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### Lab and Diagnostics News: Advances in Molecular Testing Offer New Hope for Lung Cancer Patients

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#### Leading Healthcare Organisations Issue Guideline Recommendations for Molecular Testing and Targeted Therapies.

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 individualised 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 tumours in his lungs and brain. When multiple tumours 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 organisations 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 specialise in molecular diagnostics and lung cancer collaborated to create the guideline to minimise variation and provide greater precision in the care of patients."

The CAP Pathology & Laboratory Quality Centre, (the Centre,) 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 summarise the findings and recommendations. In addition, the organisations 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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