Overview
The study evaluated the cost effectiveness of OVA1 against modified ACOG (mACOG) referral guidelines and CA-125 testing alone for use in triaging women with adnexal mass to gynecologic oncologists for possible malignancy. Patient data from previously performed, prospective national trials, that included 44 clinical sites from the years 2007 through 2012, were retrospectively analyzed for the following end points to determine cost effectiveness:

**Direct treatment costs**: CMS fee schedule was primarily used to estimate cost of test, CT scan, surgery, staging and chemotherapy

**Quality-adjusted life-year (QALY)**: A measure of quality of life that takes into account both the quantity and the quality of life generated by interventions

**Incremental cost-effectiveness ratio (ICER)**: Average incremental cost associated with one additional unit of the measure of effect (i.e., QALY) between two possible interventions. The ICER threshold, or indication of cost-effectiveness of one modality versus another, was set at the commonly accepted figure of $50,000/QALY. ICERs below $50,000/QALY indicate comparative cost effectiveness of that modality.

Key Results
- Use of OVA1 resulted in fewer projected re-operations and pre-treatment CT scans versus CA 125-II or mACOG
- OVA1 increased the quality adjusted life years (QALY) of the patient cohort
- OVA1 was shown to be cost effective versus mACOG ($35,094/QALY) or CA-125 ($12,189/ QALY) as both were below the $50,000/QALY threshold
- ICER was most affected by changes to the following parameters:
  » Sensitivity of OVA1 and mACOG
  » Percent of ovarian cancer patients not referred to gynecologic oncologist

Conclusion
Use of OVA1 was a more cost-effective triage method for women with adnexal masses than mACOG or CA-125 alone and would increase the percentage of women with ovarian cancer who are referred to gynecologic oncologists, which has been shown to improve clinical outcomes.

<table>
<thead>
<tr>
<th></th>
<th>Direct Cost</th>
<th>Δ Cost</th>
<th>QALY</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVA1</td>
<td>$12,789</td>
<td>-</td>
<td>17.005</td>
<td>-</td>
</tr>
<tr>
<td>CA-125</td>
<td>$12,540</td>
<td>$250</td>
<td>16.985</td>
<td>$12,189</td>
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<tr>
<td>Modified ACOG</td>
<td>$12,430</td>
<td>$359</td>
<td>16.995</td>
<td>$35,094</td>
</tr>
</tbody>
</table>

Threshold to be considered cost-effective $50,000

Note: Testing for BRCA1/2 mutations in women at high risk for ovarian or breast cancer was shown to have an ICER of $36,800/QALY (Li, et al., 2011 CTRC-AACR San Antonio Breast Cancer Symposium). Vanderlaan, et al. showed that use of Oncotype Dx in node-positive, early-stage breast cancer patients had a cost effectiveness ratio of $15,578/QALY (Vanderlaan, et al., 2011 AJMC).