# Put It on the Board

## Roche launches new antibodies to identify mutations in glioma patients

March 2023—Roche has launched its IDH1 R132H (MRQ-67) Rabbit Monoclonal Primary Antibody and the ATRX Rabbit Polyclonal Antibody to identify mutation status in patients diagnosed with a glioma.

The IDH1 R132H (MRQ-67) antibody can detect the IDH1 R132H mutation in adult-type gliomas and in acute myeloid leukemia. When present, IDH1 R132H is associated with a relatively favorable prognosis and is important in stratifying patients for clinical trials. The ATRX antibody detects a mutation in the *ATRX* gene.

Both assays are fully automated on the BenchMark series of instruments, and the two tests are available now in the United States. Roche says they'll likely be available in other non-CE markets later this year and in countries that accept the CE mark in 2024.

## FDA clearance, CLIA waiver for BioFire SpotFire system and Respiratory Panel

BioMérieux received FDA 510(k) clearance and CLIA waiver for its BioFire SpotFire system and its BioFire SpotFire Respiratory Panel. The company will also submit soon a 510(k) for its BioFire SpotFire Respiratory Panel Mini.

The Respiratory Panel detects 15 of the most common bacteria, viruses, and viral subtypes that cause respiratory tract infections. The Panel Mini is intended to detect SARS-CoV-2, influenza A and B, RSV, and rhinovirus.

The full commercial launch of the BioFire SpotFire system and Respiratory Panel is set for early April in the U.S. market.

## BioMérieux introduces microbiology middleware

BioMérieux has launched Maestria, microbiology middleware for managing specimens throughout each step of the laboratory workflow.

The middleware, which is part of BioMérieux's Vision Suite data-management product line, provides a state-of-the-art graphical user interface and flexible reporting options. The company's Clarion laboratory analytics module offers data visualization that allows Maestria to transform data into real-time, easy-to-access, actionable insights.

Maestria, which was created by microbiologists, is being launched progressively this year worldwide.

## Improvement initiative underway for ABPath CertLink

The American Board of Pathology launched its two-year quality assurance/quality improvement initiative for ABPath CertLink, the online longitudinal assessment platform for the continuing certification program.

"We have listened to the feedback from our diplomates and are taking action to make a great program even better," ABPath CEO Gary W. Procop, MD, MS, said in a statement.

ABPath says it will work in the next two years to update terminology, improve image quality and the content of questions, and more rapidly introduce new content from leading journals. Beginning in July, the number of new questions administered per quarter will be reduced from 15 to 10 with up to five clones.