EXECUTIVE SNAPSHOT
By Alan Lenhoff, Editor

Diagnostics for infectious diseases, cancer screening, and safeguarding the blood supply

If you were explaining Hologic to someone who is not familiar with the organization, how would you characterize its primary areas of expertise? At the highest level, Hologic is focused on enabling healthier lives, everywhere, every day, by pursuing what we call “the Science of Sure.” This means we strive to provide healthcare providers and patients progressive certainty and ever-greater peace of mind in their clinical decisions. We do this by developing, manufacturing, and commercializing premium diagnostic, medical imaging, and surgical products, many of which serve the healthcare needs of women.

How does diagnostics fit in with the company’s overall business? What are the synergies between the company’s business divisions? Diagnostics is Hologic’s largest business, representing about 45 percent of revenue last year. Many of our diagnostic products, including the ThinPrep Pap test, our Aptima assays for sexually transmitted diseases, and our iFNR test for preterm labor risk, address important issues in women’s health, as do our mammography systems and gynecologic surgical products. There are important synergies across our diagnostics franchises. For example, several of our Aptima molecular tests can be performed from a ThinPrep sample. Across the businesses, we call on different kinds of customers, so synergies are fairly limited, although we are exploring a few areas. For example, our diagnostics sales reps are beginning to share information about our Genius 3D mammograms with their OB/GYN customers.

On your watch, Hologic has accomplished a significant corporate turnaround during the last few years. How has this enhanced the company’s ability to serve its customers? Both Hologic and our diagnostics division have returned to growth, and our recent addition to the S&P500 stock index reflects this dramatic turnaround. To make it happen, we attracted an entirely new leadership team to drive long-term, sustainable, organic growth, rather than the debt-laden acquisitions from the company’s past. Based on these acquisitions, Hologic paid more in interest expense than it invested in research and development in the year before I arrived. But as results have improved, we’ve used strong cash flows to pay down debt, and consistently increased R&D spending. And we’re beginning to reap the rewards. For example, we recently launched our viral load tests for HIV, hepatitis C, and hepatitis B in Europe, and have begun to file regulatory applications in the United States. That’s a great way to serve our customers—by introducing innovative new products.

Getting back to the Aptima family of products—how do they advance diagnostics for HIV, hepatitis, and other sexually transmitted diseases? Our Aptima products include assays for sexually-transmitted infections (STIs), including chlamydia, gonorrhea, the human papillomavirus (HPV), and trichomonas. In addition to providing accurate and reliable performance, the Aptima assays run on our fully automated, random access Panther system. Panther builds on the success of our first generation automated instrument, Tigris, and incorporates customer requests for greater flexibility and walk-away time, with a small footprint. And with the addition of the viral load assays, we are actively expanding the Panther menu. Finally, we are developing a new system called Panther Fusion, which will be a “sidecar” adding PCR capabilities and a new assay format to Panther. That product will launch with our next generation of respiratory virus tests, and over time give labs the opportunity to run most of their major molecular volume on one fully automated, compact instrument.

Recently there have been proposed changes to cervical cancer screening guidelines. How is that changing testing? With reference again to our ThinPrep Pap test and the Aptima HPV technology, Pap testing has contributed to a significant reduction in cervical cancer deaths over several decades, and has proven to be one of the most successful screening programs of all time. The results are even better when Pap testing is combined with a test for HPV, an approach commonly referred to as co-testing. An HPV test was approved as a primary screen for cervical cancer in 2014, but published studies support the superior performance of co-testing. A study of 8.6 million women conducted by Quest and published last year in Cancer Cytopathology demonstrated that nearly one in five cervical cancers were missed by HPV primary screening, and a recent study led by investigators at Houston Methodist Hospital supported these findings. We firmly believe that women are best served when physicians adhere to the recommendation...
of the American College of Obstetricians and Gynecologists (ACOG), which prefers co-testing for women between the ages of 30 and 65.

How have your Procleix assays increased the safety of the blood supply by detecting the genetic material of HIV-1, hepatitis, and other viruses? Our Procleix assays, sold by our partner Grifols, were the first molecular tests approved by the FDA to screen donated blood. These tests, when combined with other screening measures, have helped reduce the risk of contracting potentially deadly viruses like HIV-1 and hepatitis C from a blood transfusion to less than one in a million. We also are developing a molecular assay to screen donated blood for the Zika virus. This demonstrates Hologic’s ability to quickly address new and emerging threats, as well as our commitment to help safeguard the donated blood supply.

Molecular diagnostics for use in infectious disease as well as oncology is obviously here to stay. What challenges does it face in terms of more widespread adoption in the clinical lab? One of the main challenges has been the relative complexity of the technology and the need for highly skilled labor. Our response has been consistent streamlining of instrument workflows and increased automation through platforms like Panther, making these tests as easy to use as possible. Developing an extensive, FDA-approved menu for a single system also contributes to simpler lab workflows. Hologic is committed to continuously improving the accuracy, reliability and accessibility of molecular testing, which benefits labs, physicians, payers, and, most importantly, patients.