



MEDCO FORUM®

PRESENTING INNOVATIVE PRODUCTS & SERVICES TO HEALTHCARE PROFESSIONALS

Medco Forum Presents: Vermillion OVA1® and ASPIRA LABS

Risk Stratification of the Persistent Ovarian Mass with OVA1
CA 125 Alone is not Enough for Surgical Planning

Encountering an undiagnosed malignancy during an anticipated benign surgical intervention is stressful for the surgeon—and devastating for the unprepared patient.

More than 21,000 women are diagnosed with ovarian cancer in the United States annually.¹ However, only an estimated one-third of women who have a malignant tumor are operated on by a gynecologic oncologist for that initial surgery.² In order to help providers find these missed cancer diagnoses, they need a highly sensitive tool which compliments both clinical impression and radiology findings.

“CA 125 became entrenched in gynecological ovarian mass evaluation due to lack of a validated and better alternative previously. That’s remarkable considering CA 125 was never FDA approved for pre-surgical use, has limited specificity, and poor sensitivity in early ovarian cancer stages. It also performs poorly in premenopausal patients.” said Hector O. Chapa M.D., F.A.C.O.G., director for the Dallas-based Women’s Specialty Center.

Multivariate Biomarker Advantage with OVA1

OVA1 is a qualitative serum test that combines the results of five immunoassays— β 2 microglobulin, CA 125II, apolipoprotein A-1, prealbumin and transferrin—into a single numerical result. The test result is reported on a scale from 0-10 taking into account menopausal status. “OVA1 provides a clinically superior alternative regardless of menopausal status or mass histology.” Dr. Chapa said.

Aid in Pre-Surgical Rule Out Protocol

OVA1 is the first FDA-cleared, protein based, in vitro diagnostic multivariate index assay (MIA) indicated for the evaluation of an ovarian mass prior to surgery.

High Sensitivity for Cancer Detection

“There are two reasons that a general OB/GYN would want to order an OVA1 test. The first is to be able to evaluate an ovarian mass for cancer before surgery and ideally have the patient triaged to a GYN oncologist if the test suggests cancer. The second reason is with the high negative predictive value of 98%—it allows an OB/GYN to feel confident a mass is most likely not malignant so there are no surprises at the time of surgery,” Atlanta-based gynecologist Michael D. Randell, M.D., F.A.C.O.G. explained. “The OVA1 test result doesn’t change the plan for surgery—it just helps decide whether a general OB/GYN or a GYN oncologist is going to perform the surgery. So, if a patient has an ovarian mass and surgery is planned, order the test.”

During the last year, new research was published in three peer-reviewed publications concluding that in more than 1,000 women studied using OVA1 prior to planned surgery, OVA1 consistently helped the OB/GYN formulate the careplan.³⁻⁶ Earlier studies, published in 2011, also confirmed these findings.⁷⁻¹⁰

“As a general OB/GYN, I don’t treat ovarian cancers but I do see a large number of patients with ovarian cysts and or masses that need to be evaluated. OVA1 has allowed us to reassure patients or refer them to the right surgeon more often than not. The sensitivity of the test has made a big impact on how we treat these patients.” San-Antonio-based obstetrician-gynecologist (OB/GYN) Valentin Almindarez, M.D., F.A.C.O.G. said.

OVA1 is the first MIA to provide a result reflective of both HOST response and TUMOR behavior:

The OVA500 results were published in the February 2013 Gynecologic Oncology in the article, "[Ovarian Malignancy Risk Stratification of the Adnexal Mass Using a Multivariate Index Assay.](#)"

OVA500 Study Summary

Results (N=494)	Clinical Impression (CI)	CA125II	OVA1	OVA1 & CI
Sensitivity %	73.9	73.9	92.4	95.7
Specificity %	92.5	94.5	53.5	50.7
PPV %	69.4	75.6	31.3	30.8
NPV %	93.9	94.1	96.8	98.1
% Cancers Missed	26.1	26.1	7.6	4.3

Source: Bristow, Robert et al. Ovarian Malignancy Risk Stratification of the Adnexal Mass Using a Multivariate Index Assay, Gynecologic Oncology, Vol 128, Issue 2, Feb 2013, p252-259

Citing the FDA clearance of OVA1, ACOG and SGO released a joint committee opinion stating that OVA1 "appears to improve the predictability of ovarian cancer in women with pelvic masses."¹⁰

OVA1 is offered through Vermillion's new CLIA Certified Laboratory, ASPIRA LABS, as well as through Quest Diagnostics. OVA1 is covered by Medicare and other insurance plans.

For more about OVA1® and ASPIRA LABS, visit www.OVA-1.com and www.aspiralab.com. Customer service can be reached at 1.844.ASPIRA1.

Speak to a representative at ACOG 2014, Booth #2129.

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