Put It on the Board

Quest acquires PhenoPath

November 2018—Quest Diagnostics has acquired PhenoPath Laboratories, which provides immunophenotyping, hematopathology, and molecular pathology services. The PhenoPath business, in Seattle, will operate as part of AmeriPath, a wholly owned business of Quest.

Steve Rusckowski, Quest chairman, president, and CEO, said in a statement: "PhenoPath has a strong record of innovation and provides several capabilities that complement and extend our own, particularly in pathology and molecular oncology. It also deepens our presence in the Pacific Northwest."

Dr. Gown

PhenoPath founder Allen Gown, MD, tells CAP TODAY that continued consolidation in the laboratory industry and insurance reimbursement challenges have posed significant risks to PhenoPath's future growth. "In Quest/AmeriPath," he says, "we found an organization that realized not only the excellence of PhenoPath's past and present but also the extraordinary future that, with their assistance, we can have." Dr. Gown founded PhenoPath in 1998.

Quest understands PhenoPath's anatomic pathology, hematopathology, and molecular oncology strengths and track record of innovation, Dr. Gown says, both of which can enhance the capabilities of Quest's national network "while it continues to serve PhenoPath's loyal clients nationwide."

Abbott introduces next generation of influenza, strep A assays

The FDA cleared Abbott's next-generation Influenza A & B 2 and Strep A 2 molecular assays for point-of-care testing. Both assays are available on the ID Now platform (formerly Alere) and have been granted a CLIA certificate of waiver.

The enhanced Influenza A & B 2 assay offers molecular detection and differentiation in 13 minutes or less, Abbott says, with early call out of positive results in as little as five minutes. It allows for room temperature storage of test components.

The Strep A 2 provides molecular detection of Group A *Streptococcus* bacterial nucleic acid in six minutes or less, with call out of positive results as early as two minutes, according to Abbott, with no culture confirmation required for negative results.

NeoGenomics to acquire Genoptix

NeoGenomics has entered into a definitive agreement to acquire Genoptix for $125 million in cash and 1 million shares of NeoGenomics common stock.

In announcing the agreement, NeoGenomics said it would advance its expansion into community oncology practices, noting that oncology practices are an "important, and under-penetrated, channel for promoting NeoGenomics' capabilities in next-generation sequencing and liquid biopsy."

FDA OKs emicizumab-kxwh for hemophilia A with or without FVIII inhibitors

The FDA in October approved emicizumab-kxwh injection (Hemlibra, Genentech) for prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A with or without factor VIII inhibitors.

Hemlibra was first approved in 2017 for patients with hemophilia A with FVIII inhibitors. (See "Hemophilia drug interferes with APTT-based assays," CAP TODAY, September 2018.)

The latest approval was based on the HAVEN 3 and HAVEN 4 clinical trials. It expanded the indication for patients with hemophilia A without factor VIII inhibitors and provided for new dosing regimens for patients with and without factor VIII inhibitors.

Leica launches integrated specimen containment and transport system

Leica Biosystems in October launched MammoPort, an integrated specimen containment and transport system for breast tissue biopsies.

"By standardizing the process of transferring breast biopsy tissue from the radiology suite to the pathology lab, MammoPort maintains the quality of core specimens," Peter Reimer, vice president of core histology at Leica Biosystems, said in a statement. MammoPort eliminates the need for manual tissue handling by radiology technologists, according to the company.

Illumina launches TSO 500

Illumina launched TruSight Oncology 500, a pan-cancer assay designed to identify known and emerging tumor biomarkers.

TruSight Oncology 500 uses DNA and RNA from tumor samples to identify key somatic variants underlying tumor progression, such as small DNA variants, fusions, and splice variants. It can measure tumor mutational burden and microsatellite instability.

TruSight Oncology 500 is for research use only and will ship in the first quarter of 2019.

New panels, expanded QCI solutions from Qiagen

Qiagen introduced at the Association for Molecular Pathology meeting last month three Sample to Insight workflows for next-generation sequencing research using Qiagen's GeneReader NGS system and other NGS platforms.

One of two new GeneRead QIAact panels for use on the GeneReader covers a broad range of cancer-causing variants. The other panel focuses on specific genes. In addition, a new QIAseq panel is being launched for use on any NGS system to measure tumor mutational burden.

The GeneRead QIAact Actionable Insights Tumor DNA UMI panel broadens coverage from 12 to 30 genes. The workflow targets more than 850 DNA variants in hotspot regions and 125 full exons.

The GeneRead QIAact BRCA Advanced UMI panel enables analysis of the full exon coding sequences of the *BRCA1, BRCA2, TP53,* and *PTEN* genes.

The QIAseq TMB Panel is designed to run on any commercial NGS platform, and the workflow targets variants in 486 genes covering full exons. In a single panel, it detects tumor mutational burden, microsatellite instability, single nucleotide variants, and indels.

Also at the AMP meeting, Qiagen launched four enhancements to its Clinical Insight (QCI) bioinformatics solutions.

It introduced QCI Analyze Universal, which delivers NGS variant calling and quality control workflows. Coupled with QCI Interpret, Qiagen says, the software provides end-to-end support for all major clinical sequencing platforms and assays.

Qiagen also improved QCI Interpret's somatic cancer clinical decision support application.

QCI Interpret assay support was expanded to include pipelines preconfigured with a best practices filter for clinical exome/genome cases, including Sanger validation and variant-to-phenotype reporting. And a new variant directory search feature in QCI Interpret makes it possible to store, manage, and view prior laboratory observations and variant classifications in lab-specific variant databases.

NGS Avenio Tumor Tissue Analysis Kits from Roche

Roche in October launched for research use only three new next-generation sequencing Avenio Tumor Tissue Analysis Kits.

The Tumor Tissue Targeted Kit is a 17-gene assay for identifying guideline-related biomarkers. The Tumor Tissue Expanded Kit is a 77-gene assay with both guideline-related and emerging biomarkers. And the Tumor Tissue Surveillance Kit contains 197 genes and is intended for baselining variants in longitudinal tumor burden monitoring applications.

600 LabCorp at Walgreens patient service centers

Walgreens and LabCorp announced in October their mutual commitment to a significant expansion of their LabCorp at Walgreens collaboration. The two companies have agreed to open at least 600 LabCorp patient service centers at Walgreens stores across the U.S. during the next four years, inclusive of the 17 locations that have opened since they first announced their consumer-focused initiative in June 2017.