

New test detects early stage ovarian cancer with 99 percent accuracy

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Researchers at Yale School of Medicine have developed a blood test with enough sensitivity and specificity to detect early stage ovarian cancer with 99 percent accuracy.

Results of this new study are published in the February 15 issue of the journal *Clinical Cancer Research*. The results build on work done by the same Yale group in 2005 showing 95 percent effectiveness of a blood test using four proteins.

“The ability to recognize almost 100 percent of new tumors will have a major impact on the high death rates of this cancer,” said Mor. “We hope this test will become the standard of care for women having routine examinations.”

Epithelial ovarian cancer is the leading cause of gynecologic cancer deaths in the United States and three times more lethal than breast cancer. It is usually not diagnosed until its advanced stages and has come to be known as the “silent killer.”

This new phase II clinical trial led by Gil Mor, M.D., associate professor in the Department of Obstetrics, Gynecology & Reproductive Sciences at Yale, included 500 patients; 350 healthy controls and 150 ovarian cancer patients. Mor and colleagues validated the previous research and used a new platform called multiplex technology to simplify the test into one single reaction using very small amounts of serum from the blood. The new platform uses six protein biomarkers instead of four, increasing

the specificity of the test from 95 to 99.4 percent. The team looked for the presence of specific proteins and quantified the concentration of those proteins in the blood.

The Early Detection Research Network (EDRN) of the National Cancer Institute (NCI) independently evaluated the results of the test.

“This is the most sensitive and specific test currently available,” said Mor. “Previous tests recognized 15 to 20 percent of new tumors. Proteins from the tumors were the only biomarkers used to test for ovarian cancer. That is okay when you have big masses of tumors, but it is not applicable in very early phases of the tumor. Testing the proteins produced by the body in response to the presence of the tumor as well as the proteins the tumors produce, helped us to create a unique picture that can detect early ovarian cancer.”

Mor and colleagues have begun a phase III evaluation in a multi-center clinical trial. In collaboration with EDRN/NCI and Laboratories Corporation of America (LabCorp), they are testing close to 2,000 patients.

The test is available at Yale through the Discovery to Cure program. Yale has licensed the test to three companies: Lab Corp in the United States, Teva in Israel and SurExam in China.

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