Roche products and acquisitions, 9/14

At the AACC Show 2014

September 2014—New products featured by Roche this year include analyzers, an automated workflow series, and assays.

The Cobas u 601 urine analyzer is a fully automated solution for urine strip testing in mid- to high-volume labs that delivers high-quality results through reagent test strips. This analyzer is not available for sale in the U.S.; a 510(k) submission is pending.

The Cobas 8100 automated workflow series is a modular solution that provides multilevel and bi-directional sample transport with hands-free add-on and repeat testing. It was specifically designed to eliminate the technical barriers of true hands-off testing.

The Cobas CT/NG v2.0 Test tests for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae DNA in symptomatic and asymptomatic patients. In addition to self-collected vaginal swabs (collected in a clinical setting) and male urine specimens, the test may be used with endocervical and clinician-collected vaginal specimens, female urine specimens collected in Cobas PCR media, and cervical specimens collected in PreservCyt solution.

The Cobas HPV Test, the first HPV test approved by the FDA for first-line primary screening of cervical cancer, is a fully automated, DNA-based test. Approved for use with women 25 and older, it provides three results in one test: individual results for HPV 16 and 18 genotypes and a pooled result for the 12 other high-risk types, all in one run from one patient sample.

Three products from the Elecsys line include the calcitonin immunoassay, an immunoassay for the in vitro quantitative determination of human calcitonin in serum and plasma; the CMV IgG assay, intended to be used as an aid in determining the serological status to CMV in individuals in which a CMV IgG test was ordered, including pregnant women; and the HBeAg immunoassay, an immunoassay for the in vitro quantitative determination of hepatitis B e antigen in human serum or plasma (K2-EDTA, lithium or sodium heparin, and sodium citrate) in adult patients with symptoms of hepatitis or at risk for hepatitis B virus infection.

In June the company announced the acquisition of Genia Technologies, a privately held company based in Mountain View, Calif. Genia is developing a single molecule, semiconductor-based DNA sequencing platform using nanopore technology. Genia's proprietary technology is expected to reduce the price of sequencing while increasing speed and sensitivity. Once the transaction is complete, Genia will be integrated into Roche's Sequencing Unit and will continue to focus on the development of this system.

Roche announced in April the acquisition of IQuum, a privately held company based in Marlborough, Mass. This acquisition will provide Roche access to IQuum's Laboratory-in-a-tube (Liat) System, which enables health care workers to perform rapid molecular diagnostic testing in a point-of-care setting, closer to patients and with minimal training. The Liat Analyzer and Liat Influenza A/B Assay, the first test available for use on the system, produce reliable and accurate lab-like results and are CE marked and FDA cleared. Once the transaction is complete, IQuum will be integrated into Roche Molecular Diagnostics.

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