

Press Release

Gold Standard Diagnostics' and DAsource ImmunoAssays' 25-OH Vitamin D, Total Assay Receives 510k FDA Clearance

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Achieve Cost Effective, Accurate and Reproducible Results Regardless of Testing Volume

DAVIS, Calif., Jul 24, 2013 (BUSINESS WIRE) -- Gold Standard Diagnostics, Corp. (GSD, www.gsdx.us), a leading manufacturer and marketer of clinical laboratory instrumentation and assays for the in vitro diagnostics market, announced 510k FDA Clearance of its 25-OH Vitamin D, Total ELISA. The competitive assay strongly correlates with established LC/MS, EIA and Chemiluminescence methods, and offers high sensitivity and specificity over a wide dynamic range. The assay can be automated on a variety of instruments, providing a cost-effective Vitamin D testing option, even at lower volumes.

"As Vitamin D levels have become an important indicator of overall health, testing volume has risen but assay choices have remained limited. Especially for labs or physicians with smaller volumes, the prohibitive cost and volume requirements of a high-throughput system can make running Vitamin D in-house difficult to justify financially. GSD has created an ELISA that can be fully-automated and cost-effective even if a lab only runs a few samples a week," says Gerrit Mueller, Product Manager for Gold Standard Diagnostics.

DAsource Collaboration

The Vitamin D assay was developed by Belgium-based DAsource ImmunoAssays S.A. Gold Standard Diagnostics and DAsource have enjoyed a successful relationship for many years. GSD is the exclusive distributor of the Vitamin D assay in the U.S. market. In turn, DAsource also distributes the GSD ThunderBolt(R) automated instrument worldwide.

"This approval is a milestone for our company. It not only proves the quality of our assay but it also allows us via GSD to enter into the US market with this exciting product that has been highly appreciated by our customers and made the assay a huge success in Europe and Asia immediately after launching in 2012," says Dr. Jef Vangenechten, CEO of DAsource.

Automation Options

The GSD Vitamin D assay features a unique pre-treatment step that allows for complete automation on virtually any open ELISA processor. Because of the simple pre-treatment step and automation capability, GSD's 25-OH Vitamin D provides fast and consistent results. All assay protocol steps are completed in a standard microtiter plate, without the need for labor-intensive, time-consuming and complicated pre-treatment done manually outside of the analyzer.

Clinical Significance of Vitamin D Testing

Vitamin D testing offers important information for general physicians and specialists alike. Long-established as an important factor for bone metabolism, new research indicates Vitamin D also plays an important role in immune function, cardiovascular disease, autoimmune conditions, diabetes, depression and cancer prevention. Many reports estimate that up to 75% of the U.S. population has a deficiency of 25-Hydroxyvitamin D.

For more information on GSD's Vitamin D assay visit our website: <http://www.gsdx.us/>

Simplify Your Laboratory Experience

Contact Gold Standard Diagnostics for more information: Email: info@gsdx.us | Phone: (530) 759-8000 | Web: <http://www.gsdx.us/>

About Gold Standard Diagnostics:

Gold Standard Diagnostics (GSD) provides comprehensive diagnostic solutions that improve lab efficiency and minimize overall costs. Through an extensive product menu, automated instrument platforms, and outstanding customer service, GSD solves real laboratory problems. The result is a seamless laboratory experience achieved through an integrated approach.

More information is available at <http://www.gsdx.us/>

About DIAsource ImmunoAssays S.A.

DIAsource ImmunoAssays (www.diasource.be) develops, manufactures and markets clinical diagnostic assays and antibodies in the field of endocrinology and infectious diseases. DIAsource has specific development and manufacturing programs for Vitamin D, Renin, Calcitonin and other specialty markers. DIAsource provides selected instrumentation Elisa reader, washer and shaker, along with open and closed fully automated Elisa platforms helping customers to automate their tests.

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