do?



Deliver NGS results in as little as 24 hours from tissue sample to report

The Oncomine Dx Express Test can eliminate the lengthy wait for a complete biomarker picture. It enables pathology labs to deliver results in as little as 24 hours, facilitating faster, more informed treatment decisions so that your patients don't have to wait weeks for results.



Bring precision oncology close to your patients

The Oncomine Dx Express Test is designed for implementation in local laboratories, enabling in-house testing. This supports timely, decentralized precision oncology by delivering NGS results close to patients.



Get results for more patients, even with a small sample size

The Oncomine Dx Express Test requires only 10 ng of DNA and RNA, which is significantly less sample input than other NGS technologies and therefore is more efficient even when tissue is limited or unavailable.

Hear from experts and users of the Oncomine Dx Express Test



David Chi
Director of Oncology Product
Management, Thermo Fisher Scientific



Gary Pestano, PhD
Chief Development Officer
Biodesix, Inc.



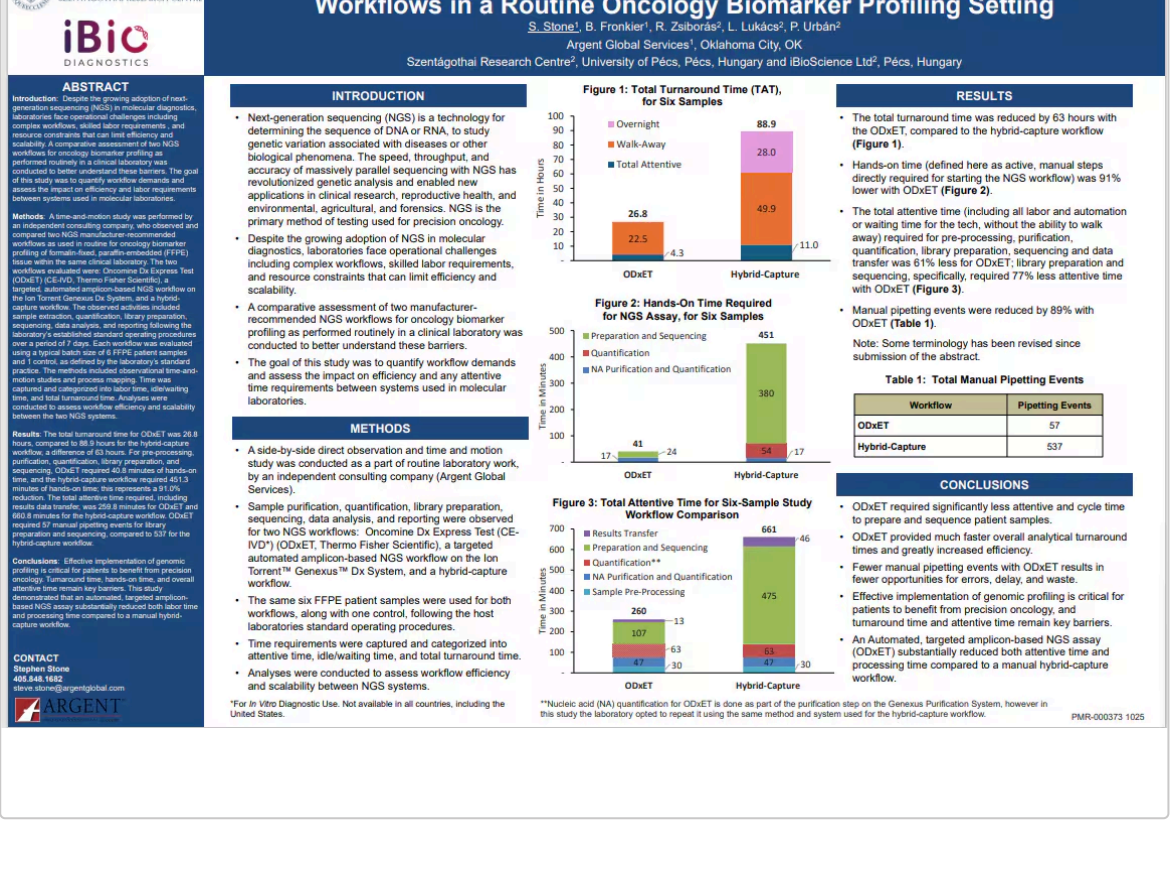
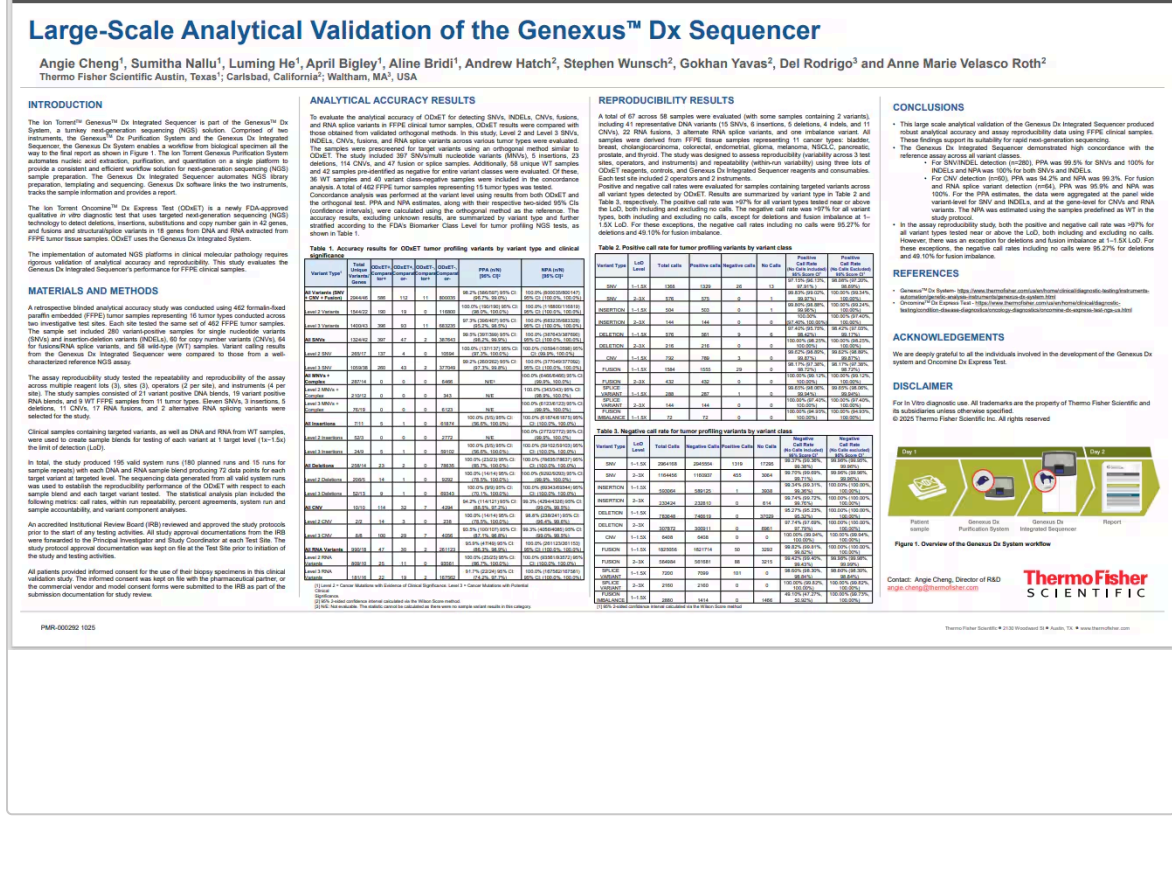
Bence Sipos, MD
Molecular Pathology
Baden-Württemberg, Stuttgart, Germany

Introduction of new FDA approved rapid NGS solution for Companion Diagnostics and tumor profiling in oncology

First experience in US and testimonials from his lab

Making an impact with rapid genomic profiling in community testing

AMP 2025 posters



Explore the Oncomine Dx Express Test

For oncologists

Explore now

For pathologists

Explore now

For pharma

Explore now

Table 1. Companion diagnostic indications

Specimen type	Tissue type	Gene	Variant	Targeted therapy
Tissue	Non-small cell lung cancer (NSCLC)	EGFR	EGFR exon 20 insertions	ZEGFROVY™ (sunitinib)
		ERBB2/HER2	ERBB2/HER2 activating mutations (SNVs in exons 18-21 within the tyrosine kinase domain and exon 20 insertions)	HYRNUO® (seabertinib)

Table 2. Oncomine Dx Express Test panel FFPE gene list for tumor profiling

DNA						RNA				
Substitutions, insertions, and deletions						Copy number variants		Fusions and splice variants		
AKT1	CDK4	ESR1	HRAS	MAP2K2	PIK3CA	AR	FGFR2	ALK	FGFR2	NTRK3
AKT2	CHEK2	FGFR1	IDH1	MET	PTEN	AFF	FGFR3	AR	FGFR3	NUTM1
AKT3	CTNNB1	FGFR2	IDH2	NRAS	RAF1	EGFR	FGFR3	BRAF	MET	RET
ALK	EGFR	FGFR3	KEAP1	NTRK1	RET	ERBB2	KRAS	EGFR	NRG1	ROS1
AR	ERBB2	FGFR4	KIT	NTRK2	ROS1	ERBB3	MET	ESR1	NTRK1	RSPO2
ARAF	ERBB3	FLT3	KRAS	NTRK3	STK11	FGFR1	PIK3CA	FGFR1	NTRK2	RSPO3
BRAF	ERBB4	GNAS	MAP2K1	PDGFRA	TP53					

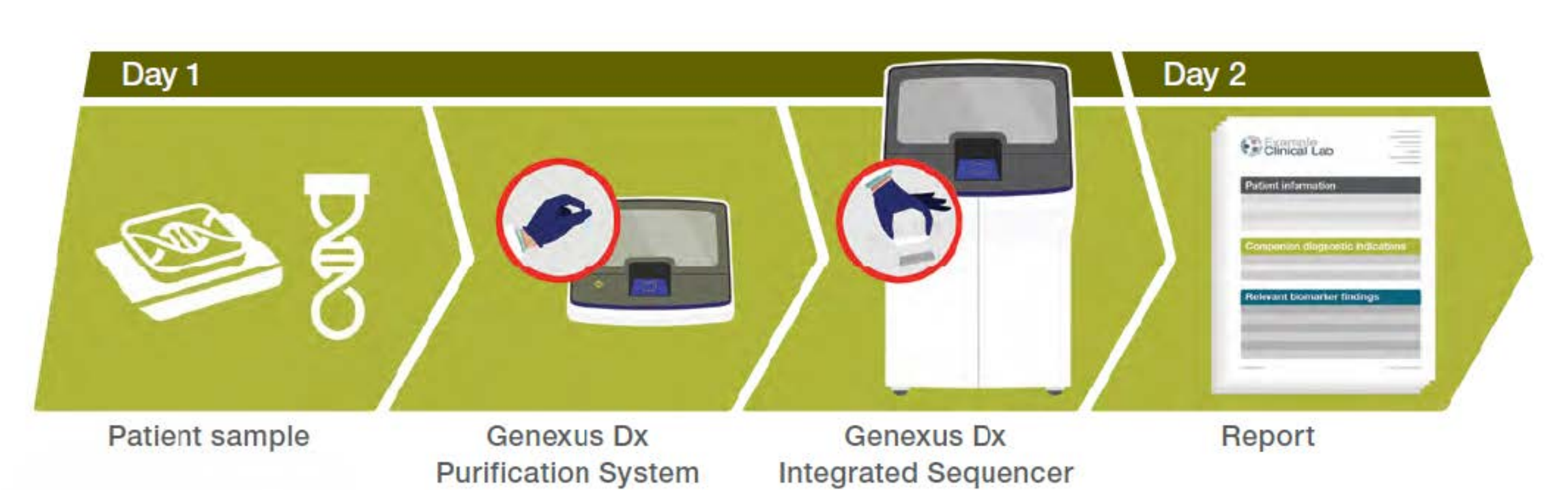
NGS made easy—2 instruments, 1 software, and as little as 20 minutes of hands-on time

The Genexus Dx System automates the NGS workflow from patient samples to reports with only two user touchpoints and as little as 20 minutes of hands-on time.

Pre-treated FFPE tissue sections are loaded onto the Genexus Dx Purification System and the instrument performs automated purification and quantification of DNA and RNA.

Library preparation, template preparation, sequencing, analysis, and reporting are performed by the Genexus Dx Integrated Sequencer. Throughout this procedure, sample and reagent information is recorded and tracked by one integrated software. This highly automated workflow helps reduce laboratory staff burden and the potential for human errors and alleviates the need for specialized bioinformatics expertise.

Infographic: Oncomine Dx Express Test



Oncomine Dx Express Test workflow

Explore now

- Flyer: Oncomine Dx Express Test for Physicians
- Flyer: Oncomine Dx Express Test
- Flyer: Oncomine Dx Express Test
- Brochure: Oncomine Dx Express Test
- Infographic: Oncomine Dx Express Test

Ordering information

Catalog #	Name	Size	Price	Qty
A54103	Oncomine™ Dx Express Test Panel	Each	Request A Quote	
				Add to cart

Ready to speak to a Thermo Fisher Scientific representative?

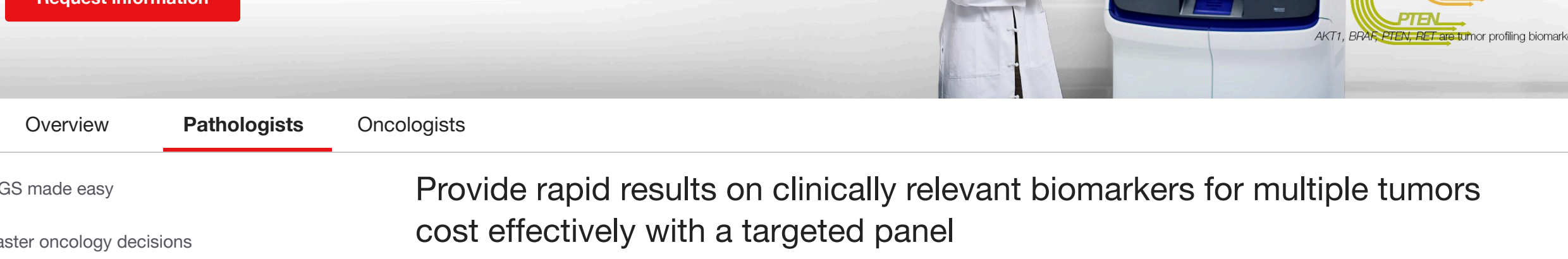
We will be happy to answer your questions about bringing NGS to your laboratory.

Request information

For In Vitro Diagnostic Use. Rx only.

Ordering	Support	Resources	About Thermo Fisher	Our Portfolio
Order Status	Help and Support	Learning Centers	About Us	Thermo Scientific
Order Help	Contact Us	Promotions	Careers	Applied Biosystems
Quick Order	Technical Support Centers	Events and Webinars	Investors	Invitrogen
Supply Center	Documents and Certificates	Social Media	News	Gibco
eProcurement	Report a Site Issue		Local Responsibility	Ion Torrent
			Trademarks	Fisher Scientific
			Consumer Health Data Privacy Policy	Unity Lab Services
			Policies and Notices	Patheon
				PPD

Oncomine Dx Express Test for Pathologists



NGS made easy

Faster oncology decisions

Analysis and reporting

One supplier

Performance characteristics

Clinical studies

Resources

Provide rapid results on clinically relevant biomarkers for multiple tumors cost effectively with a targeted panel

Whether you are currently utilizing next-generation sequencing (NGS) or still considering it, the FDA-approved Oncomine Dx Express Test is designed to streamline your workflow, minimize quantity not sufficient (QNS), and enable you to connect more patients to precision oncology fast.

The Oncomine Dx Express Test indicated as a companion diagnostic (CDx) to identify patients who may benefit from targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling.

The test also detects tumor profiling biomarkers recommended by professional guidelines for multiple solid tumors (Table 2). This includes substitutions, insertions, and deletions in 42 genes, copy number variants (CNVs) in 10 genes, and fusions or splice variants in 18 genes from DNA and RNA extracted from FFPE tumor tissue (relevant in non-small cell lung cancer (NSCLC), colorectal cancer, cholangiocarcinoma, melanoma, and others).

Table 1. Companion diagnostic indications

Specimen type	Tissue type	Gene	Variant	Targeted therapy
Tissue	Non-small cell lung cancer (NSCLC)	EGFR	EGFR exon 20 insertions	ZEGFROVY™ (sunitinib)
		ERBB2/HER2	ERBB2/HER2 activating mutations (SNVs in exons 18-21 within the tyrosine kinase domain and exon 20 insertions)	HYRNUO® (sevaterinib)

Table 2. Oncomine Dx Express Test panel FFPE gene list for tumor profiling

DNA						RNA				
Substitutions, insertions, and deletions						Copy number variants		Fusions and splice variants		
AKT1	CDK4	ESR1	HRAS	MAP2K2	PIK3CA	AR	FGFR2	ALK	FGFR2	NTRK3
AKT2	CHEK2	FGFR1	IDH1	MET	PTEN			AR	FGFR3	NUTM1
AKT3	CTNNB1	FGFR2	IDH2	NRAS	RAF1			BRF	MET	RET
ALK	EGFR	FGFR3	KEAP1	NTRK1	RET			EGFR	NTRK1	ROS1
AR	ERBB2	FGFR4	KIT	NTRK2	ROS1			ESR1	NTRK2	RSPO2
ARAF	ERBB3	FLT3	KRAS	NTRK3	STK11	FGFR1	PIK3CA	FGFR1		RSPO3
BRAF	ERBB4	GNAS	MAP2K1	PDGFRA	TP53					

NGS made easy—2 instruments, 1 software, and as little as 20 minutes of hands-on time

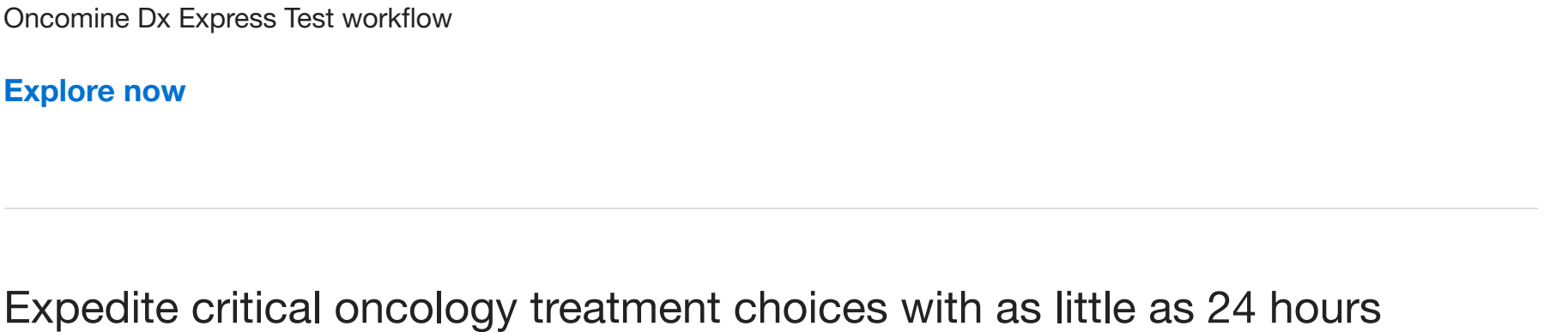
2 instruments

1 software

Pre-treated FFPE tissue sections samples are loaded onto the [Genexus Dx Purification System](#) and the instrument performs automated purification and quantification of DNA and RNA.

Library preparation, template preparation, sequencing, analysis, and reporting are performed by the Genexus Dx Integrated Sequencer. Throughout this procedure, sample and reagent information is recorded and tracked by one integrated software. This highly automated workflow helps reduce laboratory staff burden and the potential for human errors and alleviates the need for specialized bioinformatics expertise.

[Infographic: Oncomine Dx Express Test](#)



Oncomine Dx Express Test workflow

[Explore now](#)

Expedite critical oncology treatment choices with as little as 24 hours turnaround time

<24 hours

turnaround time

* Timing varies by number of samples and type of run

Table 3. FFPE sample-to-report turnaround times

Lane	Sample batch size	Turnaround time
1	2 samples	18 hours
2	6 samples	26 hours 50 minutes
4	12 samples	38 hours 25 minutes

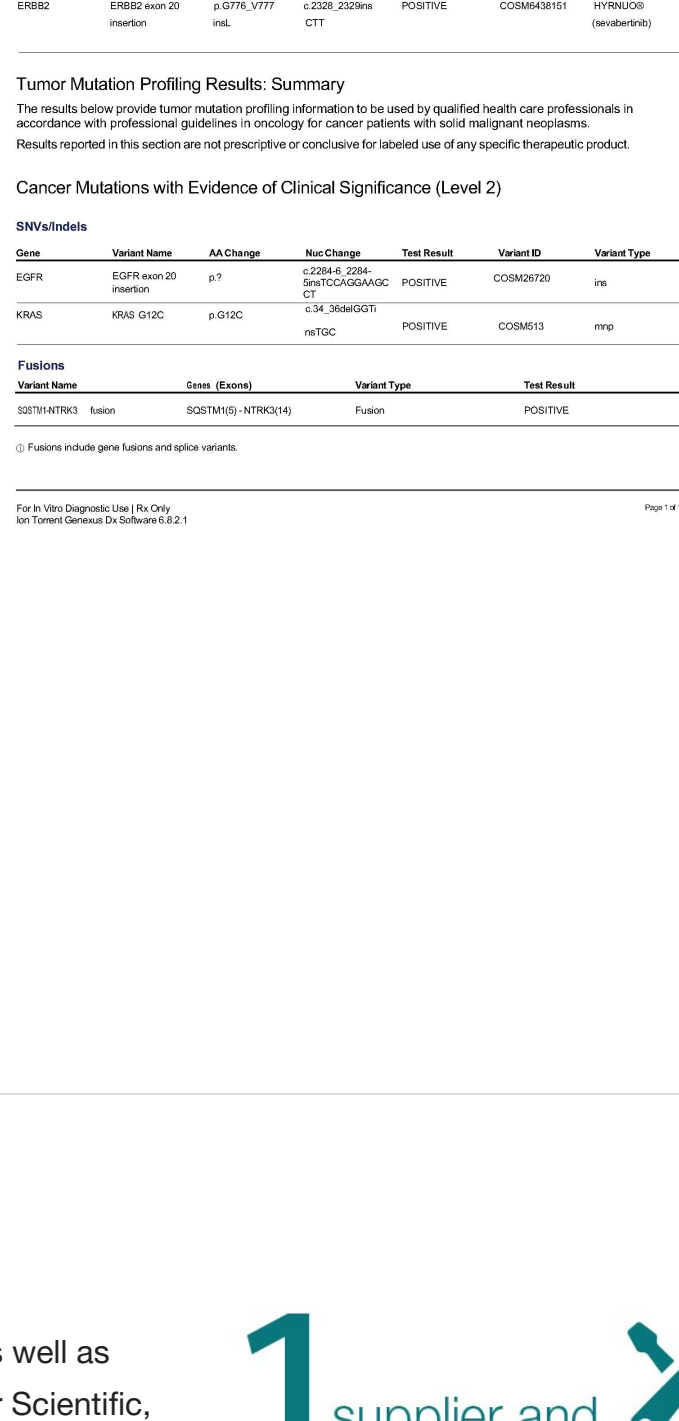
Step into NGS with confidence thanks to automated informatics and reporting

The Genexus Dx Software directs the progress of the sample from creation of a run plan through automated sample preparation, library preparation, template preparation, sequencing, and analysis. The Genexus Dx Software generates the following results and reports for each sequenced sample and its associated controls.

- Quality control, key findings, and variant screens
- Run report
- Clinical test report
- Clinical laboratory report

Quality control specifications throughout the NGS workflow are automatically applied to streamline interpretation and help ensure reportable results are accurate. Positive calls are classified into 3 biomarker levels for FFPE samples. The layout and contents of the report can be customized to facilitate a clear and concise report, providing clinicians with relevant information tailored to the patient.

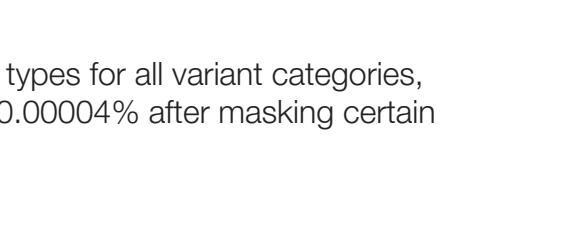
[Flyer: Oncomine Dx Express Test report](#)



© 2019 ThermoFisher Scientific. All rights reserved. All trademarks are the property of ThermoFisher Scientific and its subsidiaries unless otherwise specified.

One supplier for all your NGS needs

Everything from instruments, software, reagents, and consumables, as well as service and ongoing support, comes from one supplier: Thermo Fisher Scientific, which aims to make your implementation, as well as day-to-day running of this workflow, as simple as possible.



Rely on the proven performance of an FDA-approved test

Extensive performance studies were conducted to establish performance characteristics of the Oncomine Dx Express Test for FFPE tumor samples. A summary of selected studies is provided below. For complete studies and results, refer to the Oncomine Dx Express Test User Guide.

- Limit of blank**
 - Per-position false positive rate: 0% across 24 blank samples representing 10 tissue types for all variant categories, except for Level 3 SNVs. For Level 3 SNVs, the per-position false positive rate was 0.0004% after masking certain Level 3 SNVs with variant allele frequencies below 5% to prevent false positives.
 - Per-sample false positive rate: 0% across the same 24 blank samples and 10 tissue types for all variant categories, except for Level 3 SNVs. For Level 3 SNVs, the per-sample false positive rate was 0.52% after masking certain Level 3 SNVs with variant allele frequencies below 5% to prevent false positives.
- Limit of detection - CDx variants**
 - 3.24% to 4.38% allelic frequency for *EGFR* exon 20 insertion CDx variants with insertion lengths of 3, 6, 9, and 12 bp
 - 2.98% to 4.07% allelic frequency for *ERBB2/HER2* exon 20 insertion variants with insertion lengths of 3, 6, 9, and 12 bp
 - 3.60% to 6.42% allelic frequency for *ERBB2/HER2* SNVs
- Limit of detection - tumor profiling variants**
 - 3.24% to 7.34% allelic frequency for SNVs
 - 2.98% to 5.62% allelic frequency for insertions
 - 3.08% to 4.67% allelic frequency for deletions
 - 4.56 to 5.78 copies for CNVs
 - 5.0 to 15.5 molecular counts for RNA fusion variants
 - 1.5 to 4.93 imbalance scores for RNA fusions by expression imbalance
- Panel reproducibility study - *EGFR* exon 20 insertions**

The panel reproducibility study was conducted at multiple test sites to evaluate the repeatability and reproducibility of the Oncomine Dx Express Test for detection of CDx variants starting from extracted nucleic acid.

 - Reproducibility: The positive call rate was 100% for all *EGFR* exon 20 insertion variants, with no instances of no calls observed. The negative call rate was estimated using two wild-type (WT) NSCLC samples and was calculated for hotspots within the scope of the study. For WT samples, the negative call rate was 100.0%, excluding no calls.
 - Repeatability: Repeatability for the detection of *EGFR* exon 20 insertion variants was evaluated by assessing within-run variability. When including or excluding no call results, within-run repeatability was 100%. For WT samples, when including or excluding no call results, within-run repeatability was 100%.
- Panel reproducibility study - *ERBB2/HER2* exon 20 insertions and SNVs**
 - Reproducibility: The positive call rate was 100% for all *ERBB2/HER2* exon 20 insertion variants (3 bp, 9 bp, and 12 bp) across both LoD levels tested (1–1.5X and 2–3X LoD), with no instances of no calls observed. The negative call rate was evaluated using two wild-type (WT) NSCLC FFPE samples and calculated for relevant hotspots. For WT samples, the negative call rate was 100%, excluding no calls.
 - Reproducibility: The positive call rate was 100% for both *ERBB2/HER2* SNVs (G776V and R896H) at both LoD levels tested (1.2–3.0X LoD), with no instances of no calls observed in variant-positive samples. The negative call rate, evaluated using WT NSCLC samples and calculated for relevant hotspots, was ≥99.3%, excluding no calls (100% in one WT sample and 99.3% in the other).
 - Repeatability: Repeatability for the detection of *ERBB2/HER2* exon 20 insertion variants was evaluated by assessing within-run variability. When including or excluding no call results, within-run repeatability was 100%. For WT samples, when including or excluding no call results, within-run repeatability was ≥97.2% across all samples. For variant-positive samples, repeatability was 100%. For WT samples, repeatability ranged from 97.2% to 100% when excluding no calls, and 94.4% to 100% when including no calls.
- Panel reproducibility study – tumor profiling variants**

Analytical accuracy—tumor profiling variants

The accuracy of the Oncomine Dx Express Test for detecting SNVs, indels, CNVs, fusions, and RNA splice variants was evaluated by comparing its results with those obtained from validated orthogonal methods across three separate studies.

- Accuracy Study I**

The accuracy study I evaluated the accuracy of the Oncomine Dx Express Test in detecting various tumor profiling variants, including SNV/multi-nucleotide variants (MNVs), indels, CNVs, and RNA splice variants in FFPE clinical samples using a representative approach, comparing its results with the validated NGS orthogonal test. PPA and NPA estimates and the respective 95% confidence interval (CI) between Oncomine Dx Express Test and the orthogonal test were calculated using the orthogonal test result as reference and are summarized in Table 4.

Variant type	Oncomine Dx Express Test+, ortho test+	Oncomine Dx Express Test+, ortho test-	Oncomine Dx Express Test-, ortho test+	Oncomine Dx Express Test-, ortho test-	PPA (n/N) [95% CI]	NPA (n/N) [95% CI]
All variants	586	112	11	800,035	98.2% (586/597) [96.7%, 99.0%]	100.0% (800,035/800,147) [100.0%, 100.0%]
All SNVs	397	47	2	387,643	99.5% (397/399) [98.2%, 99.9%]	100.0% (387,634/387,690) [100.0%, 100.0%]
All insertions	5	1	0	61,874	100.0% (5/5) [85.6%, 100.0%]	100.0% (61,874/61,875) [100.0%, 100.0%]
All deletions	23	2	0	78,635	100.0% (23/23) [85.7%, 100.0%]	100.0% (78,635/78,637) [100.0%, 100.0%]
All CNVs	114	32	7	4,294	94.2% (114/121) [88.5%, 97.2%]	99.3% (4,294/4,326) [99.0%, 99.6%]
All RNA variants	47	30	2	261,123	95.9% (47/49) [86.3%, 98.9%]	100.0% (261,123/261,153) [100.0%, 100.0%]

* ortho – orthogonal

- Accuracy Study II**

The accuracy study II evaluated the accuracy of the Oncomine Dx Express Test in detecting *ERBB2* CNVs, *ALK* fusions, and *RET* fusions by comparing its results with validated orthogonal assays, as summarized in Table 5.

Variant type	Oncomine Dx Express Test+, ortho test+	Oncomine Dx Express Test+, ortho test-	Oncomine Dx Express Test-, ortho test+	Oncomine Dx Express Test-, ortho test-	PPA (n/N) [95% CI]	NPA (n/N) [95% CI]
Level 2 <i>ERBB2</i> CNVs	29	4	0	37	100.0% (29/29) [85.7%, 100.0%]	90.2% (34/37) [77.0%, 96.1%]
Level 2 <i>ALK</i>	26	1	0	41	100.0% (11/11) [87.1%, 100.0%]	97.6% (45/46) [87.7%, 99.6%]
Level 2 <i>RET</i>	17	1	0	34	100.0% (17/17) [81.6%, 100.0%]	97.1% (34/35) [85.6%, 99.5%]

* ortho – orthogonal

- Accuracy Study III**

The accuracy study III evaluated the accuracy of the Oncomine Dx Express Test in detecting *EGFR* T790M and *EGFR* L858R SNVs, and *EGFR* exon 19 deletions, by comparing its results with an orthogonal PCR method, as summarized in Table 6.

Variant type	Oncomine Dx Express Test+, ortho test+	Oncomine Dx Express Test+, ortho test-	Oncomine Dx Express Test-, ortho test+	Oncomine Dx Express Test-, ortho test-	PPA (n/N) [95% CI]	NPA (n/N) [95% CI]
All <i>EGFR</i>	23	1	0	45	100.0% (23/23) [85.7%, 100.0%]	97.6% (45/46) [87.7%, 99.6%]
Level 2 <i>EGFR</i>	23	1	0	45	100.0% (23/23) [85.7%, 100.0%]	97.6% (45/46) [87.7%, 99.6%]
SNV <i>EGFR</i>	11	1	0	45	100.0% (11/11) [87.1%, 100.0%]	97.6% (45/46) [87.7%, 99.6%]
Deletion <i>EGFR</i>	12	0	0	45	100.0% (12/12) [75.8%, 100.0%]	100.0% (45/45) [92.1%, 100.0%]

* ortho – orthogonal

- Clinical accuracy—*ERBB2/HER2* TKD activating mutations**

The ability of the Oncomine Dx Express Test in detecting *ERBB2/HER2* TKD activating mutations from FFPE tumor specimens of patients with NSCLC was also evaluated by comparing results of the Oncomine Dx Express Test to results obtained with the enrolling clinical trial assays (CTAs). All 80 mutation-positive specimens were correctly identified, and 129 of 130 mutation-negative specimens were confirmed negative by the Oncomine Dx Express Test. The PPA, NPA, and OPA were 100.0%, 99.2%, and 99.5%, respectively.

Featured resources

- [Flyer: Oncomine Dx Express Test](#)
- [Flyer: Oncomine Dx Express Test report](#)
- [Brochure: Oncomine Dx Express Test](#)
- [Infographic: Oncomine Dx Express Test](#)

Ready to speak to a Thermo Fisher Scientific representative?

We will be happy to answer your questions about bringing NGS to your laboratory.

[Request information](#)

For In Vitro Diagnostic Use. Rx only.

Ordering	Support	Resources	About Thermo Fisher	Our Portfolio
Order Status	Help and Support	Learning Centers	About Us 🔗	Thermo Scientific
Order Help	Contact Us	Promotions	Careers 🔗	Applied Biosystems
Quick Order	Technical Support Centers	Events and Webinars	Investors 🔗	Invitrogen
Supply Center	Documents and Certificates	Social Media	News 🔗	Gibco
eProcurement	Report a Site Issue		Social Responsibility 🔗	Ion Torrent
			Trademarks	Fisher Scientific
			Consumer Health Data Privacy Policy 🔗	Unity Lab Services
			Policies and Notices	Pathcon
				PPD

Oncomine Dx Express Test for Oncologists

Request information

- Overview

Pathologists

Oncologists

- Fast NGS results
- More patients results
- Improve care coordination
- Resources

Supporting faster and more informed decisions for your patients

In the rapidly advancing field of precision oncology, the growing number of targeted treatments brings new hope to your patients. However, waiting weeks for next-generation sequencing (NGS) results, and then possibly not receiving them due to quantity not sufficient (QNS) can diminish this hope. Here is how the Oncomine Dx Express Test, implemented in your pathology laboratory can enhance your patient care.

- Flyer: Oncomine Dx Express Test
- Flyer: Oncomine Dx Express Test report

Make treatment decisions without waiting for delayed NGS results



Oncomine Dx Express Test delivers genomic profiles in as little as 24 hours—so you can move quickly when timing matters most.

* Timing varies by number of samples and type of run.

Get results for more patients

How often are you left without answers because of the technology used? Oncomine Dx Express Test works reliably with minimal input—just two formalin-fixed paraffin embedded (FFPE) slides, so you get a result for your patients even when tissue is limited or unavailable.



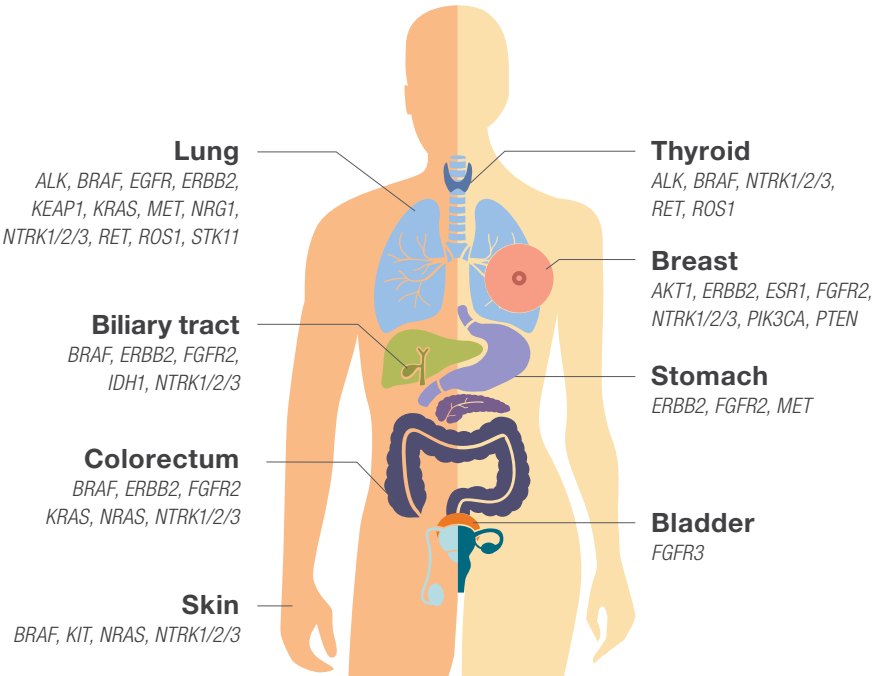
Improve care coordination



Oncomine Dx Express Test workflow can be implemented even in smaller and NGS naïve labs, so it can be implemented also in your institution. Having the pathologists and molecular pathology experts just a phone call away and available for multi-disciplinary meetings will help to improve care for your patient. In addition, the sample will stay in-house, ready for additional tests should they be needed.

Gain informative results

The Oncomine Dx Express Test interrogates 46 genes associated with multiple solid tumor types, providing broad molecular information from one test.



Featured resources

- Flyer: Oncomine Dx Express Test
- Flyer: Oncomine Dx Express Test report
- Flyer: Oncomine Dx Express Test for Physicians

Ready to speak to a Thermo Fisher Scientific representative?

We will be happy to answer your questions about bringing NGS to your laboratory.

Request information

For *In Vitro* Diagnostic Use. Rx only.

Ordering	Support	Resources	About Thermo Fisher	Our Portfolio
Order Status	Help and Support	Learning Centers	About Us ↗	Thermo Scientific
Order Help	Contact Us	Promotions	Careers ↗	Applied Biosystems
Quick Order	Technical Support Centers	Events and Webinars	Investors ↗	Invitrogen
Supply Center	Documents and Certificates	Social Media	News ↗	Gibco
eProcurement	Report a Site Issue		Social Responsibility ↗	Ion Torrent
			Trademarks	Fisher Scientific
			Consumer Health Data Privacy Policy ↗	Unity Lab Services
			Policies and Notices	Patheon
				PPD



All the biomarkers are for tumor profiling except for EGFR exon 20 insertion and ERBB2/HER2 activating mutation.

Accelerate treatment decisions for your cancer patients with rapid NGS results from your local lab

In the rapidly advancing field of precision oncology, the growing number of targeted treatments brings new hope to your patients. Now, with our in-house rapid NGS solution, the Ion Torrent™ Oncomine™ Dx Express Test, we can help you connect your patients with these treatments fast.



Results of clinically relevant biomarkers

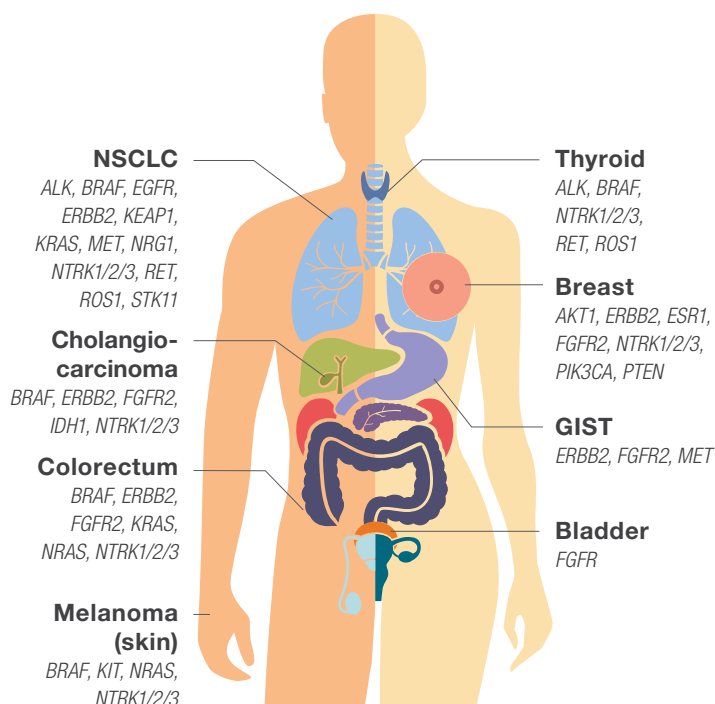


Within 3 days on average



Even for small samples

Clinical guidelines recommend genomic profiling to assess multiple biomarkers in a number of advanced cancers. In addition, it is recommended to profile for tumor-agnostic alterations (NTRK1/2/3, RET, BRAF, FGFR1/2/3) in patients with metastatic cancers where access to matched therapies is available, and in cancer of unknown primary.



Do you have questions?

We are just a phone call or email away

No time or tissue to waste!

Faster answers...

Longer TAT means more patients begin therapy **without** molecular results and miss first-line targeted options; recent US real-world analyses explicitly flag **long test TAT as lowering receipt of appropriate targeted therapy**. Our rapid NGS test can deliver results **in 3 days**.

...from less tissue...

Compared to other NGS technologies, the OncoPrint Dx Express Test requires **significantly less sample input**, and it is also compatible with core-needle biopsies and fine-needle aspirates. Using less sample conserves it for potential next tests required and results **in less QNS for your patients**, allowing them to potentially benefit from targeted treatments.

...with the OncoPrint Dx Express Test

Other NGS technologies



OncoPrint Dx Express Test



Figure 1. Comparison of specimen requirements.

Table 3. The OncoPrint Dx Express Test FFPE panel gene list.

DNA						RNA				
Substitutions, insertions, and deletions						Copy number variants		Fusions and splicing variants		
AKT1	CDK4	ESR1	HRAS	MAP2K2	PIK3CA	AR	FGFR2	ALK	FGFR2	NTRK3
AKT2	CHEK2	FGFR1	IDH1	MET	PTEN	EGFR	FGFR3	AR	FGFR3	NUTM1
AKT3	CTNNB1	FGFR2	IDH2	NRAS	RAF1	ERBB2	KRAS	BRAF	MET	RET
ALK	EGFR	FGFR3	KEAP1	NTRK1	RET	ERBB3	MET	EGFR	NRG1	ROS1
AR	ERBB2	FGFR4	KIT	NTRK2	ROS1	FGFR1	PIK3CA	ESR1	NTRK1	RSPO2
ARAF	ERBB3	FLT3	KRAS	NTRK3	STK11			FGFR1	NTRK2	RSPO3
BRAF	ERBB4	GNAS	MAP2K1	PDGFRA	TP53					

Laboratory ordering information

Together, let's elevate the care for cancer patients in
Molecular Tumor Boards with rapid results from our laboratory.



Do you have questions?
We are just a phone call or email away

The Oncomine Dx Express Test can enhance your patient care



Rapid

First-line therapy decisions depend on timely genomic insights. Next-generation sequencing (NGS) testing that once took weeks is now achievable in as little as 24 hours* with the Ion Torrent™ Oncomine™ Dx Express Test.



Accessible

A validated and highly automated end-to-end workflow—with software and a reporting solution that doesn't require bioinformatics expertise—enables implementation even in labs without NGS expertise or extensive resources.

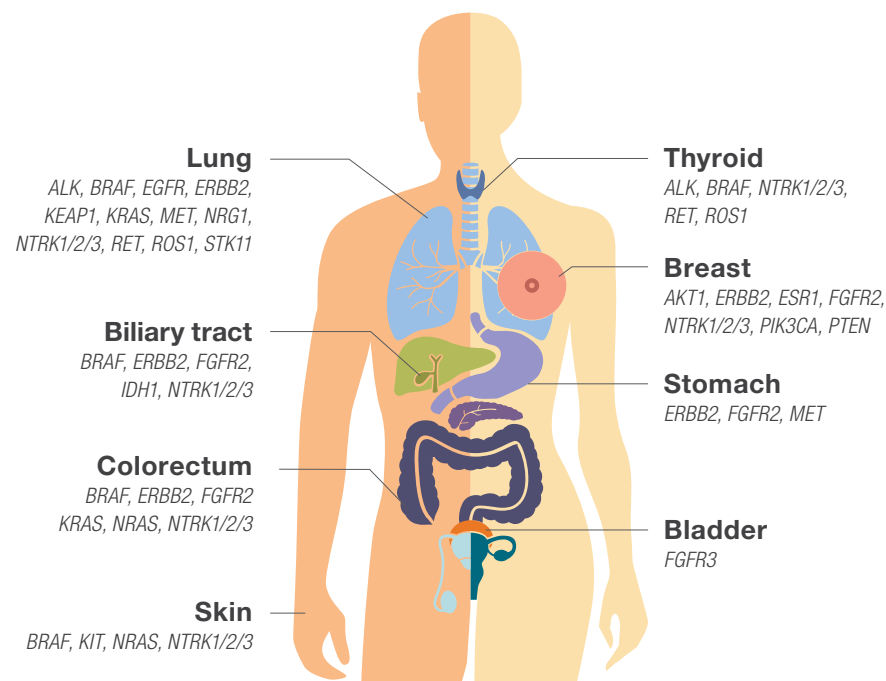


Sample saving

The Oncomine Dx Express Test works reliably with minimal input—just two formalin-fixed paraffin-embedded (FFPE) slides, so you get a result for your patients even when tissue is limited.

Informative

The Oncomine Dx Express Test analyzes 46 genes from FFPE tumor tissue relevant across multiple solid tumors.



Ask your local pathology lab for rapid NGS results with Oncomine Dx Express Test.

*Timing varies by number of samples and type of run.

Learn more at thermofisher.com/oncomine-express-test



Ask your local pathology lab for rapid NGS results with Oncomine Dx Express Test.

Learn more at thermofisher.com/oncomine-express-test

For In Vitro Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **FLY-13611825 0226**



AKT1, ALK, ESR1, RET are tumor profiling biomarkers.

Genexus Dx Software

Clinical NGS analysis and reporting—without the need for bioinformatics expertise

The Ion Torrent™ Genexus™ Dx System consists of two instruments, the Ion Torrent™ Genexus™ Dx Purification System and the Ion Torrent™ Genexus™ Dx Integrated Sequencer—both controlled by the powerful and intuitive Ion Torrent™ Genexus™ Dx Software. This clinical NGS platform automates the workflow, from patient specimen to clinical report. The workflow requires only 2 manual touchpoints and as little as 20 minutes of hands-on time, and is controlled by one software from beginning to end. The Genexus Dx System enables clinical laboratories to deliver biomarker results in as little as 24 hours.



ion torrent

The Genexus Dx Software makes in-house clinical NGS testing fast and easy with existing laboratory staff and minimal training required. This simple software directs the user through the following steps of the clinical NGS workflow:

1. One run plan creation for the entire workflow from nucleic acid extraction to report
2. Analysis, including automatically applied quality control parameters to help ensure generated results are accurate
3. Clinical report generation

During and after sequencing, the software automatically generates base calls, trims reads, and determines quality values (primary analysis), then aligns reads, calls variants, and generates reports (secondary analysis).

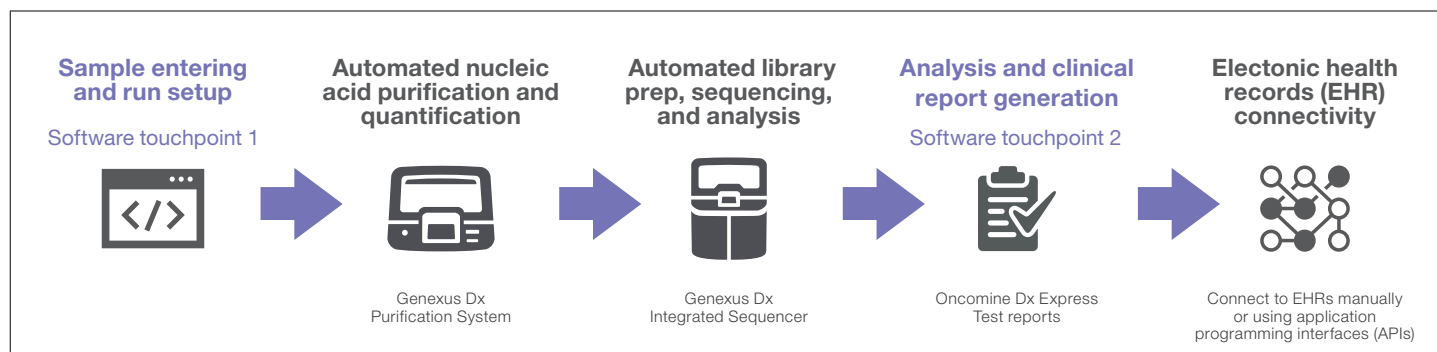


Figure 1. Genexus Dx Software powers the *in vitro* diagnostic (IVD) Ion Torrent™ Oncomine™ Dx Express Test for solid tumor genomic profiling. A single intuitive software guides users through the clinical NGS workflow, from run setup through informatics and reporting.

One interface to manage the complete workflow

Genexus Dx | Ion Torrent

Samples / Manage Samples

Filter Samples by... Manage Tags + Create Sample Columns

Selected Samples: 1 Clear Edit Copy Delete Export Assign Tags Prepare Library Batch

Sample Name	Patient ID	Ordering Physician	Collection Date	Application Category	Cancer Type
☐ SRTTestSample05	P105	ph101	2018-04-30	Cancer	Non-Small Cell Lung Cancer
☒ SRTTestSample04	P104	ph104	2018-04-30	Cancer	Non-Small Cell Lung Cancer
☐ SRTTestSample03	P103	ph103	2018-04-30	Cancer	Non-Small Cell Lung Cancer

- ① **Dashboard**—View recent run history, and current sequencing run status.
- ② **Samples**—Add new samples, import samples, prepare library batches, import library batches, and manage attributes.
- ③ **Runs**—Plan a run starting from a nucleic acid sample or a library. View, edit, and manage runs.
- ④ **Results**—View sample results, run results, and verification results.
- ⑤ **Assays**—View and manage assays.
- ⑥ **Notifications**—Receive alerts and messages for password expiration, system critical service failures, system backup failures, available software updates, and full disk space.
- ⑦ **Settings**—Access audit records and run logs, configure network settings, manage backup settings, restore runs, link to Connect user accounts, check for software updates, and manage data archiving, disk space, and users.
- ⑧ **Profile**—Access the Help system, manage and edit user profile settings, configure an SSH key (system administrator only), and sign out.

OncoPrint Dx Express Test reports

The OncoPrint Dx Express Test provides two types of reports in Genexus Dx Software.

1. Variant reports:

- Clinical Test Report: includes variants generated for each sample in a sequencing run
- Clinical Laboratory Report: contains all the information in the Clinical Test Report, in addition to the QC Metrics, Sequencing Run Details, Reagents, and Kit Barcodes sections

2. Run report: includes assay metrics and the record of reagents that were used in a run

In the variant reports, the positive calls are classified into biomarker categories, from companion diagnostics (CDx) biomarkers to biomarkers with potential clinical significance.

The customizable layout and contents of the OncoPrint Dx Express Test report are clear and concise, providing clinicians with relevant and actionable information tailored to the patient—all without any manual analysis or the need for extensive bioinformatics experience or expertise.

Patient sample information includes details such as cancer type, cancer stage, sample type, and cellularity. You can customize the format of the sample details.

Level 1: Companion Diagnostics (CDx) Biomarkers—gene variants that have companion diagnostics claims in the corresponding cancer type that are associated with an FDA-approved therapy as listed in Table 1 of the Intended Use Statement.

Level 2: Cancer Mutations with Evidence of Clinical Significance—gene variants that are not prescriptive or conclusive for labeled use of a specific therapeutic product, and for which clinical validation has not been performed, but which have curated clinical evidence associated with FDA-approved therapies and/or clinical guidelines in the sample cancer type.

Level 3: Cancer Mutations with Potential Clinical Significance—gene variants not considered Level 1 or Level 2 biomarkers that can be described as cancer mutations with potential clinical significance. These variants are not prescriptive or conclusive for labeled use of a specific therapeutic product, and clinical validation has not been performed. These variants have curated clinical evidence associated with clinical guidelines in a different cancer type or in any cancer type. They may also have curated evidence as an enrollment criterion in clinical trials or biomarkers with evidence in peer-reviewed literature.

Clinical Laboratory Report: OncoPrint™ Dx Express Test - FFPE - RS v5.0.0

Patient ID: PID01

Date of Birth: 30 MAR 1975

Date: 26 JUN 2025

180 Oyster Point Blvd
South San Francisco

Sample	Patient
Sample Name: FFPE01_D7_420	Patient ID: PID01
Cancer Type: Non-Small Cell Lung Cancer	Gender: Male
Cancer Stage: Stage IV	Date of Birth: 30 MAR 1975
Sample Type: FFPE	Collection Date: 22 FEB 2021
%Cellularity: 100	Ordering Physician: Dr. Lee
%Necrosis:	Created On: 02 APR 2025 21:29

Companion Diagnostics (CDx) Biomarkers

SNVs/Indels

Gene	Variant Name	AA Change	Nuc Change	Test Result	Variant ID	Associated Therapy
ERBB2	ERBB2 L755P	p.L755P	c.2263_2264del TTinsCC	POSITIVE	COSM683	HYRNUO® (sevabertinib)

Tumor Mutation Profiling Results: Summary

The results below provide tumor mutation profiling information to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with solid malignant neoplasms. Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product.

Cancer Mutations with Evidence of Clinical Significance (Level 2)

SNVs/Indels

None Detected

Fusions

None Detected

① Fusions include gene fusions and splice variants.

CNVs

None Detected

Cancer Mutations with Potential Clinical Significance (Level 3)

SNVs/Indels

For In Vitro Diagnostic Use | Rx Only
Ion Torrent Genexus Dx Software 6.8.2.1

Page 1 of 152

Figure 2. OncoPrint Dx Express Test FFPE report



OncoPrint Knowledgebase

Biomarker interpretation and variant classifications in the OncoPrint Dx Express Test clinical report are powered by the Ion Torrent™ OncoPrint™ Knowledgebase, an expertly curated proprietary knowledgebase of biologically and clinically (diagnostic, prognostic, and therapeutic) relevant and actionable biomarkers.

OncoPrint Knowledgebase compiles the latest publicly available information from:

- Clinical trials
- Clinical guideline recommendations
- Approved cancer therapies from regulatory agencies
- Peer-reviewed publications

The knowledgebase is curated by a dedicated team of scientists who study genetic variants, helping ensure that confident patient management decisions are made based on the most current and relevant clinical evidence.

Connectivity to the information systems

The Genexus Dx Software can connect and integrate with your preferred information software systems through its APIs. You can use the Genexus Dx Software APIs to enable connectivity with your laboratory information management system (LIMS), allowing you to create the samples and access the clinical reports. You can then optionally connect to your EHR or other information technology (IT) systems.

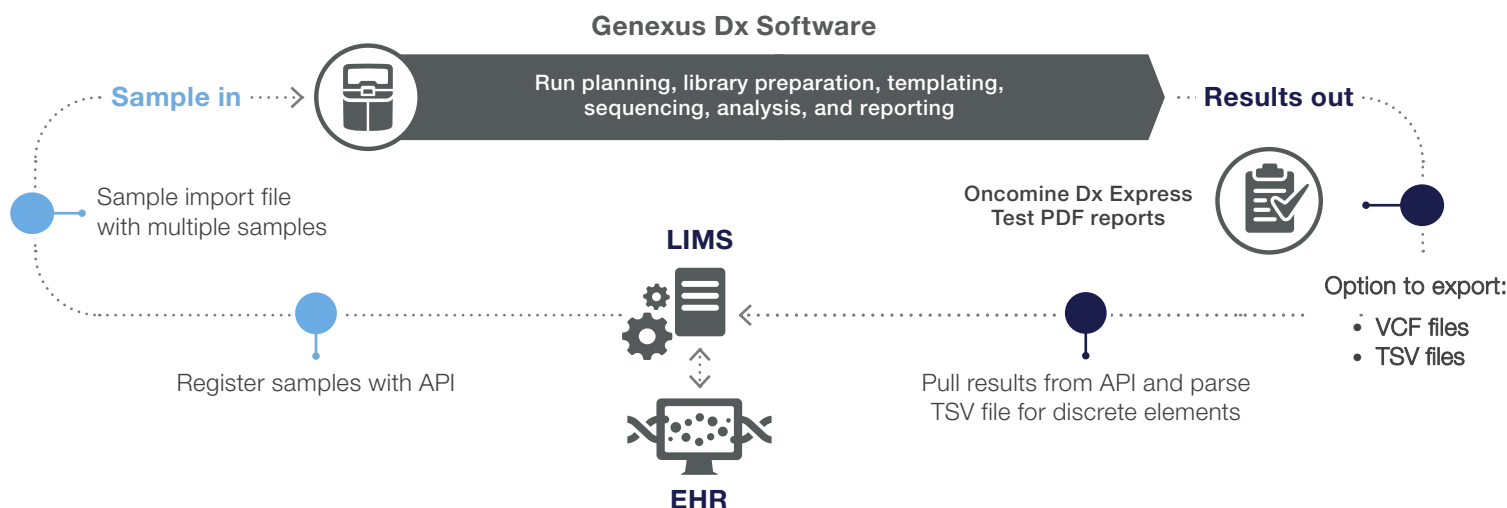


Figure 3. Integrate sample registration and clinical reporting with your existing EHR using APIs.

Flexible capabilities

The Genexus Dx Software has dual-mode capabilities, allowing users to run IVD assays and research assays on a single NGS platform. While the IVD mode provides a guided workflow from patient specimen to clinical report when using compatible IVD-certified assays—OncoPrint Dx Express Test—the Assay Development mode also has a guided workflow and enables a variety of research applications and customized assays to be run on the Genexus Dx Integrated Sequencer for clinical research. Run IVD assays or research assays on the same instruments with dual-mode software.

Learn more about the Genexus Dx System
at thermofisher.com/genexusdx and
thermofisher.com/oncoPrint-express-test

ion torrent

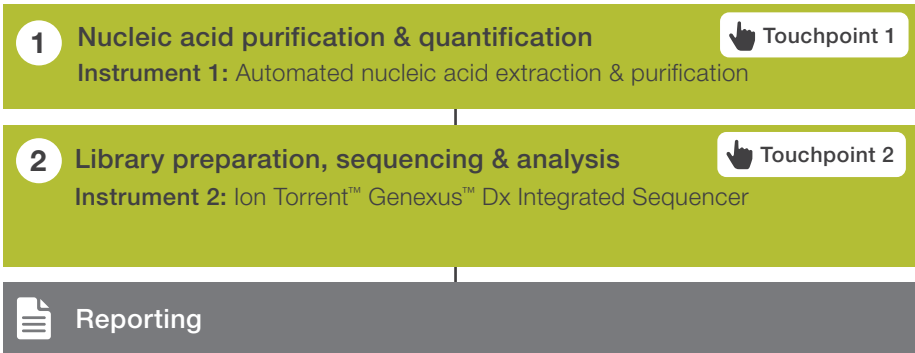
Unlock efficiency in your pathology laboratory with automated amplicon-based NGS

Reduce hands-on time, accelerate turnaround time, and maximize productive time with an integrated and efficient NGS system

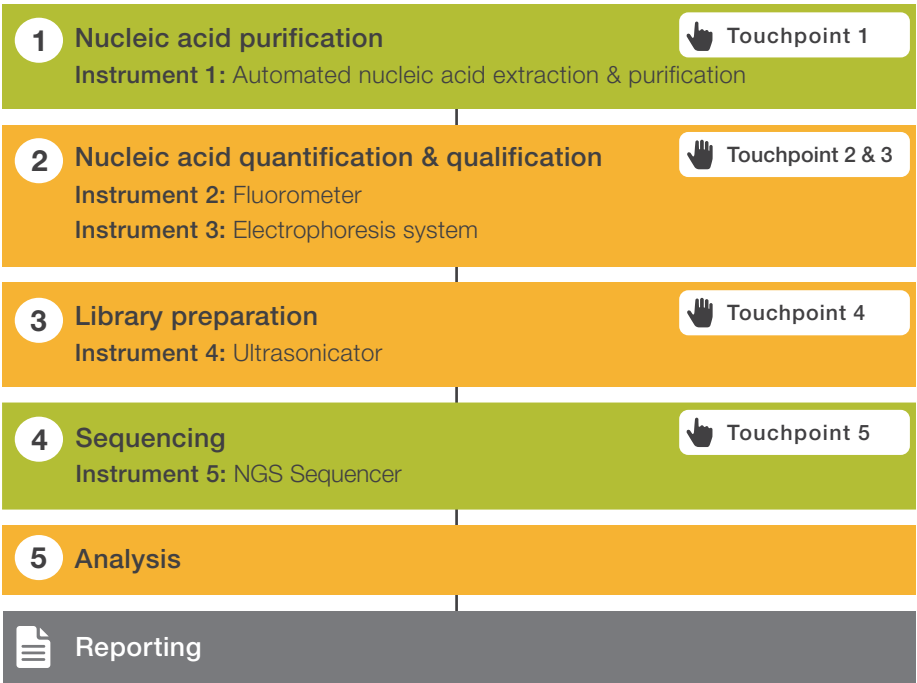
Operational challenges—including complex workflows, skilled staff requirements, and fragmented workflows with numerous touchpoints limit efficiency and scalability in pathology laboratories. A real-world time-and-motion study revealed hybrid-capture NGS workflows can compound these challenges through extensive pipetting and reagent preparation, prolonged hands-on time, and idle time that cannot be repurposed for other work. Automated, amplicon-based NGS addresses these inefficiencies by streamlining workflows into two instruments, reducing manual interventions, and enabling consistent results within existing staff and space.

Automated Manual

Ion Torrent™ Oncomine™ Dx Express Test

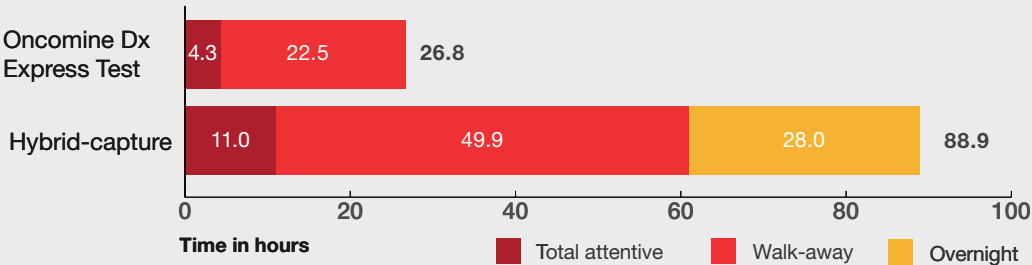


Hybrid-capture NGS workflow

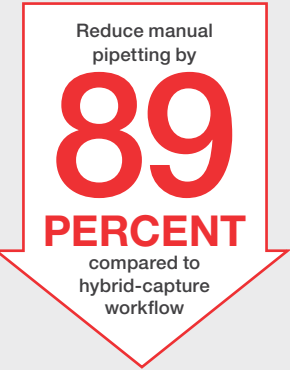


Reduce turnaround time for clinical decisions

Total turnaround time (TAT) for six samples

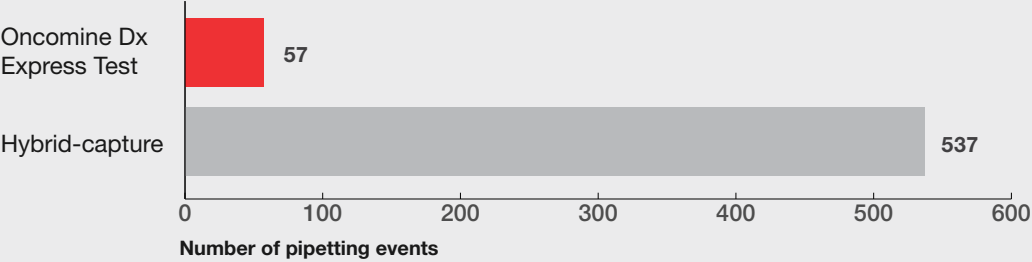


Reduce turnaround time for faster reporting and supporting timely treatment decisions.

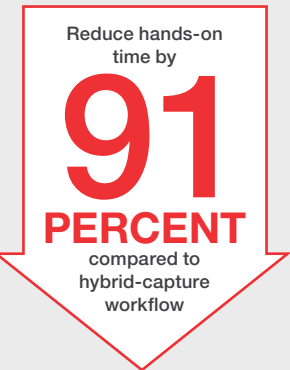


Reduce manual pipetting

Manual pipetting events for 6 samples

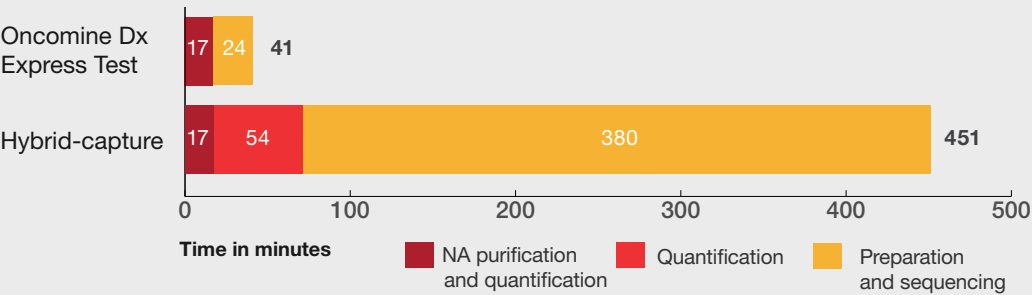


Reducing pipetting events supports testing consistency, reducing the opportunities for errors, delay, and waste.



Reduce total hands-on time

Hands-on time required for NGS assay for six samples



Significantly less hands-on time allows staff to focus on higher-value activities, supporting lab scalability and increasing overall productivity.

Learn more at thermofisher.com/oncomine-express-test

For *In Vitro* Diagnostic Use. Rx only. © 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. FLY-13612420 0226

References:
1. Stone S, Fronkier B, Zsiborás R, Lukács L, and Urbán P. (2025), Results of a Time and Motion Study of Two Next-Generation Sequencing Workflows in a Routine Oncology Biomarker Profiling Setting. *The Journal of Molecular Diagnostics*, Volume 27, Issue 11, S1 - S206