



## Ortho Clinical Diagnostics Receives FDA Clearance for Intact Parathyroid Hormone Assay

### Assay Consolidates Routine and Intraoperative iPTH Testing

**RARITAN, N.J.** (November 1, 2010) - Ortho Clinical Diagnostics today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of the VITROS® intact Parathyroid Hormone (iPTH) Assay. The VITROS® iPTH Assay measures intact parathyroid hormone levels and utilizes one protocol for both routine and intraoperative testing with results available in 18 minutes. The VITROS® iPTH Assay is designed to be run in a fully automated, random access format on the VITROS® ECi/ECiQ and 3600 Immunodiagnostic Systems, and can also be run on the VITROS® 5600 Integrated System to combine clinical chemistry, routine and infectious disease immunoassay testing on a single platform. Equivalent analytical results are generated across all three systems.

"The VITROS® iPTH Assay will allow our hospital to provide expanded surgical options for our patients," said Matthew Burtelow, M.D., Ph.D., of Boise Pathology at St. Luke's Boise Medical Center in Boise, Idaho. "During parathyroid surgery, we can now run the iPTH test on our VITROS® Systems to help us determine if the procedure to remove the suspected parathyroid tumor was successful."

Measuring intact parathyroid hormone levels aids in the differential diagnosis of hyperparathyroidism, hypoparathyroidism or hypercalcemia of malignancy. Hyperparathyroidism is excess production of calcium resulting from overactivity in the parathyroid glands.<sup>1</sup> Complications of hyperparathyroidism are primarily related to the long-term effect of calcium imbalances in a patient's bones and bloodstream, and may be associated with a number of health conditions, such as cardiovascular disease, kidney stones and osteoporosis.<sup>2</sup>

"The launch of the VITROS® iPTH Assay underscores the commitment Ortho Clinical Diagnostics has to expanding its menu offerings to best meet the needs of clinical laboratories and their patients," said Bob Roda, Vice President, Worldwide Marketing, Clinical Laboratories and Donor Screening. "By being able to run an iPTH test as part of routine assay testing on the VITROS® Systems, laboratorians will be able to consolidate their workload onto a single system, helping to further improve productivity and efficiency."

Ortho Clinical Diagnostics has a broad, world-class menu of assays offering all of the most important clinical chemistry tests that cover major disease states including cardiology, oncology, endocrinology, infectious disease, thyroid, metabolic conditions and anemia. The VITROS® assay menu covers up to 90 percent of the top 100 assays and 99 percent of laboratory test volume, with numerous other assays in development. In addition, standardized VITROS® reagents will enable laboratories to better manage inventories and costs in addition to producing consistent test results from platform-to-platform. This is particularly beneficial for laboratories with multiple VITROS® platforms in their facilities.

#### **About the VITROS® 3600 Immunodiagnostic System**

The VITROS® 3600 Immunodiagnostic System is a high-capacity immunoassay system with Intelligent Sample Management for routine and specialty testing. The VITROS® 3600 Immunodiagnostic System offers a broad menu of immunoassays worldwide, covering disease states such as cardiology, oncology, endocrinology, infectious disease, thyroid, metabolic conditions and anemia.

#### **About the VITROS® 5600 Integrated System**

The VITROS® 5600 Integrated System is a high-capacity system that integrates clinical chemistry and immunoassay testing on one platform using innovative Sample Centered Processing. The VITROS® 5600 platform is smaller than many other systems and does not have any water or drainage requirements, making the most of limited lab space while allowing flexibility in instrument location.

#### **About the VITROS® ECi/ECiQ Immunodiagnostic System**

The VITROS® ECi/ECiQ Immunodiagnostic System is a high-capacity immunoassay system with Intelligent Sample Management for routine and specialty testing designed for low- to mid-volume laboratories that require continuous processing. The VITROS® ECi/ECiQ Immunodiagnostic System offers a broad menu of immunoassays worldwide, covering disease states such as cardiology, oncology, endocrinology, infectious disease, thyroid, metabolic conditions and anemia.

#### **About Ortho Clinical Diagnostics**

Ortho-Clinical Diagnostics, Inc., part of the Johnson & Johnson Family of Companies, delivers the high-quality *in vitro* diagnostic products that give healthcare professionals around the world the knowledge they need to make better treatment decisions sooner. The company serves the global transfusion medicine community with donor screening and blood typing products to

help ensure every patient receives blood that is safe, the right type and the right unit. Ortho Clinical Diagnostics also brings sophisticated information management, testing technologies, and automation and interpretation tools to clinical laboratories worldwide to help them run more efficiently and improve patient care. For more information, visit [www.orthoclinical.com](http://www.orthoclinical.com).

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- 1 MayoClinic.com, Hyperparathyroidism Definition. Available at: <http://www.mayoclinic.com/health/hyperparathyroidism/DS00396>. Accessed July 15, 2010.
- 2 MayoClinic.com, Hyperparathyroidism Complications. Available at: <http://www.mayoclinic.com/health/hyperparathyroidism/DS00396/DSECTION=complications>. Accessed July 15, 2010.
- 3 OCD Data on File