Put It on the Board

Hologic assay is first FDA-cleared test to detect *M. genitalium*

February 2019—The Food and Drug Administration granted clearance for Hologic's Aptima *Mycoplasma genitalium* assay. This is the first test the FDA has authorized for *M. genitalium* detection.

The FDA reviewed data from a clinical study that included testing of 11,774 samples. The FDA says the study showed that the Aptima assay correctly identified *M. genitalium* in approximately 90 percent of vaginal, male urethral, male urine, and penile samples. It correctly identified *M. genitalium* in female urine and endocervical samples 77.8 percent of the time and 81.5 percent of the time, respectively. Vaginal swabs are the preferred sample type owing to better clinical performance. Alternative sample types, such as urine, can be used if vaginal swabs are not available. In addition, the study showed that the test correctly identified samples that did not have *M. genitalium* present 97.8 to 99.6 percent of the time.

The FDA reviewed the Aptima *M. genitalium* assay through the de novo premarket pathway.

Roche launches uPath enterprise software

Roche launched its uPath enterprise software for digital pathology, which the company says improves on Ventana Virtuoso, its previous version. uPath software reduces image rendering times, integrates automated image analysis, and improves efficiency, Roche says, by enabling an improved workflow for sharing cases between pathologists.

To aid in the development of uPath software, Roche acquired the Leeds Virtual Microscope (LVM) technology from the University of Leeds, U.K., and the Leeds Teaching Hospitals NHS Trust. With this technology, pathologists can diagnose a patient case more quickly by viewing all slides in a case in a single seamless view and viewing all patient information simultaneously. Multiple slides appear on a canvas-like display, enabling pathologists to move seamlessly between a variety of stains in a single view. The LVM technology operates on displays that range from laptops to ultra-high definition Powerwalls.

"With this launch, we are able to deliver an improved digital pathology experience consisting of the Ventana DP 200 slide scanner and uPath software, which are the foundation to further enrich our portfolio of automated clinical algorithms for pathologists," Jill German, head of Roche Tissue Diagnostics, said in a statement.

This launch follows the March 2018 release of the Ventana DP 200 slide scanner.

FDA clears DiaSorin Molecular *Bordetella* test

DiaSorin Molecular received FDA clearance for its Simplexa Bordetella Direct moderate-complexity assay.

It is designed for use on the Liaison MDX to provide qualitative detection and differentiation of *Bordetella pertussis* and *Bordetella parapertussis* in nasopharyngeal swabs. The assay is performed directly from nasopharyngeal swab samples without extraction and provides results in about an hour.

While most of the pertussis cases are caused by *B. pertussis*, some milder cases have been linked to *B. parapertussis*.

Biocare Medical unveils IVD staining platform

Biocare Medical released its Valent IVD open and fully automated staining platform.

"Valent breaks the 30-slide barrier," the company said in a statement, "processing 48 slides simultaneously and supporting unparalleled throughput with minimal hands-on time." It employs a high-capacity lithium battery to

boost the antigen retrieval process and safeguard staining runs in the event of power loss.

Valent has automatic sensors that minimize errors before and during runs. The software's intuitive user interface places frequently used functions in a color-coded block on the main screen. The onboard mixing capability allows for walkaway operation, and with a 50-µL reagent vial dead volume, reagent loss is minimized. A dual-axis inclinometer and motorized legs make it possible for the platform to self-level.

Qiagen reports plans for next-gen digital PCR

Qiagen announced in January the development of a range of next-generation systems for digital PCR and said it expects to launch a fully integrated solution in 2020.

The new systems, which the company said are in advanced stages of development, have been created through the combination of Qiagen technologies and automation with digital PCR assets that are being acquired from Formulatrix, a developer of laboratory automation solutions. Qiagen has reached an agreement to acquire the assets from Formulatrix, and the transaction is expected to be completed this year.

Qiagen said the systems are fully integrated and rapid. Partitioning, thermal cycling, imaging, and analysis are integrated in one instrument. The digital PCR plates deliver a streamlined workflow, Qiagen said, with rapid imaging capabilities that enable results in about 90 minutes. Standard plate formats allow front-end automation of sample preparation.

Health Network Labs acquires Connective Tissue Gene Tests

Health Network Laboratories has acquired Connective Tissue Gene Tests, a provider of molecular diagnostic testing services for inherited genetic disorders.

"The acquisition of CTGT will complement HNL's comprehensive clinical genetic laboratory service programs in cancer, infectious disease, perinatal disease, and pharmacogenomics by providing intellectual, bioinformatics, and technical synergies amongst all the molecular genetic testing laboratories of HNL, and significantly enhance our capabilities in inherited disease diagnostic services," Jeff Wisotzkey, PhD, HNL's clinical lab director and scientific officer, said in a statement. Both companies have their headquarters in Allentown, Pa.