

**CLINICAL REPORT - POSTMENOPAUSAL**

**PATIENT AND ORDER INFORMATION**

<b>Name:</b> JANE DOE	<b>Accession No:</b>
<b>MRN:</b>	<b>Client No:</b> <b>Released by:</b>
<b>DOB:</b> <b>Age:</b> <b>Sex:</b>	<b>Final Report Date:</b>
<b>Date Specimen Collected:</b>	<b>Date Specimen Received:</b>

**CLIENT INFORMATION**

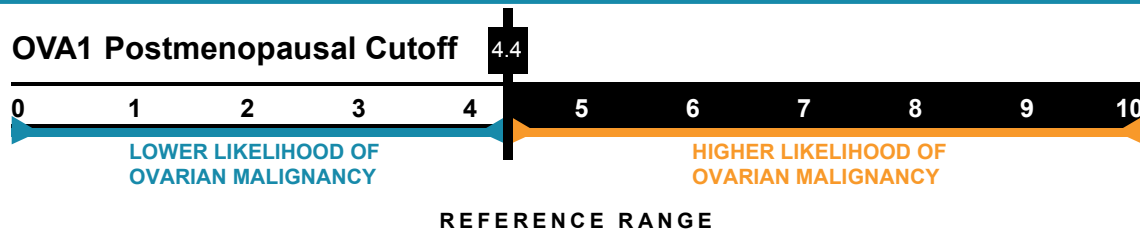
**PHYSICIAN INFORMATION**

<b>Ordering Physician:</b>	<b>Copy-to-Physician:</b>
<b>TEL:</b>	
<b>FAX:</b>	

**OVA1<sup>®</sup> TEST RESULT**

<b>OVA1 Score: 6.1</b>	<b>Elevated Risk of Ovarian Malignancy</b>
------------------------	--

**OVA1 REFERENCE RANGE**



In a study of 125 postmenopausal subjects with a pelvic mass, in which 46 subjects were found to have ovarian cancer, OVA1's performance data was: 91.3% sensitivity and 41.8% specificity.

**INTERPRETING THE OVA1 TEST:**

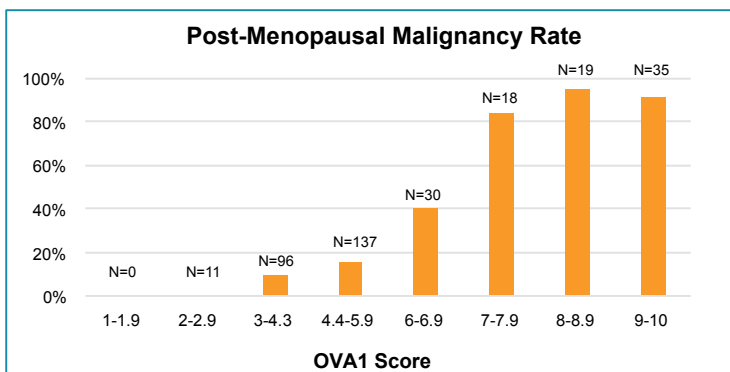
OVA1 should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1 carries the risk of unnecessary testing, surgery, and/or delayed diagnosis. OVA1 measures the levels of five proteins in the blood and then uses the OvaCalc software to calculate a single score. A woman's likelihood of cancer depends largely on how high or low the score, based on a scale of 0 to 10. However, the cutoffs are rigid in that the risk of malignancy is significantly different for patients with a score that is above or below the cutoff. A high OVA1 score is not a diagnosis of cancer, rather it indicates an increased risk.

CA 125 II testing was performed on a elecsys 2010 system as a component of OVA1.

**PHYSICIAN NOTES:**

**CA 125 II result is available upon request.**

**REFERENCE MATERIAL**



**Selected postmenopausal demographic information:** The study from which this performance data was generated included 346 postmenopausal subjects. Overall, 239 patients (69.1%) had benign pathology, 107 patients (30.9%) had a pelvic malignancy. There were 75 primary ovarian cancers, with 49.3% of these patients having Stage I/II disease. Selected inclusion criteria includes, females age >18 years and a documented pelvic mass planned for surgical intervention within 3 months of imaging. This performance data and the OVA1 Instructions for Use indicate that referral should use a Boolean "OR" combining physician assessment and OVA1 risk stratification, so that a positive result from either will trigger patient evaluation by a gynecologic oncologist.

**Reference:** Data on file based on combined cohorts from Ueland FR, et al., Effectiveness of a multivariate index assay in the preoperative assessment of ovarian tumors. *Obstet Gynecol* 2011;117:1289-1297 and Bristow RE, Smith A, Zhang Z, et al., Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. *Gynecol Oncol.* 2013;128:252-259. Vermillion, Inc.