



APPIA News Release

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APPIA Article in AIMM Journal Recommends Solutions for Low-Incidence Validation of Rare Tissues and Antigens

A new article published in the Applied Immunohistochemistry & Molecular Morphology Journal outlines recommendations from the Anatomical Pathology Patient Interest Association (APPIA) for practical solutions available to anatomic pathology laboratories for validation of immunohistochemistry (IHC) staining for low-incidence, rare tissues and antigens with low frequency of occurrence.

These recommendations are in response to the comprehensive guidelines for the verification and validation of new immunohistochemical tests introduced into the laboratory menu published by the College of American Pathologists (CAP).

The article, published in May 2021, addresses two challenges for implementing CAP guidelines in cases with a low frequency of occurrence in the population or no expression in normal tissues. These challenges include the low incidences of validation cases and time/staff resource limitations.

The authors recommend practical solutions available to anatomic pathology laboratories including development of internal resources using the laboratory information system with retrospective and prospective searches of archival material and purchase of tissue microarray blocks, slides or cell lines from external resources.

The article also outlines an alternative approach - conducting a thorough literature search and correlating staining patterns of the new test to the expected results. These solutions may be used uniquely or together to assure consistent standardized testing.

“As companion diagnostics linked to a therapy for low incidence diseases become more available, it is imperative that clinical validation occurs to assure a quality diagnosis. This publication assists labs on how to validate when these rare cases are not abundant and options to meet the published guidelines.” Said Beth Sheppard, President of APPIA.

Co-authors are Robert Lott, BS, HTL (ASCP), Peter V. Riccelli, PhD, Elizabeth A. Sheppard, MBA, Keith A. Warton Jr., MD, Eric E. Walk, MD, George Kennedy, MBA, and Bryce Portier, MD, PhD.

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About APPIA

[APPIA](#) is a not-for-profit membership organization dedicated to the issues affecting laboratory practices, quality, and ultimately the safety of patients. In keeping with the organization’s mission, to ensure accuracy and reduce variation in test results, proper validation studies are needed at the onset of clinical test implementation. However, laboratories worldwide face challenges in gathering enough tissues and cases for antigens with rare occurrence in the population or from patients with a specific rare disease to perform required verification and validation studies for new laboratory products and immunohistochemical tests.

About AIMM

Applied Immunohistochemistry and Molecular Morphology is the official publication of the International Society for Immunohistochemistry and Molecular Morphology, an organization formed in 2016 as an initiative of the external quality control and assurance agencies, NordiQC, CIQC, UKNEQAS, IQNPath (and others), and editorial board members of AIMM, which is the affiliated journal of the new society.

APPIA

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