FDA expands use of Vitros HIV Combo test

September 2019—Ortho Clinical Diagnostics announced that its Vitros Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator (Vitros HIV Combo test) has been granted FDA premarket approval for use on Ortho's Vitros XT 7600 Integrated System. The Vitros HIV Combo is a fourth-generation test that detects HIV-1 and HIV-2 antibodies and the p24 antigen.

The company announced in July the CE marking of an enhanced version of its Vitros NT-proBNP II assay, designed as an aid in diagnosing heart failure and for the risk stratification of acute coronary syndrome and heart failure. It is further indicated as an aid in the assessment of increased risk of cardiovascular events and mortality in patients who have stable coronary artery disease and in the assessment of heart failure severity in patients diagnosed with heart failure.

The CE mark of the NT-proBNP II assay comes on the heels of Ortho's launch of its High Sensitivity Troponin I assay, also CE marked. Both the Vitros NT-proBNP II and hs Troponin I assays can run on the Vitros XT 7600 Integrated System, the Vitros 5600 Integrated System, the Vitros 3600 Immunodiagnostic System, and the Vitros ECi/ECiQ Immunodiagnostic Systems.

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