

The OVA1 Test Improves The Preoperative Assessment of Ovarian Tumors

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Objectives: OVA1 is an *in vitro* diagnostic multivariate index assay (IVDMIA) that combines five immunoassays into a single numerical result, including CA125 II, transthyretin (prealbumin), apolipoprotein A1, beta 2microglobulin, and transferrin. Our objective was to evaluate the performance of OVA1 in the preoperative assessment of ovarian tumors.

Methods: OVA1 was evaluated in women scheduled for surgery for a known ovarian tumor in a prospective, multi-institutional trial involving 27 primary care and specialty sites throughout the United States. Preoperative serum was collected and the OVA1 results were correlated with the physician assessment and surgical pathology. The preoperative malignancy assessment was documented by the enrolling physician after consideration of all available clinical information. Women were excluded from analysis if surgery was not performed, pathology report was not available, or blood specimen was unusable.

Results: The study enrolled 590 women and 516 were evaluable with a pre-surgical assessment. Fifty two percent were enrolled by non-GO surgeons. There were 151 ovarian malignancies (29.3%), including: 96 epithelial ovarian cancers (EOC), 9 non-epithelial ovarian malignancies (non-EOC), 28 tumors of low malignant potential (LMP), and 18 malignancies metastatic to the ovary (met). The 235 premenopausal

women enrolled (45.5%) accounted for 42 ovarian malignancies. The OVA1 test had the following performance: sensitivity 92.5%, specificity 42.8%, PPV 42.3%, and NPV 92.7%. OVA1 significantly improved the clinician's pre-surgical assessment for both non-GO and GO physicians. Sensitivity improved from 72.2% to 91.7% (95% CI= 83.0 to 96.1) for non-GO, and 77.5% to 98.9% (95% CI= 93.9 to 99.8) for GO. The NPV improved from 89.1% to 93.2% (95% CI= 85.9 to 96.8) for non-GO, and 85.5% to 97.6% (95% CI= 87.7 to 99.6) for GO. OVA1 correctly identified 70% (non-GO) and 95% (GO) of malignancies missed by the preoperative physician assessment alone. The OVA1 sensitivity by histologic subtype was: EOC 99.0% (95/96), non-EOC 77.8% (7/9), LMP 75.0% (21/28), and met 94.4% (17/18).

Conclusions: The OVA1 test significantly improved sensitivity and correctly identified the majority of patients with ovarian malignancies that were missed by preoperative physician assessment alone. These data support the use of OVA1 in women scheduled for surgery for an ovarian tumor, to facilitate surgical planning, and decisions about referral to a gynecologic oncologist before surgery.