High-volume platforms, inventory solutions, 10/16

At the AACC show 2016

October 2016—Roche launched its presence by featuring several next-generation diagnostic testing platforms and a virtual reality experience that was designed to give attendees an “under the hood” look at a lab of the future and a concept Roche calls the “Roche connected lab.”

Products featured at Roche’s booth included the Cobas c 513 analyzer, a dedicated high-volume HbA1c testing solution designed to fulfill the needs of high-volume laboratories while also meeting the new requirements for HbA1c testing. It is available in countries accepting the CE mark and is pending 510(k) clearance.

The Cobas Connection Modules (CCM) is a high-volume automation solution that provides convenient sample loading, quality and quantity checks, and workflow flexibility and connectivity to third-party platforms and across disciplines, such as molecular diagnostics, hematology, and coagulation. Roche is the first IVD manufacturer to connect molecular testing solutions validated for cross-contamination compliance, according to a company statement.

The Cobas Influenza A/B & RSV test for the Cobas Liat system is a CLIA-waived, real-time PCR test that differentiates flu and respiratory syncytial virus in 20 minutes.

Roche Inventory Solutions is an inventory management application designed to optimize supply chain processes and provide real-time management insights for laboratories. Based on user-defined min-max levels, consumption patterns, and order data, the system indicates upcoming shortages and can suggest or even automatically trigger an order.

The CoaguChek XS mPOC App Kit is a mobile iOS solution designed to work seamlessly with the CoaguChek XS meter to allow patient self-testers to wirelessly transmit their PT/INR test results from their meter at home directly to CoaguChek Patient Services and their health care provider. This product is in development and not commercially available in the U.S.

The FDA has approved Roche’s Ventana PD-L1 (SP142) Assay as a complementary diagnostic for patients who are considering treatment with the FDA-approved Roche immunotherapy Tecentriq (atezolizumab) for metastatic urothelial cancer. This test evaluates patient PD-L1 status using immune cell staining and scoring within the tumor microenvironment. The assay can identify patients most likely to respond to treatment with Tecentriq, as demonstrated by higher overall response rates in cohort two of the IMvigor 210 clinical trial. The novel approach uses immunohistochemistry technology designed to visually enhance and score PD-L1 protein on tumor-infiltrating immune cells. In an analysis based on 14.4 months of median follow-up, Tecentriq shrank tumors in 15 percent of people evaluable for efficacy whose disease progressed after platinum-based chemotherapy. Tecentriq shrank tumors in 26 percent of people whose disease had medium and high levels of PD-L1 expression. PD-L1 testing is not required for the use of Tecentriq, but it may provide additional information for physicians and inform patient dialogue.

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