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Revvity Receives FDA Clearance for Total Testosterone Assay Enabling Comprehensive Automated Testosterone Testing Solution

- ***Delivers the only FDA-cleared ChLIA testosterone testing portfolio with direct measurement of total testosterone, free testosterone, and sex hormone-binding globulin***
- ***Simplifies clinical workflow on a single platform***
- ***Expands the Company's endocrinology portfolio and capabilities***

WALTHAM, Mass. – May 13, 2026 – Revvity, Inc., through its subsidiary, Immunodiagnostic Systems (IDS), today announced that it received clearance from the U.S. Food and Drug Administration (FDA) for its Total Testosterone automated chemiluminescence immunoassay (ChLIA). This offering complements the Company's FDA-cleared ChLIA tests for free testosterone and sex hormone-binding globulin (SHBG), delivering a first of its kind, complete solution for testosterone-related disorders on a single platform.

This comprehensive portfolio enables direct ChLIA measurements of total testosterone, SHBG, and free testosterone, providing first- and second-line diagnostic testing capabilities for suspected hypogonadism in men. Processed on IDS' random-access automation platforms, the expanded portfolio allows for single platform testing and replacement of equilibrium dialysis-liquid chromatography/mass spectrometry (ED-LC/MS) methods that require complex technologies and calculations with operational and reproducibility challenges, thereby significantly streamlining workflow without compromising accuracy and reliability.

"Adding the total testosterone assay to our automated ChLIA platform transforms the offering to a wholly integrated solution that supports diagnostic testing for androgen-related conditions in both men and women," said Arvind Kothandaraman, vice president and general manager, Euroimmun North America. "This clearance demonstrates our commitment to continued expansion of our portfolio to aid in the timely diagnosis of endocrine disorders."

Additional FDA cleared assays in the Company's reproductive endocrine disorders portfolio include 17-OH progesterone (17-OHP), androstenedione and prolactin.

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 2025 revenue of $2.9 billion and approximately 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 160 countries.

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