Ortho Clinical Diagnostics

Ortho Clinical Diagnostics Launches Ortho's VITROS® C-peptide Assay

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Assay is now commercially available in the U.S. and countries accepting CE Mark

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, today announced the launch of Ortho's VITROS ® Immunodiagnostic Products C-peptide Reagent Pack and Calibrators, which broadens the company's menu of tests for all aspects of diabetes and other pancreatic disorders. The assay is now commercially available in the U.S. and countries that accept the CE Mark.

C-peptide measurement is used in the diagnosis and management of different types of diabetes and related conditions. C-peptide is produced and secreted by pancreatic beta cells. Its measurement aids in differentiating between type 1 diabetes, type 2 diabetes, Latent Autoimmune Diabetes (LADA) and Maturity Onset Diabetes of the Young (MODY). It is also used to detect absolute deficiency of insulin.[1,2] In conjunction with insulin and glucose results, C-peptide measurement also helps differentiate between factitious hypoglycemia and endogenous hyperinsulinism caused by insulinoma or other disorders.[3,4]

"Our goal at Ortho is to provide the broad range of tools health care providers need to monitor and manage complex metabolic diseases and conditions like diabetes," said Robert Yates, Ortho's chief operating officer. "Adding C-peptide to Ortho's VITROS ® menu demonstrates our continued commitment to innovation that helps our customers achieve their goals."

According to the World Health Organization, diabetes affects 9 percent of people 18 years or older worldwide.[5] What's more, 191 million people with diabetes are currently undiagnosed.[6] Diabetes is managed as a chronic, lifelong condition with several significant co-morbidities, so it is vital that laboratories have a partner that supports the continuum of diabetes diagnostics.

The launch follows Ortho's July 2017 global launch of its Insulin assay, joining an existing, comprehensive diabetes menu that includes HbA1c, Glucose, Beta Hydroxybutyrate, BUN/Urea Creatinine and Microalbumin. On a worldwide basis from mid-2014 through the end of 2018, Ortho is on track to bring about 60 new or enhanced assays to market for its customers.

About the VITROS® Systems

The VITROS® Chemistry, Immunodiagnostics and Integrated Systems from Ortho Clinical Diagnostics is a portfolio of products and patented enabling technologies that help clinical laboratories diagnose, monitor and treat disease. VITROS® Products are engineered to help clinical laboratories with organizational, operational and economic challenges.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics serving the global 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. Ortho brings sophisticated testing technologies, automation and information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. 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'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.

1. http://www.who.int/diabetes/global-report/en/

2. https://www.idf.org/about-diabetes/what-is-diabetes.html

3. Johansen O et al. C-peptide Levels in Latent Autoimmune Diabetes in Adults Treated With Linagliptin Versus Glimepiride: Exploratory Results From a 2-Year Double-Blind, Randomized, Controlled Study. Diabetes Care 2014;37: e11-e12.

4. Thanabalasingham G et al. Systematic assessment of etiology in adults with a clinical diagnosis of young-onset type 2 diabetes is a successful strategy for identifying maturity-onset diabetes of the young. Diabetes Care. 2012 Jun; 35(6): 1206-12.

5. Scarlett JA et al. Factitious hypoglycemia. Diagnosis by measurement of serum C-peptide immunoreactivity and insulin-binding antibodies. N Engl J Med. 1977 Nov 10;297(19): 1029-32.

6. Service FJ et al. C-peptide during the prolonged fast in insulinoma. J Clin Endocrinol Metab.1993 Mar;76(3):655-9

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