Revvity Announces FDA Clearance for First Automated Free Testosterone Test

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WALTHAM, Mass.--(BUSINESS WIRE)-- **Revvity, Inc.** (NYSE: RVTY), today announced that it received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for EUROIMMUN's automated chemiluminescence-based immunoassay (ChLIA) **test** for free testosterone. This innovative test is the first of its kind to receive FDA clearance for direct quantitative measurement of free testosterone levels, marking a significant advancement in diagnostic capabilities for androgen disorders.

Key features of the new test include:

- The only FDA-cleared ChLIA assay for direct quantitative measurement of free testosterone in human serum or plasma.
- Rapid results on EUROIMMUN's ChLIA platforms with the first result available in just 48 minutes and an estimated throughput of nearly 60 tests per hour.
- Incorporation of monoclonal antibodies to ensure specificity and consistent performance across test batches.

The state-of-the-art assay is processed on the Company's random-access **iSYS**TM or **i10** TM instruments to deliver quick turnaround times and high-throughput testing with minimal technician training and expertise, while maintaining superior accuracy and reliability. The assay provides direct measurement of free testosterone levels in a single test, enhancing diagnostic capabilities for conditions such as hypogonadism, impotence, polycystic ovarian syndrome (PCOS), and other androgenital syndromes.

"Laboratory customers have been asking for a user-friendly FDA-cleared test, on a random-access platform, for direct measurement of free testosterone," said Jonathan Friend, general manager at Revvity's EUROIMMUN US. "This clearance reinforces our commitment to expanding the FDA-cleared menu for the EUROIMMUN family of ChLIA automation solutions with assays that serve diverse patient populations across all demographics."

For more information about EUROIMMUN and its diagnostic solutions, please visit **this webpage**.

About Revvity

At Revvity, “impossible” is inspiration, and “can’t be done” is a call to action. Revvity provides health science solutions, technologies, expertise, and services that deliver complete workflows from discovery to development, and diagnosis to cure. Revvity is revolutionizing what’s possible in healthcare, with specialized focus areas in translational multi-omics technologies, biomarker identification, imaging, prediction, screening, detection and diagnosis, informatics and more.

With 2023 revenue of more than $2.7 billion and over 11,000 employees, Revvity serves customers across pharmaceutical and biotech, diagnostic labs, academia and governments. It is part of the S&P 500 index and has customers in more than 190 countries.

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