Put In on the Board

Qiagen touts one-stop shop for next-gen sequencing

December 2015—Despite launching years after the next-generation sequencing systems from Illumina and Thermo Fisher, officials at the German molecular biology company Qiagen see an opening for their GeneReader NGS offering.

“Labs struggle with NGS adoption, whether it’s with fragmented workflows or the technical challenges,” says Jonathan Arnold, senior director of marketing at Qiagen, whose North American headquarters are in Germantown, Md. “We’re not launching a sequencer or a box, but launching a complete solution in itself.”

Arnold

The system was unveiled in November at the Association for Molecular Pathology’s annual meeting. It runs a gene panel that targets 12 clinically actionable genes for the most common types of cancer and can detect up to 1,250 genetic mutations in a tumor sample, the company said. The system includes scalable batch sizes and continuous loading of multiple flow cells, and will be offered on a price-per-test commercial model.

“This is the first fully integrated sample-to-insight NGS system,” Qiagen chief medical officer Tadd S. Lazarus, MD, told CAP TODAY on the AMP exhibit floor. “Others have focused on the hardware, the sequencer, to the detriment of sample preparation, library preparation, and most importantly data. You know, these sequencers put out an extraordinary amount of information and, in and of itself, it’s completely meaningless.”

“What we do is we have a report that is fully actionable, and it allows the laboratory to pass on these insights to the physician to use immediately,” Dr. Lazarus added. He says that Qiagen Clinical Insight, the bioinformatics engine of the GeneReader NGS System, delineates which notations are pathological and their significance, the best drugs for treatment, the peer-reviewed literature citations, and the clinical trials in which the patient might be able to enroll.

“It’s really an extraordinary advance,” Dr. Lazarus said.

Dr. Lazarus

The Broad Institute of MIT and Harvard evaluated the GeneReader NGS System and presented its findings at an AMP workshop. The Broad analysis showed that data from the GeneReader NGS System were 100 percent concordant with results of Qiagen’s FDA-approved Therascreen KRAS RGQ PCR assay, as well as its CE-marked Therascreen RAS Extension Pyro Assay. The system scored 100 percent agreement with Illumina’s MiSeq sequencer, and the GeneReader NGS data had fewer FFPE artifacts because it uses a different method of sample extraction.

The Dartmouth-Hitchcock Medical Center also has helped evaluate the Qiagen system. Gregory J. Tsongalis, PhD, is director of Dartmouth's clinical genomics laboratory.

"The GeneReader system offers another NGS alternative and the precision of Qiagen engineering," he says. "The panels they have developed are robust, and the menu continues to increase. Qiagen also has the added advantage of being able to provide a true analytical solution for managing the massive amounts of data produced."

Notwithstanding the big launch at the AMP meeting, the GeneReader NGS System remains research use only for now.

"We're working closely with these [regulatory] agencies, because this is really the first integrated system and it is rather different than what the agencies have seen before," Dr. Lazarus said. "It's a different ballgame."

Upon FDA approval, Qiagen officials see an opportunity to target smaller laboratories that have held off on NGS due to the cost of sequencing systems, uncertainties over reimbursement, or the lack of bioinformatics expertise. Dr. Lazarus said that some laboratories doing next-gen sequencing work with as many as 15 vendors end to end. Arnold says Qiagen's system will provide a different model.

"As a vendor, we are offering everything an NGS lab needs to get up to running from scratch," he says. A laboratory implementing the GeneReader NGS System "doesn't need a full-time bioinformatician to do this," Arnold adds.

"Illumina makes a great sequencer—there's no doubt about that. Thermo does as well. A lot of laboratories that want a sequencer are more than happy to put the pieces together, and they have the capability to do that," Arnold says. "Basically, we have put the pieces together. And there is a large number of labs that want that or need that."—*Kevin B. O'Reilly*

Surgical museum highlights pathologist's role

In Chicago on CAP business a few years ago, S. Robert Freedman, MD, took the opportunity to visit one of the Windy City's lesser known attractions, the International Museum of Surgical Science. Housed inside a historic chateau-style mansion on Lake Shore Drive, the museum is devoted to furthering the public's "understanding of the history, development, and advances of surgery and related subjects in health and medicine."

Dr. Freedman, a member of the CAP's Council on Membership and Professional Development, greatly enjoyed the museum's exhibits and its collection of more than 20,000 medical artifacts. But he was struck by the "conspicuous absence" of information on pathology's critical role in surgery.

With a little prodding and assistance from Dr. Freedman and other pathologists, that glaring omission has been corrected. The museum now features an exhibit, "Diagnostic Detectives: Pathology in Modern Medical Practice," that endeavors to explain the essential part pathologists play in surgical practice.

The titles of exhibit panels such as "Smoking Gun" and "Modus Operandi" are meant to playfully draw visitors—including the many schoolchildren who come each year—into the topic of pathology, said Justina Doyle, IMSS manager of education and events.

The gallstone collection on

display at Chicago's International Museum of Surgical Science

"When I say 'pathologists' to these kids, a lot of them think I'm saying 'mythology,' and so they start talking about Greek gods and goddesses," Doyle said in a YouTube video produced by the CAP. "So we're really trying to get the word out about pathology at the museum."

One highlight of the exhibit, Doyle said, is a collection of gallstones that Dr. Freedman donated. He had collected the thousands of gallstones of many different sizes, shapes, colors, and consistencies during his three-plus decades of pathology practice in the San Jose–Los Gatos, Calif., area. They are displayed in the two fishbowls Dr. Freedman used to store them. The star of the show is a gallstone measuring eight cm at its longest dimension, donated by fellow CAP council member Michael Misialek, MD.

The museum also features microscopes dating to the 18th and 19th centuries and a statue of Giovanni Battista Morgagni, the 18th-century Italian anatomist widely considered a founder of anatomic pathology. In the CAP's YouTube video, IMSS curator Collin Pressler said officials would like to expand the size and scope of the pathology elements at the museum.

"For a museum committed to representing surgical science in all of its multifaceted components, really recognizing pathology's significance in the field is something we're certainly committed to," he said. The YouTube video is available at http://j.mp/dx_detectives.—*Kevin B. O'Reilly*

Roche EGFR test approved as Tagrisso companion

The FDA granted accelerated approval for an oral medication to treat patients with advanced non-small cell lung cancer, along with a companion diagnostic test. AstraZeneca's Tagrisso (osimertinib) was approved for patients whose tumors have epidermal growth factor receptor mutation T790M and whose disease worsened after treatment with other EGFR-blocking therapy.

The agency also approved the first companion diagnostic test, Roche's Cobas EGFR Mutation Test v2, to detect the type of *EGFR* resistance mutation that Tagrisso is known to target. The newly approved version of the test adds the T790M mutation to the clinically relevant mutations detected by the original Cobas EGFR Mutation Test (v1).

"The approval of safe and effective companion diagnostic tests and drugs continue to be important developments in oncology," Alberto Gutierrez, PhD, director of the FDA's Office of In Vitro Diagnostics and Radiological Health, said in a statement. "The availability of the Cobas EGFR Mutation Test v2 meets a need for the detection of this important *EGFR* gene mutation, which can alter treatment effectiveness."

The safety and efficacy of Tagrisso were demonstrated in two multicenter, single-arm studies involving a total of 411 patients. Fifty-seven percent of patients in the first study and 61 percent of patients in the second study experienced a complete or partial reduction in their tumor size. Continued approval for this indication may be contingent upon further confirmatory studies, the FDA said.

Sectra offers pathology-radiology solution

Sectra demonstrated software designed to improve collaboration between radiology and pathology at the Radiological Society of North America's meeting in early December.

"The solution supports radiologists and pathologists in conducting more efficient, patient-centered, multidisciplinary team meetings or tumor boards, with an enhanced level of quality, by providing access to all relevant clinical information and a complete patient imaging record," Mats Björnemo, Sectra's vice president of product management, said in a statement. "For the IT department, a common backbone has clear advantages. For example, it results in one less IT system and departmental infrastructure to manage, as well as less integration and

fewer interfaces with surrounding healthcare IT systems, such as the EMR."

Sectra's solution for digital pathology is built on the same platform as its radiology PACS, enabling bidirectional sharing of images and reports, thus creating transparency across cancer care pathways. This transparency aims to allow for correlation of findings and provide a broader view of patient disease that helps physicians reach more accurate diagnoses and treatment decisions. In addition, hospitals' maintenance and operating costs are reduced by digitizing pathology on the same platform as radiology.

Sectra's solutions for radiology and pathology include functionality for preparation and presentation at multidisciplinary team meetings. The joint platform enables pathologists and radiologists to add images to the same list during the actual review work. The annotations and image settings established during the review are then applied automatically, streamlining the preparation workflow. During the presentation, radiologists and pathologists can use the same system to show images and annotations and to manage follow-up tasks.

Digital pathology for primary diagnosis has not yet been approved by the FDA. The solution was demonstrated as a work in progress for U.S. customers.

CE mark for Biocartis' respiratory panel

Belgian molecular diagnostics company Biocartis has launched its first infectious disease test on the Idylla platform. The Idylla Respiratory IFV-RSV Panel was developed by Janssen Diagnostics and is intended for the detection of various strains of the influenza and respiratory syncytial viruses. The panel received CE-IVD marking Nov. 18 and is being launched for commercial use in Europe and other areas that recognize the CE mark. Janssen has appointed Biocartis as co-exclusive worldwide distributor of the test.

The Idylla Respiratory IFV-RSV Panel aims to combine the speed of rapid tests with the quality and sensitivity standards of central laboratory tests. It is designed for the qualitative detection of nucleic acids of influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype 2009 H1, H275Y mutation of influenza A subtype 2009 H1, influenza B, and RSV subtypes A and B from nasopharyngeal swabs of adult and pediatric patients.

The panel can be performed in as little as 50 minutes and requires less than one minute of hands-on time, the company said. The Idylla Rapid Ebola Virus Triage Test, developed in association with Janssen Diagnostics and the Institute for Tropical Medicine in Antwerp, is expected to be the next infectious disease test on the Idylla platform.