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Advances in Molecular Testing Offer New Hope for Lung Cancer Patients
Leading Health Care Organizations Issue
Guideline Recommendations for Molecular Testing and Targeted Therapies

NORTHFIELD, ILL.— The emergence of molecular diagnostic testing in lung cancer offers new hope for patients battling the number one cancer killer in the United States and abroad. Now, for the first time after a decade of biomarker testing in lung cancer, a uniform approach for testing for the *EGFR* mutation and *ALK* rearrangement along with the availability of targeted therapies offer lung cancer patients the chance for improved quality of life and more time with their loved ones.

The College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP) have developed an evidence-based guideline, "[Molecular Testing Guideline for the Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors](#)," which establishes recommendations for *EGFR* and *ALK* testing, helping to guide targeted therapies. The guideline was released on April 3, 2013, in [Archives of Pathology & Laboratory Medicine \(APLM\)](#), [Journal of Thoracic Oncology](#), and [The Journal of Molecular Diagnostics](#).

"The key recommendation of the guideline, and perhaps most important to lung cancer patients, is that all patients with advanced lung adenocarcinoma should be tested for *EGFR* and *ALK* abnormalities, that would qualify them for tyrosine kinase inhibitor therapy, regardless of their clinical variables, such as smoking history, gender, or ethnicity," said Marc Ladanyi, MD, attending pathologist in the Molecular Diagnostics Service at Memorial Sloan-Kettering Cancer Center in New York, and IASLC member.

Similar to the testing done in breast cancer, matching a cancer patient's molecular profile with the appropriate targeted therapy provides individualized treatment options. The guideline answers important clinical questions, including:

- When should testing be performed?
- How should testing be performed?
- Should other genes be routinely tested in lung cancer?
- How should molecular testing of lung cancer be implemented?

"In the U.S. up to 20 percent of patients with lung adenocarcinoma, the most common type of lung cancer, will test positive for one of the two biomarkers," said Philip T. Cagle, MD, FCAP, medical director of Pulmonary Pathology in the Department of Pathology and Genomic Medicine at The Methodist Hospital in Houston, Texas, APLM editor, and CAP member. "It is critical to identify these patients because they stand to benefit more from new targeted drugs than from conventional chemotherapy, and with fewer side effects."

For lung cancer survivor Richard Heimler, molecular diagnostic testing has meant five additional years with his family, including his daughter and son. After his initial diagnosis in 2004, Heimler had surgery to remove cancer tumors in his lungs and brain. When multiple tumors returned in 2008, Heimler participated in a clinical trial to determine if he was a candidate for targeted therapies.

"After testing positive for the abnormal *ALK* gene, I began taking a targeted drug in the form of a pill," said Heimler. "It was wonderful to not experience the debilitating side effects that I had with chemotherapy. This new world of science has given me hope that I will have more time to create memories with my children and watch them grow up."

In an era of precision medicine, the guideline provides recommendations for pathologists, oncologists, and other cancer health professionals on the current state-of-the-art recommendations for the molecular testing of lung cancer.

"The three organizations came together to address the variance in practice around the world about how this testing should be performed," said Neal I. Lindeman, MD, director of Molecular Diagnostics at Brigham and Women's Hospital and associate professor of Pathology at Harvard Medical School in Boston, and AMP member. "Pathologists who specialize in molecular diagnostics and lung cancer collaborated to create the guideline to minimize variation and provide greater precision in the care of patients." The CAP Pathology & Laboratory Quality Center ([the Center](#)), a forum for developing evidence-based guidelines and consensus recommendations, provided the process for creating the guideline. Expert panels made up of renowned worldwide leaders in the field collaborated to develop the recommendations.

"The guideline is an important step in making sure that patients benefit from the new molecular understanding of lung cancer," said Dr. Ladanyi. "As new studies lead to further evidence-based recommendations, we hope to develop additional guidelines for other biomarkers related to this disease."

In conjunction with the publishing of the guideline, [CAP](#), [IASLC](#), and [AMP](#) have developed clinical tools and resources for pathologists and oncologists that summarize the findings and recommendations. In addition, the organizations have developed a [patient guide](#) for further understanding, including questions for patients to ask their physicians. A series of videos featuring three of the guideline authors and a lung cancer survivor can be found on the [CAP](#), [IASLC](#), and [AMP](#) YouTube Channels.

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About the College of American Pathologists

As the leading organization for board-certified pathologists, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. With more than 18,000 physician members, the CAP has led as the gold standard in laboratory accreditation for 50 years with more than 7,300 CAP-accredited laboratories in 50 countries. Find more information about the CAP at cap.org.

About IASLC

The International Association for the Study of Lung Cancer (IASLC) is the only global organization dedicated to the study of lung cancer. Founded in 1974, the association's membership includes more than 3,500 lung cancer specialists in 80 countries.

About AMP

The Association for Molecular Pathology (AMP) is an international medical professional association dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of molecular biology, genetics, and genomics.