

FDA NEWS RELEASE

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FDA Clears a Test for Ovarian Cancer

Test can help identify potential malignancies, guide surgical decisions

The U.S. Food and Drug Administration today cleared a test that can help detect ovarian cancer in a pelvic mass that is already known to require surgery. The test, called OVA1, helps patients and health care professionals decide what type of surgery should be done and by whom.

OVA1 identifies some women who will benefit from referral to a gynecological oncologist for their surgery, despite negative results from other clinical and radiographic tests for ovarian cancer. If other test results suggest cancer, referral to an oncologist is appropriate even with a negative OVA1 result.

OVA1 should be used by primary care physicians or gynecologists as an adjunctive test to complement, not replace, other diagnostic and clinical procedures.

OVA1 uses a blood sample to test for levels of five proteins that change due to ovarian cancer. The test combines the five separate results into a single numerical score between 0 and 10 to indicate the likelihood that the pelvic mass is benign or malignant.

OVA1 is intended only for women, 18 years and older, who are already selected for surgery because of their pelvic mass. It is not intended for ovarian cancer screening or for a definitive diagnosis of ovarian cancer. Interpreting the test result requires knowledge of whether the woman is pre- or post-menopausal.

The American College of Obstetricians and Gynecologists and the Society of Gynecologic Oncologists published recommendations in 2002 for the role of generalist obstetrician-gynecologists in the early detection of ovarian cancer, which included a recommendation of patient referral to a gynecological oncologist when specific indicators of malignancy are present.

These recommendations and later reports indicate that patients with ovarian cancer have improved survival when the surgery is performed by gynecologic oncologists as opposed to general gynecologists or surgeons.

"Tests such as OVA1 personalize and improve public health by providing patients and health care providers with more information to support medical decisions that impact survival rates and reduce surgical complications," said Jeffrey Shuren, M.D., J.D., acting director of the FDA's Center for Devices and Radiological Health.

The FDA reviewed a study of 516 patients, including 269 evaluated by non-gynecological oncologists, which compared OVA1 results with biopsy results. When combined with pre-surgical information, such as radiography and other laboratory tests, results from the OVA1

tests identified additional patients who might benefit from oncology referral who were not identified using pre-surgical information alone.

OVA1 is developed by Vermillion Inc., headquartered in Fremont, Calif., in conjunction with researchers at The Johns Hopkins University in Baltimore.