illumina®

Bring tumor molecular profiling in house

Faster access to actionable biomarker insights



Meeting the evolving standards in biomarker testing

Oncology clinical practice guidelines increasingly recommend multigene next-generation sequencing (NGS).

European Society for Medical Oncology (ESMO)

Recommends multigene NGS in non-squamous non-small cell lung cancer (NSCLC), prostate cancers, ovarian cancers, and cholangiocarcinoma.[1]

SCAN TO ACCESS LATEST GUIDELINES

American Society of Clinical Oncology

Recommends multigene NGS when more than one biomarker-linked therapy is approved for the patient's cancer type.[2]

SCAN TO ACCESS LATEST GUIDELINES

Comparing single-gene and multigene testing

Sequential single-gene testing was once the standard approach for assessing specific biomarkers, but it has drawbacks. NGS-based testing can address many of these challenges.

Single-gene testing	Multigene NGS
Requires multiple tests of different modalities to assess multiple biomarkers	Assesses multiple biomarker types with a single test
Consumes additional sample material at each step	Conserves precious sample by assessing all biomarkers in a single run
Introduces multiple chain-of-custody handoffs	Provides fewer opportunities for human error
Extends overall turnaround time (TAT) because results return one at a time	Delivers all biomarker results together, shortening the overall profiling timeline
Often behind evolving guideline recommendations	Easily updated to align with evolving professional guideline recommendations

BRING TUMOR MOLECULAR PROFILING IN HOUSE

The cost of under-testing

Across diverse tumor types, treatment with biomarker-matched targeted therapy has been associated with improved patient outcomes.[3]

Incomplete implementation of guideline-recommended biomarker testing can have negative impacts on patients, including:

- → **Delayed access to targeted therapies and immunotherapies**
- → **Increased reliance on empiric, trial-and-error treatment**

NGS panels consolidate guideline biomarkers into a single test, simplifying the implementation of guideline-aligned testing while reducing the need for multiple sequential assays.

By returning data across all target biomarkers at once, NGS-based testing increases the likelihood of identifying actionable biomarkers and improves the ability to match a patient with a targeted therapy.[3]

Under-testing in advanced NSCLC

< 50%

of patients received all guideline-recommended tests[4]

~20%

of patients had no biomarker results available before initiating therapy[4]

~64%

of eligible patients missed appropriate targeted therapy due to practice gaps[5]





BRING TUMOR MOLECULAR PROFILING IN HOUSE

Sample to insights in days, not weeks

In-house NGS biomarker testing reduces workflow complexity and improves operational efficiency compared to send-out testing. By completing the entire process within the health system, in-house workflows support timely decisions with rapid access to actionable biomarker insights.

< 24 hours

In-house NGS workflows have achieved end-to-end TATs in less than 24 hours.[6] In contrast, send-out testing TATs can range from 9 to 30 days.[7]

47.6%

of NSCLC physicians would start nontargeted treatment if results took longer than two weeks.[8]

NGS testing One workflow, one run

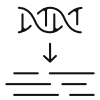


One panel order received

One test, all actionable targets

NGS panel order

Order receipt and accession

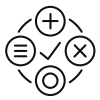


Single workflow

One NGS run

Tumor enrichment

Pre-analytics



Unified analysis pipeline

One pipeline, one QC
Reduced inter-assay handoffs

DNA/RNA → Result

Analytics



One consolidated report

One-stop reporting, data reanalysis at anytime

Integrated findings

Post-analytics

Sequential gene testing Multiple assays over time

Multiple orders received

Submitted one by one
More ordered as needed

EGFR *KRAS*
ALK ...

Order receipt and accession

Repeated prep per assay

New prep for each assay
Tissue used every time

Slide 1 Slide 2
Slide 3 ...

Pre-analytics

Many sequential handoffs

Separate QC per assay
Coordination overhead

Assay 1 Assay 2
Assay 3 ...

Analytics

Fragmented reports

Results arrive staggered
Manual reconciliation

Report 1 Report 2
Report 3 ...

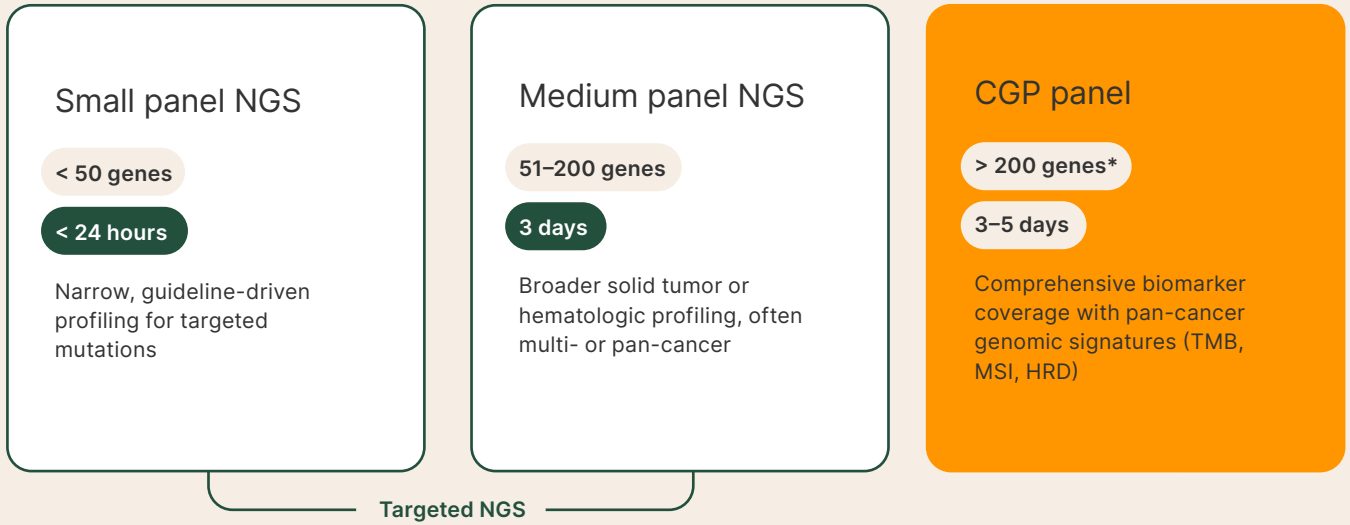
Post-analytics

BRING TUMOR MOLECULAR PROFILING IN HOUSE

Choose the right strategy

Targeted NGS panels typically deliver faster results than more broad panels and can be particularly useful when treatment decisions are focused on common guideline-recommended biomarkers.

Comprehensive genomic profiling (CGP) analyzes hundreds of genetic alterations at once, including rarer variants and genomic signatures, providing a broader molecular view.



*Increasing number of genes for TMB, MSI, or HRD.
HRD, homologous recombination deficiency; MSI, microsatellite instability; TMB, tumor mutational burden

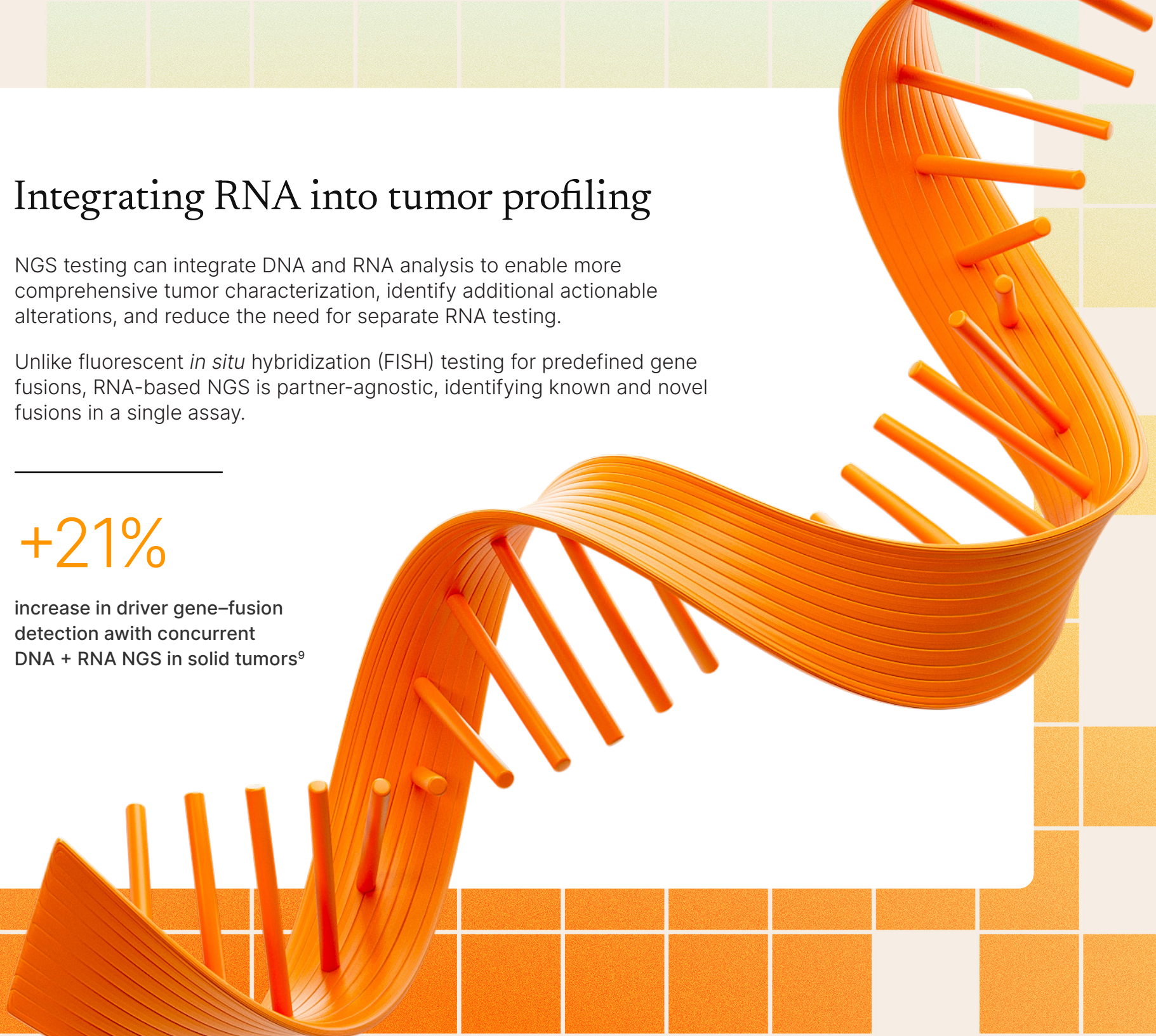
Integrating RNA into tumor profiling

NGS testing can integrate DNA and RNA analysis to enable more comprehensive tumor characterization, identify additional actionable alterations, and reduce the need for separate RNA testing.

Unlike fluorescent *in situ* hybridization (FISH) testing for predefined gene fusions, RNA-based NGS is partner-agnostic, identifying known and novel fusions in a single assay.

+21%

increase in driver gene–fusion detection awith concurrent DNA + RNA NGS in solid tumors[9]



Benefits of in-house NGS testing for lab operations and stakeholders[10–16]

Faster biomarker insights

Keeping samples in house lets labs shepherd logistics and optimize turnaround for rapid NGS

Fewer QNS* results

One full sample covers all testing with NGS, instead of being depleted across separate assays

*QNS, quantity not sufficient.

Better informed tumor boards

Short in-house turnaround time gives the molecular tumor board a stronger basis for care decisions

Stronger data control

Labs own the data from in-house NGS, keeping it available for institutional use

Stronger pathology leadership

Lab personnel can have an active voice in patient care and better support oncologists and tumor boards

References

1. Mosele F, Remon J, Mateo J, et al. Recommendations for the use of next-generation sequencing (NGS) for patients with metastatic cancers: a report from the ESMO Precision Medicine Working Group. *Ann Oncol*. 2020;31(11):1491-1505. doi:10.1016/j.annonc.2020.07.014
2. Chakravarty D, Johnson A, Sklar J, et al. Somatic genomic testing in patients with metastatic or advanced cancer: ASCO provisional clinical opinion. *J Clin Oncol*. 2022;40(11):1231-1258. doi:10.1200/JCO.21.02767
3. Nakamura Y, Yamashita R, Okamoto W, et al. Efficacy of Targeted Trials and Signaling Pathway Landscape in Advanced Gastrointestinal Cancers From SCRUM-Japan GI-SCREEN: A Nationwide Genomic Profiling Program. *JCO Precis Oncol*. 2023;7:e2200653. doi:10.1200/PO.22.00653
4. Robert NJ, Espirito JL, Chen L, et al. Biomarker testing and tissue journey among patients with metastatic non-small cell lung cancer receiving first-line therapy in The US Oncology Network. *Lung Cancer*. 2022;166:197-204. doi:10.1016/j.lungcan.2022.03.004
5. Sadik H, Pritchard D, Keeling DM, et al. Impact of clinical practice gaps on the implementation of personalized medicine in advanced non–small-cell lung cancer. *JCO Precis Oncol*. 2022;(6):e2200246. doi:10.1200/PO.22.00246
6. Roy A, Zaidinski M, DiNapoli SE, et al. Validation of a rapid targeted next generation sequencing oncology panel. Poster presented at: Association for Molecular Pathology (AMP) Annual Meeting; November 19-23, 2024; Vancouver, BC, Canada.
7. Silas U, et al. Fast in-house next-generation sequencing in the diagnosis of metastatic non-small cell lung cancer: a hospital budget impact analysis. *J Health Econ Outcomes Res*. 2023;10(1):111-118. doi:10.36469/001c.77686
8. Mileham KF, Schenkel C, Bruinooge SS, et al. Defining comprehensive biomarker-related testing and treatment practices for advanced non-small-cell lung cancer: Results of a survey of U.S. oncologists. *Cancer Med*. 2022;11(2):530-538. doi:10.1002/cam4.4459
9. Gai L, Bowles B, Hockenberry AJ, et al. Molecular characterization of oncogenic gene fusions in a large real-world cohort of solid tumors. *Cancer Res Commun*. 2025;5(11):1967-1976. doi:10.1158/2767-9764.CRC-25-0329
10. Scott JA, Lennerz J, Johnson ML, et al. Compromised outcomes in stage IV non–small-cell lung cancer with actionable mutations initially treated without tyrosine kinase inhibitors: A retrospective analysis of real-world data. *JCO Oncol Pract*. 2024;20(1):145-153. doi:10.1200/OP.22.00611
11. Yu TM, Morrison C, Gold EJ, Tradonsky A, Layton AJ. Multiple biomarker testing tissue consumption and completion rates with single-gene tests and investigational use of Oncomine Dx target test for advanced non–small-cell lung cancer: A single-center analysis. *Clin Lung Cancer*. 2019;20(1):20-29.e8
12. Hagemann IS, Devarakonda S, Lockwood CM, et al. Clinical next-generation sequencing in patients with non-small cell lung cancer. *Cancer*. 2015;121(4):631-639. doi:10.1002/cncr.29089
13. Aggarwal C, Thompson JC, Black TA, et al. Clinical implications of plasma-based genotyping with the delivery of personalized therapy in metastatic non-small cell lung cancer. *JAMA Oncol*. 2019;5(2):173-180. doi:10.1001/jamaoncol.2018.4305
14. Sholl LM, Do K, Shivdasani P, et al. Institutional implementation of clinical tumor profiling on an unselected cancer population. *JCI Insight*. 2016;1(19):e87062. doi:10.1172/jci.insight.87062
15. Meric-Bernstam F, Brusco L, Shaw K, et al. Feasibility of large-scale genomic testing to facilitate enrollment onto genomically matched clinical trials. *J Clin Oncol*. 2015;33(25):2753-2762. doi:10.1200/JCO.2014.60.4165
16. Kato S, Kim KH, Lim HJ, et al. Real-world data from a molecular tumor board demonstrates improved outcomes with a precision N-of-one strategy. *Nat Commun*. 2020;11(1):4965. doi:10.1038/s41467-020-18613-3

illumina®



1.800.809.4566 toll-free (US) | +1.858.202.4566 tel
techsupport@illumina.com | www.illumina.com

© 2026 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners. For specific trademark information, see www.illumina.com/company/legal.html.
M-GL-04511 v1.0