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Revisions to Molecular Testing Guidelines Continues to Give Hope to Lung Cancer Patients

BETHESDA, MD. —The College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP) are teaming to revise the evidence-based guideline, “Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors.”

The updated guideline will include new recommendations for ALK testing by IHC, ALK-EGFR resistance, and a number of emerging target molecular targets which will include, but is not limited to, ROS1, MET, ERBB2, RET, NTRK1. Multiplexed "Next Generation Sequencing" multigene panels and the reassessment of immunohistochemistry will be reviewed. The role of rebiopsy and repeat analysis in the setting of post-treatment relapse, along with testing of blood samples for mutations in circulating tumor cells, cell free tumor DNA, or exosomes will be considered.

The revision of the guideline will again be based on evidence from unbiased review of published experimental literature. The revisions will be recommended by an expert panel made up of renowned worldwide leaders in the field. The revision will start in early 2015, taking around 18 months to complete. The three organizations collaborated in 2013 to develop the original version of the guideline which addressed which patients and samples should be tested and when and how testing should be performed.

"Although only one year has passed since the molecular testing guideline was published, rapid accumulation of scientific knowledge and new evidence in this field indicate that the guidelines should be updated. Thus, an update has begun that includes an expanded list of genes and new methods that are clinically relevant," said Yasushi Yatabe, MD, PhD, chief, Department of Pathology and Molecular Diagnostics, Aichi Cancer Center, Nagoya, Japan and IASLC member.

Patients battling lung cancer in the United States and abroad have continued hope with the benefits of these guidelines. Testing for the EGFR mutation and ALK rearrangements and the use of targeted therapies have given lung cancer patients the chance for survival, along with improved quality of life and time with loved ones.

“More than 224,200 new cases of lung cancer were diagnosed in 2014 in the United States,” 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, *Archives of Pathology and Laboratory Medicine* editor-in-chief, and CAP member. “Rapid advancements in genetic testing offer new treatment options for patients with advanced lung cancer. The updates to the guideline will help pathologists and oncologists to provide more accurate testing, leading to more optimal patient care.”

As an active and asymptomatic recently retired, exceedingly proud new grandmother, Linda Wilkinson was completely taken aback by the diagnosis of Stage 4 lung cancer. She underwent three rounds of genomic testing and was identified as having the EML4-ALK translocation in June and has been on Xalkori since then with visible improvement in the shrinkage of her primary tumor.

No new metastases have been noted "I live in gratitude for all the professionals working in the area of genomic testing and targeted treatment. Since going on a targeted agent which specifically addresses my genetic mutation, I have felt renewed hope, energy and enthusiasm for life. It has lengthened my time horizon immensely and I foresee the day when these technologies (and new drug developments) make living with cancer something that can be successfully managed for years and years."

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.

“Molecular testing of the lung cancer patient’s tumor is today crucial for selection the most optimal therapy from the treatment start”, says Professor Fred R. Hirsch, MD, PhD, University of Colorado and CEO of the International Association for the Study of Lung Cancer (IASLC). “It is also necessary to address eventual molecular testing of tumors from patients, who eventually progress on first-line therapy in order to learn about biological mechanisms for treatment failure and for guiding subsequent therapy today and in the future,” continues Dr. Hirsch.

“The approach will be similar and will again be based on evidence from unbiased review of published experimental literature, but will be accelerated by concentrating on a smaller number of topics,” 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.”

In October of 2014, The American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines Committee (CPGC) endorsed the CAP/IASLC/AMP guideline for EGFR and ALK molecular testing. This is significant to the CAP/ IASLC/AMP guidelines because it reinforces the importance of molecular testing. The goal is to give providers and patients the best recommendations to treat their lung cancer

In conjunction with the publishing of the guideline, [CAP](#), [IASLC](#), and [AMP](#) 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.

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About the College of American Pathologists

As the leading organization with more than 18,000 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. The CAP's Laboratory Improvement Programs, initiated 65 years ago, currently has customers in more than 100 countries, accrediting 7,600 laboratories and providing proficiency testing to 20,000 laboratories worldwide. Find more information about the CAP at cap.org. Follow CAP on Twitter: [@pathologists](https://twitter.com/pathologists).

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 nearly 4,000 lung cancer specialists in 80 countries. IASLC members promote the study of etiology, epidemiology, prevention, diagnosis, treatment and all other aspects of lung cancer and thoracic malignancies. IASLC disseminates information about lung cancer to scientists, members of the medical community and the public, and uses all available means to eliminate lung cancer as a health threat for the individual patients and throughout the world. Membership is open to any physician, scientist, nurse or allied health professional interested in lung cancer, including patients, survivors, caregivers and advocates. To learn more about IASLC please visit <http://www.iaslc.org/>

About AMP

The Association for Molecular Pathology (AMP) is a not-for-profit scientific society that advances the clinical practice, science, and excellence of molecular and genomic laboratory medicine through education, innovation, and advocacy to enable highest quality health care. AMP's 2,000+ members are from nearly 50 countries and include individuals from academic and community medical centers, government, and industry; including, basic and translational scientists, pathologist and doctoral scientist laboratory directors, medical technologists, and trainees. www.amp.org.