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Revvity announces US FDA clearance for first automated free testosterone test

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The only FDA-cleared ChLIA assay for direct quantitative measurement of free testosterone in human serum or plasma



Revvity, Inc. has received 510(k) clearance from the US 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.

It is the only FDA-cleared ChLIA assay for direct quantitative measurement of free testosterone in human serum or plasma. It provides 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.

The state-of-the-art assay is processed on the company's random-access iSYS or i10 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."