Clinical Information:  

Ultrasound Results Unknown

Menopausal Status:  

Premenopausal

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Result</th>
<th>Status</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ova1</td>
<td>2.5</td>
<td>Low Risk</td>
<td>PreMenopausal Low Risk &lt; 5.0 Elevated Risk ≥ 5.0</td>
</tr>
</tbody>
</table>

Interpretation:

A LOW RISK OVA1 results in a Risk of Malignancy of 1%, or 2% 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 98%.

Providing Menopausal status and Ultrasound results helps to narrow down the risk of Malignancy

Risk of Malignancy: 1% (premenopausal, low risk ultrasound)  
Risk of Malignancy: 2% (premenopausal, high risk ultrasound)

*Risk of Malignancy is a combination of the OVA1 Result, Menopausal status and Ultrasound results

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

Interpretation: 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.

Notes:

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.

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.