



Ortho Clinical Diagnostics Expands Menu, Applies for FDA Clearance of Vitros XT 7600 System

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NEW YORK (360Dx) – Ortho Clinical Diagnostics has applied for US Food and Drug Administration clearance of an integrated system for mid- and high-volume labs that it anticipates launching in the US early next year.

The high-throughput system combines automated clinical chemistry and immunoassay testing for a broad range of assays with thin film, dry slide technology that speeds throughput for selected assays.

The FDA will begin reviewing its application for clearance of the Vitros XT 7600 this month, Jay Snyder, Ortho's vice president of business fields, clinical laboratory platforms, and solutions, said in an interview.

Further, the firm is developing a second system, the Vitros XT 3400, that's designed to run clinical chemistry tests for low- and medium-volume labs and can be added as an option to the higher-volume automated platform. Ortho anticipates the 3400 will receive CE marking later this year, and the company will subsequently apply for FDA clearance, Snyder said at the 70th American Association for Clinical Chemistry Scientific Meeting & Clinical Lab Expo in Chicago last week.

Earlier this year, the firm received [CE marking](#) for the higher volume XT 7600 enabling its marketing in parts of Europe that recognize the designation. The system is also available in certain markets in the Middle East, Africa, Asia, and Latin America.

Both systems use similar technologies that are unique to Ortho, Snyder said. They employ dry-slide technology that eliminates washing and other steps that could normally introduce errors in testing, he said. Because dry slide technology does not require water in its operations, it eliminates the need for high-quality water as a testing requirement.

In Ortho's dry-slide technology, spreading, masking, scavenger, and reagent layers are discretely combined on one postage-stamp-sized slide. When plasma, serum, urine, or cerebrospinal fluid contact these dry chemical layers, a spectral reaction occurs that can be measured by the system. Using a spectrophotometer to measure color density that corresponds to analytes, the technology enables two separate lab tests to be run simultaneously for selected assays, Snyder said.

Laboratorians can leverage the format to run pairs of tests on one slide for 12 highly utilized analytes in clinical chemistry. "We paired the analytes in a way that is logical, combining two tests that are frequently ordered together," Snyder said. "A good example is two renal markers, blood urea nitrogen (BUN) and creatinine, which are ordered together 95 percent of the time. With the XT capability, we improve the number of tests per hour that we run on the instrument, and that provides a workflow benefit to our customers."

The technology inherently requires less patient sample needed per test, which can be "quite meaningful for certain patient types, such as pediatric and geriatric patients where you want to draw as little sample as possible. ...[T]hat is important to laboratories who have customers that serve those patient populations," Snyder said.

He said that with dry slide technology, the system aspirates the sample, dispenses it onto the slide, and reads the result. Wet chemistry systems in most analyzers require washing of cuvettes and probes, aspirating reagents and samples into cuvettes, and steps involving mixing and incubation, he said.

In all, the large volume XT 7600 has around 145 assays and can run 1,200 tests per hour.

The firm said that it continues to add new tests and further broaden its menu in response to customer demands. Ortho said at the AACC meeting that among other indications, it is currently developing assays for endocrinology; cardiology, including an assay to detect high-sensitivity troponin I; and infectious diseases, including assays to detect Chagas infections and procalcitonin which is used in sepsis diagnostics.

"Modeling customer workflows, we see a 30 to 40 percent improvement in throughput by combining digital imaging capability with XT dry slide technology," Snyder said. In practice, workflow improvements depend on the number and types of tests that a physician orders, and how many of them correlate to the pairs that are available in the two-test format.

The firm's XT 3400, which is in development, is intended for smaller laboratories that don't require the full menu and full throughput of the XT 7600, Snyder said. In that customer segment, the firm currently markets a platform called the Vitros 350. The new system has about three times the throughput of the 350 within the same footprint, "a step change in performance per square meter," Snyder said. The 350 analyzer processes up to 300 results per hour and has 45 clinical chemistry assays.

All of Ortho's instruments are designed to connect with the firm's automated Vitros platform, so depending on customers' testing mix and volume requirements, they can mix and match systems. It is feasible to combine the XT 7600 with the XT 3400 to obtain testing throughput and menu coverage that meets testing needs in a large lab, he said.

"More testing is happening all the time, and that increase in volume presents challenges when laboratories are already struggling to attract and retain qualified staff," Snyder said. "Decreasing reimbursement, budgetary constraints, and a regulatory environment that is ever changing makes it more difficult for labs to keep up."

As a result, he said, laboratories are seeking solutions that improve workflow, require less operator intervention, and at the same time improve quality.

Snyder said that compared to its competitors in the *in vitro* diagnostic industry, Ortho is solely focused on the core lab disciplines of clinical chemistry and immunoassay systems, and transfusion medicine. The focus reflects its management team's philosophy of setting priorities. "We have invested heavily in those disciplines and view it as an advantage that we have not been distracted by other testing disciplines," he said.