NEWS RELEASE

First Blood Test for Endometriosis Launched by Kephera Diagnostics

Framingham, MA – July 24, 2025

Kephera Diagnostics, a CLIA-certified and CAP-accredited diagnostic laboratory, announced the launch today of EndomTest™, the first non-invasive commercially available diagnostic test for endometriosis in the United States. This innovative test only requires a blood sample, offering a novel alternative to the current gold standard, which relies on surgical procedures.

There are 6.5 million women living with endometriosis in the United States, yet it is still notoriously difficult to diagnose, with a definitive diagnosis taking an average of 7 years. “Endometriosis is a serious medical and gynecological condition affecting many women, of all ages.” says Dr. Michael Krychman, a women’s health specialist at University of California Irvine Medical Center. “Currently, our only diagnostic approach is laparoscopic surgery, an invasive procedure that carries inherent risks and side effects. A simple non-invasive test for endometriosis has the potential to transform patient care. It can shorten the time to diagnosis for many women, who might otherwise go undiagnosed or misdiagnosed.”

Lack of a timely diagnosis can leave women to endure many years of symptoms such as severe pelvic pain, painful intercourse, fatigue and infertility. “People are told that their symptoms are normal when they are experiencing disabling pain” says endometriosis patient and advocate Caroline Leithner. “As a patient who has had a laparoscopy and treatment with 18 months of a GnRH agonist, this test would have offered me the option for less invasive testing and more options for earlier treatment of my disease.”

Backed by over a decade of academic research and offered by Kephera under exclusive license from Exeltis, a global leader in women's health innovation, EndomTest™ measures two biomarkers, combining results with clinical variables using an algorithm that provides a rule-in diagnostic tool. Published clinical validation studies demonstrate 100% specificity, or no false positives, for this methodology. The test offers patients and providers reliable diagnostic results through a non-surgical approach, which can inform treatment decisions including the need for eventual surgery.

“We are proud to be launching the first non-invasive test for endometriosis in the United States” said Andrew Levin, Kephera’s Chief Executive and Scientific Officer. “EndomTest™ leverages Kephera’s scientific expertise in *in-vitro* assays for challenging diseases. With the launch of this test through our CLIA lab, we hope to provide a diagnostic solution that will improve healthcare for thousands of patients who are affected by endometriosis.“

EndomTest™ is available in the U.S. exclusively through Kephera Diagnostics. Further details on how to order EndomTest ™ are available at the company’s website, www.kephera.com.

About EndomTest ™

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EndomTest™ is a Laboratory Developed Test (LDT). The performance characteristics of the test were determined by Kephera Diagnostics, LLC following CLIA and CAP requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration. EndomTest™ is intended to be used as an aid in the differential diagnosis of endometriosis.

About Kephera Diagnostics

Kephera Diagnostics is a CLIA-certified and CAP-accredited diagnostic laboratory delivering excellence in specialized diagnostics. We focus on diagnostic solutions for diseases where there are significant gaps in addressing patient needs, particularly in underserved areas of healthcare including women's health and infectious diseases. Our mission is to promote more effective and affordable medical treatment through faster diagnosis. We collaborate with a global community of researchers and clinicians to develop and translate new technologies into accessible products for clinical diagnostics and research applications.

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Sources

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