Ortho Clinical Diagnostics

Ortho Receives CE Mark for Enhanced VITROS® Immunodiagnostic Products NT-proBNP II Assay, an Aid in Diagnosing and Assessing Heart Failure

July 23, 2019

Improved assay quality with the use of monoclonal antibodies ; Enhanced robustness to potential interferences; Rule-in and rule-out clinical performance allows clinicians to efficiently assess heart failure patients

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, announced the CE Mark of an enhanced version of its VITROS® NT-proBNP II assay, part of Ortho's expansive cardiac menu. The analytical characteristics and clinical performance of the VITROS NT-proBNP II assay allow clinicians to efficiently assess heart failure patients. The assay is designed for the aid in diagnosis of 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.

> ***"We are committed to continued expansion of our cardiac offering with new and improved assays," said Heidi Casaletto, head of product portfolio and marketing at Ortho. "With NT-proBNP II, clinicians can have confidence in test results to aid in diagnosis, assess severity and support the management of heart failure."***

Patients experiencing heart failure need quick and accurate diagnoses. According to the World Health Organization, there are 17.9 million deaths each year from cardiovascular diseases, including heart failure, that make up approximately 31 percent of all deaths worldwide.[i]

N-terminal pro Brain Natriuretic Peptide (NT-proBNP), measured by the VITROS NT-proBNP II assay, is recommended and used as an aid in the diagnosis of heart failure. NT-proBNP is not a target for the angiotensin receptor-neprilysin inhibitors (Entresto®), a guideline recommended treatment for heart failure patients. NT-proBNP is not a neprilysin substrate and is a more suitable biomarker than BNP for heart failure in these patients.[ii] The clinical performance of the VITROS NT-proBNP II assay was validated at three age-dependent rule-in cutoffs and at one age-independent rule-out cutoff. These cutoffs have been previously validated in the International Collaborative of NT-proBNP (ICON) and ICON Reloaded studies.[iii] In addition, the assay has enhanced robustness to endogenous and exogenous interferences.

The CE Mark of the VITROS NT-proBNP II assay comes on the heels of Ortho's recent launch of its High Sensitivity Troponin I assay, also CE Marked and a critical tool for clinicians who are seeking improved strategies to more rapidly and accurately identify patients suffering from a heart attack. Both the VITROS NT-proBNP II and hs Troponin I assays can run on Ortho's VITROS® XT 7600 Integrated System, the VITROS® 5600 Integrated System, VITROS® 3600 Immunodiagnostic System and the VITROS® ECi/ECiQ Immunodiagnostic Systems.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics serving the clinical laboratory and immunohematology communities. Across hospitals, hospital networks, blood banks and labs in more than 125 countries and territories, Ortho's high-quality products and services enable health care professionals to make better-informed treatment decisions. For the immunohematology community, Ortho's blood typing products help ensure every patient receives blood that is safe, the right type and the right unit. Ortho brings sophisticated testing technologies, automation, information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. Ortho's purpose is to improve and save lives with diagnostics, and it does that by reimagining what's possible. This is what has defined Ortho for more than 75 years, and it's what drives Ortho forward.

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[i] https://www.who.int/cardiovascular_diseases/en

[ii] Karen Titus, CAP Today, November 2015, p66

[iii] https://www.ncbi.nlm.nih.gov/pubmed/29544601; https://www.ncbi.nlm.nih.gov/pubmed/16293638

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