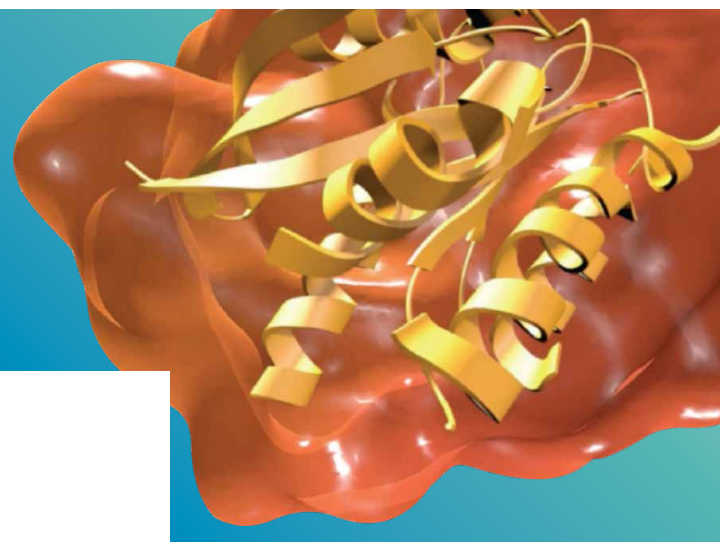
AMGEN®
Oncology

Biomarker Testing:
Know Your Lung Cancer



Overview

Personalized cancer treatment plans should begin at diagnosis, and it is widely recognized that biomarker testing drives targeted treatments.[1,2] However, even with more targeted therapies available to treat actionable mutations, the need to raise awareness of the importance of biomarker testing remains.[3]

Biomarker testing involves a single test, or group of tests, that look for the presence of molecular signs obtained from the blood, body fluids or tissue. It may also be called "molecular testing" or "genetic testing." After diagnosis, biomarker tests can also be utilized to develop a patient's personalized treatment approach and to track treatment results.[4]

Prevalent oncogenic mutations observed in lung cancer patients include *KRAS, EGFR, ALK, MET, BRAF, ROS1, RET, NTRK,* and *PIK3CA*.[6] Of these, mutated *KRAS* is one of the most common driver mutations in non-small cell lung cancer (NSCLC).[6,7]

FAST FACTS

- Biomarker testing looks for the presence of molecular signs of health or disease, obtained from blood, body fluid or tissue samples.[4]
- *KRAS G12C* is a major driver of cancer tumors and is the most common driver of mutations in patients with NSCLC.[5]
- Multiple international medical organizations recommend *KRAS G12C* biomarker testing for patients with NSCLC, however significant underutilization of testing remains.[8,9]
- Amgen Oncology is encouraging biomarker testing to deliver appropriate targeted treatment plans.

Biomarker Testing is Critical for Identifying Mutations and Personalizing Treatment Plans

Changes in genes, including mutations and chromosomal abnormalities, play an important role in the development of cancer. Mutations are permanent changes in the DNA sequence of a gene that can cause a cell to make (or not make) proteins that affect how the cell grows and divides into new cells. Certain mutations can cause cells to grow out of control, which can lead to cancer.[10]

About *KRAS G12C*

The *RAS* gene family, which has been the subject of almost four decades of research, contains some of the most frequently mutated oncogenes in human cancers.[15,16] Targeting the *KRAS* protein, the most commonly altered family member in solid tumors, has been one of the toughest challenges in cancer research.[15]

A specific mutation known as *KRAS G12C* is a major driver of tumor growth, occurring broadly across solid tumors. In the U.S., about 13% of patients with non-squamous NSCLC harbor the *KRAS G12C* mutation.[17] It is also found in approximately 3-5% of CRC and 1-2% of numerous other solid tumors, making this among the most broadly represented mutations across cancer patient subgroups.[18-22]

Investigating a unique surface groove in the $KRAS^{G12C}$ protein, Amgen is exploring the potential of $KRAS^{G12C}$ inhibition across multiple tumor types for patients. Advances in understanding the structure of *KRAS* has prompted further investigations.[15,23]

KRAS G12C can be detected by various testing methods.[8,11] Expanded panels or single gene tests can detect the biomarker, and both tissue and liquid biopsy tests can be utilized. In fact, the College of American Pathologists, the International Association for the Study of Lung Cancer, the Association for Molecular Pathology and the American Society of Clinical Oncology all recommend broad molecular profiling at diagnosis for eligible patients with advanced NSCLC, including *KRAS* as part of an expanded panel.[8,9] Despite guideline recommendations however, many patients do not receive testing for biomarkers.[12-14]

Knowing the status of biomarkers is critical for developing a personalized treatment plan for NSCLC patients, so Amgen Oncology has made it a priority to advance biomarker awareness and testing. Amgen is also working with advocacy groups to increase awareness of the *KRAS G12C* gene mutation and provide information about the importance of biomarker testing.

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USA-510-80295

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