



ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

AMP Bolsters Position on Consumer Genomic Testing

Updated position statement reflects emerging technology landscape, highlights privacy best practices, and expands conditions for clinically-meaningful tests

ROCKVILLE, Md. – June 10, 2019 – The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, today revised its official position for all consumer genomic testing. Based on a recent assessment of the current market landscape and privacy best practices, the latest position statement features an expanded list of conditions that must be met before AMP can support a clinically-meaningful test. AMP remains neutral to all recreational, novelty and ancestry testing that may create educational opportunities for the public.

“AMP’s more than 2,500 members are among the early adopters and users of clinical genomic testing, including consumer genomic testing, and this revised position statement is based on our collective knowledge and expertise of this rapidly developing field,” said Victoria M. Pratt, PhD, FACMG, Associate Professor, Director of Pharmacogenetics and Molecular Genetics Laboratories at Indiana University School of Medicine, and President of AMP. “We will continue to update our official consumer genomic testing position as needed to better account for all of the emerging technologies and privacy best practices. As with any test relevant to a patient’s health, we continue to strongly encourage consumers to consult with their healthcare providers before making clinical care decisions.”

Over the past 12 years, AMP has been closely monitoring and evaluating the consumer genomic test market. In 2007, AMP issued a [Direct to Consumer \(DTC\) Testing statement](#) that concluded that healthcare-related genetic testing should be available only through appropriately qualified health professionals who order tests from CLIA-certified laboratories. In 2015, that [statement was revised](#) to support clinically meaningful direct access genetic testing, as long as certain conditions are met.

Since 2015, a working group of AMP leaders has continued to evaluate the current landscape of consumer genomic testing. The results of that evaluation revealed important updates and expansions to the conditions that must be met before AMP can support such testing. The new conditions reflect the range of currently available technologies, highlight privacy best practices and encourage consumers to consult with their healthcare providers before making clinical care decisions. The expanded set of conditions include:

- All health-related claims must have well-established clinical validity.
- The consumer genomic testing provider must comply with the CLIA statute and regulations. Test validation and interpretation should be performed by board-certified molecular laboratory professionals.
- Information regarding the analytical and clinical validity of the tests should be present in all marketing materials and included in each report of results.
- The consumer genomic test report should be in lay language and describe the limitations of the test, an interpretation of the finding(s) and significance for the consumer's health status, as well as implications for family members.
- Test providers should adhere to The Future of Privacy Forum’s “Privacy Best Practices for Consumer Genetic Testing Services.”

- Consumer genomic testing providers should refer consumers to appropriate genetic counselors and recommend that they discuss any actionable test results with their physicians.

AMP continues to strongly oppose consumer genomic testing that provides information that is either not clinically valid or is used to sell secondary products or services, such as unsubstantiated claims concerning athleticism, diet, exercise, or cosmetics. The society recommends that policy mechanisms be created to ensure that marketing materials and reports clearly identify the lack of data to support health management and the secondary business interests associated with the test.

To read the full position statement on consumer genomic testing, please visit <https://www.amp.org/2019GenomicTestStatement>.

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,500+ members practice various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. Our members are pathologists, clinical laboratory directors, basic and translational scientists, technologists, and trainees that practice in a variety of settings including academic and community medical centers, government, and industry. 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 www.amp.org and follow AMP on Twitter: [@AMPath](https://twitter.com/AMPath).

MEDIA CONTACT:

Andrew Noble
anoble@amp.org
415-722-2129

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