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# Clinical Practice Guideline Focuses on Molecular Biomarker Testing for Patients with Colorectal Cancer

Chicago, IL, Northfield, IL, Bethesda, MD, Alexandria, VA—A new, evidenced-based clinical practice guideline on molecular biomarker testing for patients with colorectal cancer identifies opportunities for improving patient outcomes.

The American Society for Clinical Pathology (ASCP), the College of American Pathologists (CAP), the Association for Molecular Pathology (AMP), and the American Society of Clinical Oncology (ASCO) collaborated to develop the *Molecular Biomarkers for the Evaluation of Colorectal Cancer* guideline. The guideline will be published online on Feb. 6, 2017, in <u>AJCP/American Journal of Clinical Pathology</u>, <u>Archives of Pathology & Laboratory Medicine</u>, <u>JMD/Journal of Molecular Diagnostics</u> and <u>JCO/Journal of Clinical Oncology</u>, from each collaborating organization, respectively.

This pivotal guideline addresses testing a wide range of molecular biomarkers in patients with early and advanced colorectal cancer. It will help establish standard molecular biomarker testing, guide targeted therapy decisions, and advance personalized care for patients with colorectal cancer, which is the second leading cause of cancer-related death in the U.S. for women and men combined\*.

"Realizing that molecular diagnostics is a rapidly evolving field of medicine, the collaborating organizations of CAP, ASCP, AMP, and ASCO are committed to updating this guideline routinely in order to capture and make recommendations for new discoveries in the field," said Stanley R. Hamilton, MD, FCAP, AGAF, the University of Texas MD Anderson Cancer Center, project co-chair on behalf of the CAP.

A multi-disciplinary panel of experts, appointed by each of the organizations, included pathologists, oncologists, methodologists, and patient representatives, who worked collaboratively to develop the guideline through an evidence-based process following the Institute of Medicine standards for guideline development.

"The evidence-based recommendations for this guideline focused on molecular biomarkers identified as the most useful in patients with colorectal cancer, in order to select patients who can benefit from enhanced treatment with targeted therapies," said Antonia R. Sepulveda, MD, PhD, FASCP, FCAP, Columbia University, project co-chair on behalf of AMP.

"This guideline was created to offer physicians and patients guidance concerning the value of each of the new biomarkers relevant to colorectal cancer," said Carmen Allegra, MD, University of Florida Health Cancer Center, project co-chair on behalf of ASCO. "Hopefully, the widespread application of these recommendations will result in improved outcomes for all patients with colorectal cancer."

"While many existing recommendations cover the application of individual molecular biomarkers in colorectal cancer, this guideline fills the need for an overarching set of recommendations spanning the breadth of current knowledge," said Wayne W. Grody, MD, PhD, FASCP, FCAP, UCLA School of Medicine, project co-chair on behalf of ASCP. "This comprehensive guideline will prove useful for pathologists and oncologists to support decision-making on what molecular tests to order for patients with colorectal cancer."

Twenty-one guideline statements were established (eight recommendations, 10 expert consensus opinions, and three "no recommendation") based on evidence from a comprehensive literature review, which included over 4,000 articles. The guideline supports mutational testing for genes in the epidermal growth factor receptor (EGFR) pathway to inform targeted therapy decisions. Additional recommendations are intended to streamline molecular testing processes and contribute to improving patient outcomes.

An ongoing communication and information dissemination campaign to the professionals and the public will be launched for awareness and to assist in the integration of guideline recommendations into pathology, laboratory, and clinical practice. The guideline will be reviewed every four years, or earlier in the event of publication of substantive and high-quality evidence that could potentially alter the original guideline recommendations.

\* Cancer Facts & Figures 2017. American Cancer Society, 2017.

## **About the American Society for Clinical Pathology**

Founded in 1922 in Chicago, ASCP unites more than 120,000 anatomic and clinical pathologists, residents and fellows, medical laboratory professionals and students to accelerate the advancement of laboratory medicine to better improve patient care through knowledge, collaboration and global community. ASCP's mission is to provide excellence in education, certification, and advocacy on behalf of the patients, pathologists, and laboratory professionals across the globe. To learn more, visit www.ascp.org. Follow us on Twitter at and connect with us on Facebook.

## **About the College of American Pathologists**

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, 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. For more information, READ THE CAP ANNUAL REPORT at cap.org.

#### **About the Association for Molecular Pathology**

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,300+ members practice in the various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions and oncology. They include individuals from academic and community medical centers, government, and industry; including pathologist and doctoral scientist laboratory directors; basic and translational scientists; technologists; and trainees. Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. For more information, visit <a href="https://www.amp.org">www.amp.org</a>. Follow AMP on Twitter: <a href="mailto:QAMPath.">QAMPath</a>.

### **About the American Society of Clinical Oncology**

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world's leading organization of its kind, ASCO represents more than 40,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at <a href="https://www.ASCO.org">www.ASCO.org</a>, explore patient education resources at <a href="www.Cancer.Net">www.Cancer.Net</a>, and follow us on <a href="facebook, Twitter">Facebook, Twitter</a>, LinkedIn, and <a href="YouTube">YouTube</a>.

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