Interpretation

A LOW RISK OVERA predicts a Risk of Malignancy of 3.1% or 11.0% when combined with ultrasound results (see below). Results should be interpreted along with clinical and ultrasound assessment. A low risk value has been determined to have a negative predictive value of 97%.

Risk of Malignancy: 3.1%  
(Postmenopausal, Low Risk Ultrasound)

Risk of Malignancy: 11.0%  
(Postmenopausal, High Risk Ultrasound)

Epithelial Tumor Markers

CA-125 II  
33.0 U/mL  
Normal

Postmenopausal
0.0 - 35.0 U/mL

*CA-125 results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

HE4  
45.0 pmol/L  
Normal

Ages ≤ 49 y
≤ 63.6 pmol/L

Notes:
Results in the normal range may suggest low risk for ovarian cancer. Epithelial cell tumors make up an average of 75% of all ovarian cancer tumor types, including serous, mucinous, endometrioid, clear cell, and Brenner tumors.
Disclaimer
Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease and should always be interpreted in combination with clinical assessment. Values obtained with different assay methods or kits cannot be used interchangeably.

Methods And Limitations
1. CA-125 II is a component of the OVA1 Test. The CA-125 II assay method used is manufactured by Roche Diagnostics. The diagnostic sensitivity and specificity of the Roche Diagnostics CA-125 II test was calculated by comparing ovarian carcinoma patients at primary diagnosis (FIGO stage I to IV) with patients suffering from benign gynecological diseases. At a cutoff value of 65u/mL, the sensitivity is 79% (at a low specificity of 82%). The optimal clinical value is reached at 150 U/mL sensitivity 69%, specificity 93%).
2. High-risk imaging was defined as any complex ovarian tumor with evidence of solid or papillary components.
3. Low-risk imaging was defined as unilocular or septate cystic ovarian tumor without high-risk findings.
4. HE4 was performed using Roche Diagnostics Electrochemiluminescence Immunoassay (ECLIA).

References
1. In a study of 494 subjects with a pelvic mass, the OVA1 performance data was: Sensitivity - 92.4% and Specificity - 53.5%. Bristow RE, et al., Gynecol Oncol. 2013; 128:252-259
3. In a study of 493 subjects with a pelvic mass, Overa’s performance date was: Sensitivity - 91.3% and Specificity - 69.1%. Coleman RL, et al. Am J Obstet Gynecol. 2016 J82.e1-82.eii