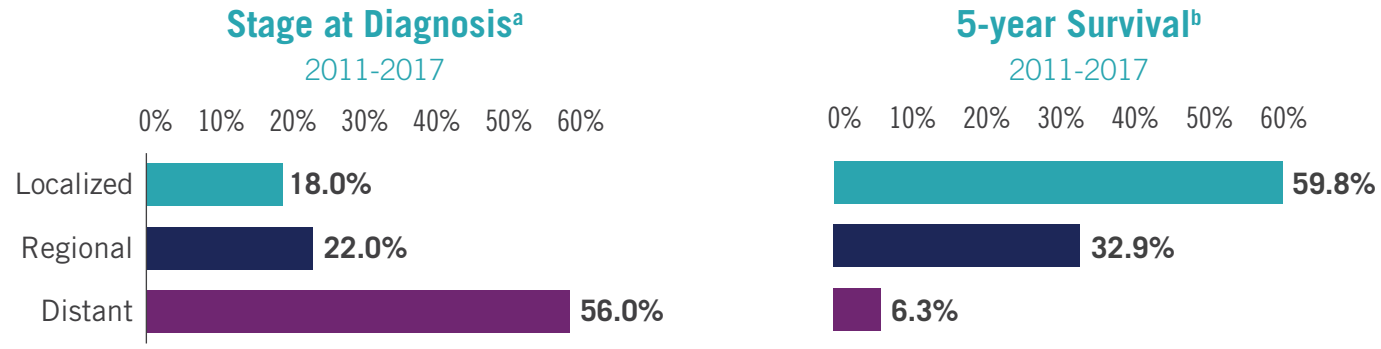
BIOMARKER TESTING IN LUNG CANCER:
NAVIGATING AN EVOLVING LANDSCAPE

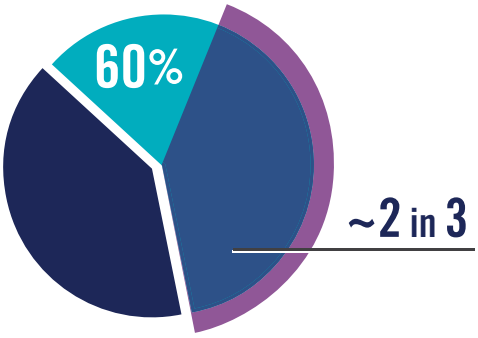
Survival Remains Poor in Lung Cancer

- Advanced disease, which accounts for 56% of all lung cancer cases, has the lowest 5-year relative survival rate (≈6.3%)[1]



[a]4% of patients are unknown stage at diagnosis. [b]9.6% 5-year survival rate for patients with unstaged lung and bronchus cancer.

Biomarker testing plays a critical role in informing treatment decisions for patients with NSCLC[2]



More than 60% of all non-squamous mNSCLC patients have oncogenic drivers—and of these patients, about 2 in 3 have an actionable biomarker[3-7]

Targeted therapies may help impact outcomes in patients with actionable biomarkers[8-11]

The presence of actionable biomarkers in patients with metastatic NSCLC allows for personalized treatment options[9,11]

Consider a personalized therapeutic approach for patients with NSCLC[2]

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NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) and CAP/IASLC/AMP Guidelines Recommend Biomarker Testing for All Eligible Patients With Advanced NSCLC[12-14]

NCCN
RECOMMENDATION

NCCN Guidelines® for Non–Small Cell Lung Cancer recommends, when feasible, that molecular testing is done for eligible patients with metastatic NSCLC using a broad, panel-based approach, most typically by NGS[12,a]

	ACTIONABLE BIOMARKERS[b]									EMERGING BIOMARKERS[b]		
	EGFR	*ALK*	*ROS1*	*BRAF*	*RET*	*NTRK 1/2/3*	*MET*ex14	*KRAS*	PD-L1	TMB[c,d]	*MET*amp	HER2
NCCN Recommended[8]	NGS PCR	NGS IHC FISH	NGS IHC FISH	NGS PCR	NGS PCR FISH	NGS IHC FISH PCR	NGS	N/A	IHC	N/A	NGS	
CAP/IASLC/AMP Recommended[9,10]	NGS PCR Liquid biopsy	NGS IHC FISH	NGS IHC FISH PCR	NGS	NGS	N/A			N/A	N/A		

● SINGLE or EXPANDED GENE PANEL recommended ● EXPANDED GENE PANEL recommended

NGS, PCR, FISH, and IHC are recommended methodologies for testing actionable biomarkers in metastatic NSCLC[12-14]

[a]The NCCN Guidelines for NSCLC provide recommendations for certain individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays or commercial laboratories.
[b]Some actionable biomarkers and emerging biomarkers do not have available biomarker tests that are recommended by clinical guidelines, which is denoted by "N/A."
[c]Clinical guidelines currently do not provide recommendations for TMB testing methodologies.
[d]TMB is not an emerging biomarker in the NCCN Guidelines for NSCLC; the guidelines do not recommend TMB testing.[12]

Biomarker testing is recommended for advanced NSCLC to identify the evolving number of actionable biomarkers for which effective therapies are available[12,13]

There Are Potential Opportunities Across the Patient Journey to Improve Biomarker Testing and Help Impact Patient Outcomes[15]

- The 2017 CAP/IASLC/AMP guidelines recommend MDT decision-making for biomarker testing[13]
- Establishing a biomarker testing algorithm at your institution may help optimize the process of treatment selection for metastatic NSCLC[13]

Identifying and addressing challenges in biomarker testing may improve the patient diagnostic journey[16]

To learn more about comprehensive biomarker testing and guideline recommendations for metastatic NSCLC, please visit www.biomarkertesting.com

ALK = anaplastic lymphoma kinase; AMP = Association for Molecular Pathology; CI = confidence interval; CAP = College of American Pathologists; *BRAF* = v-Raf murine sarcoma viral oncogene homolog B1; *EGFR* = epidermal growth factor receptor; FISH = fluorescence in situ hybridization; HER2 = human epidermal growth factor receptor 2; IASLC = International Association for the Study of Lung Cancer; *BRAF* = v-Raf murine sarcoma viral oncogene homolog B1; IHC = immunohistochemistry; *KRAS* = Kirsten rat sarcoma 2 viral oncogene homolog; MDT = multidisciplinary team; METamp = MET amplification; METex14 = MET exon 14 skipping; mNSCLC = metastatic non-small cell lung cancer; NCCN = National Comprehensive Cancer Network; NSCLC = non-small cell lung cancer; NGS = next-generation sequencing; *NTRK* = neurotrophic tyrosine receptor kinase; PCR = polymerase chain reaction; PD-L1 = programmed death-ligand 1; *RET* = rearranged during transfection; *ROS1* = c-ros oncogene; TMB = tumor mutational burden.

References: 1. Surveillance, Epidemiology, and End Results Program. National Cancer Institute. https://seer.cancer.gov/statfacts/html/lungb.html. Accessed September 2, 2021; **2.** Sandler JE, et al. *J Thorac Dis.* 2019;11:2117-2125.; **3.** Hirsch FR, et al. *Lancet.* 2017;389:299-311; **4.** VanderLaan PA, et al. *Cancer Cytopathol.* 2021;129:179-181; **5.** US Food and Drug Administration. FDA grants accelerated approval for KRAS G12C mutated NSCLC. https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-sotorasib-kras-g12c-mutated-nsclc. Accessed June 10, 2021; **6.** König D, et al. *Cancers* (Basel). 2021;13:804; **7.** Peters S, et al. *Ann Oncol.* 2019;30:884-896; **8.** Kris MG, et al. Using multiplexed assays of oncogenic drivers in lung cancers to select targeted drugs. *JAMA.* 2014;311(19):1998-2006; **9.** Barlesi F, et al. Lancet. 2016;287(10026):1415-1426; **10.** Solomon BJ, et al. *J Clin Oncol.* 2018;36(22):2251-2258; **11.** Gutierrez ME, et al. *Clin Lung Cancer.* 2017;18(6):651-659; **12.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V1.2022. © National Comprehensive Cancer Network, Inc., 2021. All rights reserved. Accessed December 10, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way; **13.** Lindeman NI. *Arch Pathol Lab Med.* 2018;142:321-346; **14.** Lindeman NI, et al. *J Thorac Oncol.* 2013;8:823-859; **15.** Gregg JP, et al. *Transl Lung Cancer Res.* 2019;8:286-301; **16.** Smeltzer MP, et al. *J Thorac Oncol.* 2020;15:P1434-P1448.

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