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OVA1 Blood Test Detects Ovarian Cancer More Accurately Than Medically Accepted CA 125 Method for Evaluating Women with Ovarian Mass

Obstetrics & Gynecology study also considers OVA1's place in future surgical referral guidelines

MADISON, N.J. and AUSTIN, TX. – May 12, 2011 – A study published online ahead of print in the June 2011 edition of *Obstetrics & Gynecology* demonstrated that American College of Obstetrics and Gynecology (ACOG) guidelines for determining the likelihood that an ovarian mass is cancerous prior to surgery would accurately identify more women with ovarian cancer if the OVA1 blood test were used in place of the currently recommended CA 125 blood test. The study builds on prior research that shows accurate assessment of an ovarian mass for cancer prior to surgery can affect both treatment decisions and health outcomes for women with ovarian cancer.

OVA1 is the first test cleared by the U.S. Food and Drug Administration (FDA) for aiding in the pre-surgical evaluation of a woman's ovarian mass for cancer. Vermillion, Inc. (Nasdaq: VRML), a molecular diagnostics company, developed OVA1, and Quest Diagnostics Incorporated (NYSE: DGX), the world's leading diagnostic testing company, offers OVA1 testing services in the United States and India. Quest Diagnostics and Vermillion both participated in the study and Vermillion also helped fund the study. Neither company had any involvement in the development of the manuscript.

Clinical practice guidelines recommend that women with ovarian cancer be under the care of a gynecologic oncologist, although only an estimated one-third of initial surgeries for ovarian cancer are performed by these specialists. ACOG guidelines for the management of ovarian masses recommend that physicians evaluate several factors, including menopausal status, imaging findings, family history, and CA 125 blood test levels, to divide women into low- and high-risk categories on which treatment plans, including surgical referral, are based.

The study evaluated the performance of the ACOG guidelines using the CA 125 test versus the OVA1 test in 516 women scheduled for surgery for an ovarian mass across a diverse group of primary and specialty care centers. When OVA1 was used in place of CA 125 as recommend in the guidelines, 94% of malignancies in women of all ages in the study were accurately detected compared to 77% with CA 125. In addition, OVA1 improved sensitivity in premenopausal women, accurately detecting 91% of women with ovarian cancer in fewer than 58% with CA 125.

“The high sensitivity in premenopausal women and early stage cancers is where CA 125 and the College guidelines have underperformed,” wrote investigator Rachel Ware Miller, M.D., assistant professor gynecologic oncology at the University of Kentucky’s Markey Cancer Center, in the study. “Identifying these patients for referral is valuable because many are not receiving appropriate surgical staging and treatment. An effective preoperative test, particularly for younger women and early-stage cancers, can have a favorable effect on women’s health as survival is better in these populations.”

OVA1 when used with the College guidelines was also effective at detecting advanced disease, when surgery and chemotherapy can “improve overall survival,”wrote Dr. Miller.

The study also showed that the OVA1 test was about two times more likely to incorrectly identify women as high risk for ovarian cancer when they were not (a “false positive”) than the CA-125 test overall. However, as OVA1 is only indicated for women for whom surgery is already planned, a higher rate of false positives would increase the possibility that a woman’s surgery is performed by a gynecologic oncologist rather than a gynecologist or other non-specialist.

The study follows the March 2011 publication in *Obstetrics & Gynecology*, the official publication of ACOG, of an updated committee opinion, “The Role Of The Obstetrician-Gynecologist In The Early Detection Of Epithelial Ovarian Cancer,” by ACOG and Society of Gynecologic Oncologists (SGO) that cited the FDA clearance of OVA1 (in 2009) and indicated that OVA1 "appears to improve the predictability of ovarian cancer in women with pelvic masses” and "may be useful for evaluating women with a pelvic mass."

“Prior to OVA1’s clearance by the FDA, the only lab test physicians could use to assess the likelihood that an ovarian mass was malignant prior to surgery was CA 125, even though CA 125 is not indicated for this use and its performance is variable,” said Dr. Eric T. Fung, chief science officer, Vermillion, Inc. “These data should give physicians more confidence to refer women whose OVA1 test result indicates a high likelihood of cancer to a gynecologic oncologist for surgery.”

Ovarian cancer is the leading cause of death from gynecologic cancers in the United States and the fifth-leading cause of cancer deaths in women. Ovarian masses affect an estimated one million women and lead to as many 300,000 ovarian mass surgeries in the United States each year, according to an analysis by third parties on behalf of Quest Diagnostics.

The study is titled “Performance of the American College of Obstetricians and Gynecologists’ Ovarian Tumor Referral Guidelines With a Multivariate Index Assay” (doi: 10.1097/AOG.0b013e31821b1d80).

About OVA1®

OVA1 is the first test cleared by FDA for aiding in the pre-surgical evaluation of a woman’s ovarian mass for cancer, and also is the first protein-based In Vitro Diagnostic Multi-Variate Index Assays (IVDMIA), a new class of state of the art software-based diagnostics. The test utilizes five well-established biomarkers -- Transthyretin (TT or prealbumin), Apolipoprotein A-1 (Apo A-1), β2-Microglobulin (β2M), Transferrin (Tfr) and Cancer Antigen 125 (CA 125 II) -- and proprietary software to determine the likelihood of malignancy in women with ovarian mass for whom surgery is planned.

OVA1 is indicated for women who meet the following criteria: over age 18, ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist. It is an aid to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy. The test should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of the OVA1 Test carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at www.QuestDiagnostics.com.

About Vermillion, Inc.

Vermillion, Inc. is dedicated to the development and commercialization of novel high-value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Vermillion, along with its prestigious scientific collaborators, has diagnostic programs in oncology, cardiology and women's health. Additional information about Vermillion can be found on the Web at www.vermillion.com.

Certain matters discussed in this press release contain forward-looking statements that involve significant risks and uncertainties, including statements regarding Vermillion's plans, objectives, expectations and intentions. These forward-looking statements are based on Vermillion's current expectations. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, Vermillion notes that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward looking statements. Factors that could cause actual results to materially differ include but are not limited to: (1) uncertainty as to Vermillion's ability to protect and promote its proprietary technology; (2) limited track record of Vermillion in developing and commercializing diagnostic products; (3) uncertainty as to whether Vermillion will be able to obtain any required regulatory approval of its future diagnostic products; (4) uncertainty of the size of market for its existing diagnostic tests or future diagnostic products, including the risk that its products will not be competitive with products offered by other companies, or that users will not be entitled to receive adequate reimbursement for its products from third party payers such as private insurance companies and government insurance plans; (5) uncertainty that Vermillion will successfully license or otherwise successfully partner with third parties to commercialize its future products; (6) uncertainty whether the trading in Vermillion's stock will become significantly less liquid; and (7) other factors that might be described from time to time in Vermillion's filings with the Securities and Exchange Commission. All information in this press release is as of the date of

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SOURCE: Quest Diagnostics Incorporated and Vermillion, Inc.