Q: Why is OVA1 superior to other assessment tools?

- Test performance with high sensitivity, which helps determine cancer care (*Figure 1*)
- Strong evidence of early stage sensitivity (*Figure 2*)
- Sensitivity across a broad range of subtypes (*Figure 3*)

Figure 1

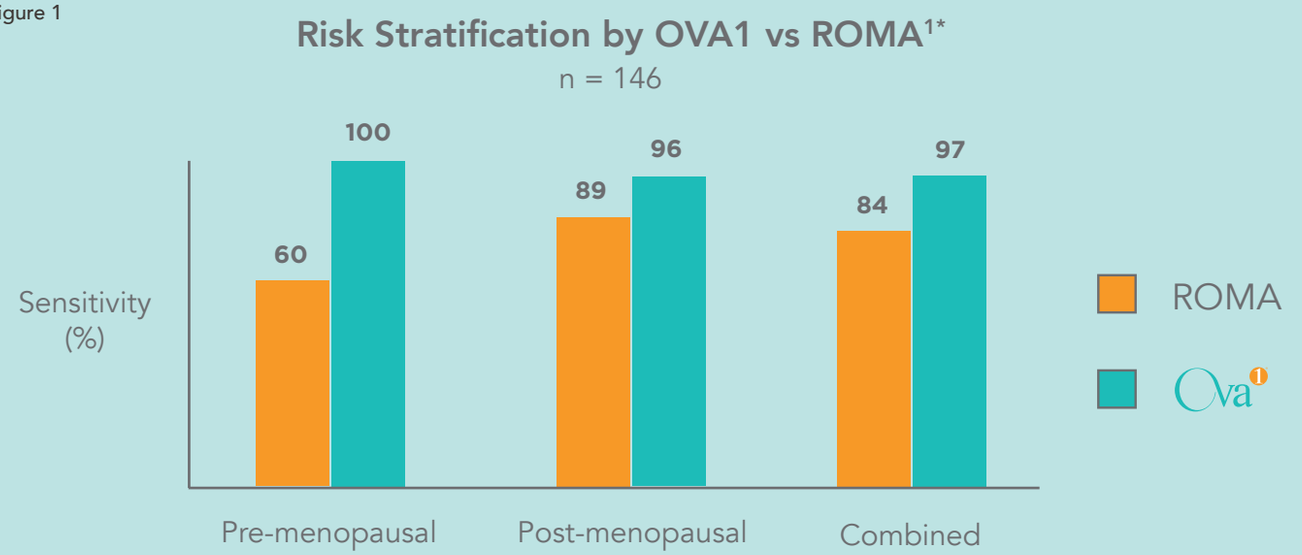


Figure 2

Moore et al., 2011 validation study[2]		
ROMA	**Sensitivity**	***n***
Stage 1	n/a	-
Stage 2	n/a	-
Early stage	75%	12

Longoria et al., 2013 validation study[3]		
OVA1**	**Sensitivity**	***n***
Stage 1	89%	61
Stage 2	100%	25
Early stage	92%	86

Figure 3

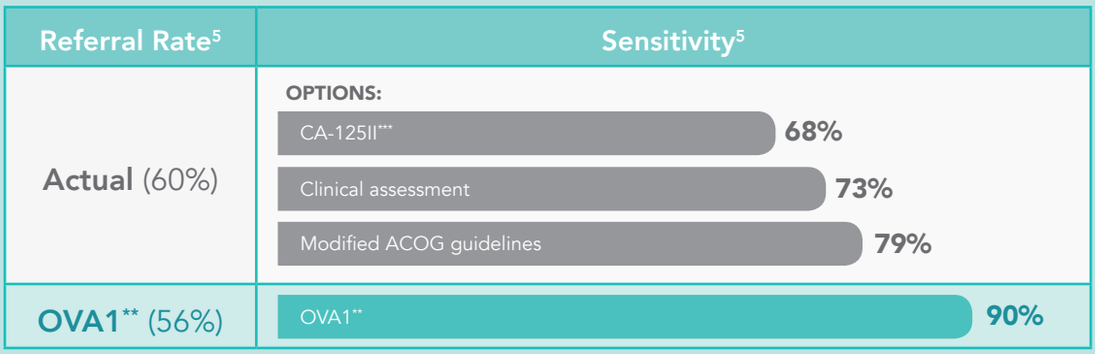
Moore et al., 2011 validation study[2]	
ROMA	**Sensitivity**
Epithelial ovarian cancer	94%
Non-epithelial ovarian cancer	50%
Borderline/LMP	74%
Metastatic to ovary	50%
Other malignancies	61%
Overall	**81%**

Bristow et al., 2013 validation study[4]	
OVA1**	**Sensitivity**
Epithelial ovarian cancer	95%
Non-epithelial ovarian cancer	80%
Borderline/LMP	82%
Metastatic to ovary	100%
Other malignancies	100%
Overall	**92%**

Q: How does incorporating OVA1 impact my referral rate?

- In a study by Bristow et al.,[5] use of OVA1 was associated with referral patterns comparable to actual clinical practice with higher sensitivity for malignancy than other options. (*Figure 4*)

Figure 4



Q: What can OVA1 offer in an environment with well established ultrasound (US) imaging?

- OVA1 is complementary to quality imaging as a critical aspect of assessment. It can improve sensitivity from 77% (descriptive US alone) to 98% (OVA1 with US)[6]
- OVA1 is not susceptible to inter-operator variation in image quality or sensitivity[7,8]
- OVA1 can be scaled up without the barriers of specialized training and experience

Q: Why is referring all adnexal masses to a Gyn Onc not practical?

- Only ~1000 Gyn Oncs in the US[9]
- 100% false positive rate can add ~70,000 mostly benign cases to Gyn Onc load per year[10]
- Inefficient care pathways that may increase patient wait times, anxiety, and expenses

*Risk stratification by each test using cut-offs specified by FDA intended use **Standalone risk stratification; intended use is with clinical assessment ***High risk cutoff: premenopausal subjects CA125>200U/ml; postmenopausal subjects CA125-II>35U/ml. †With clinical assessment **1.** Grenache DG, et al., Clinical performance of two multi-marker blood tests for predicting malignancy in women with an adnexal mass. Clin Chim Acta. 2015 Jan 1;438:358-63. doi: 10.1016/j.cca.2014.09.028. **2.** Moore RG et al., Evaluation of the diagnostic accuracy of the risk of ovarian malignancy algorithm in women with a pelvic mass. Obstet Gynecol. 2011 Aug;118(2 Pt 1):280-8. **3.** Longoria TC, et al., Clinical performance of a multivariate index assay for detecting early-stage ovarian cancer. Am J Obstet Gynecol. 2014 Jan;210(1):78.e1-9. **4.** Bristow RE et al., Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. Gynecol Oncol. 2013;128:252-259. **5.** Bristow RE, et al., Impact of a multivariate index assay on referral patterns for surgical management of an adnexal mass. Am J Obstet Gynecol. 2013 Dec;209(6):581.e1-8. doi: 10.1016/j.ajog.2013.08.009. **6.** Goodrich ST, et al., The effect of ovarian imaging on the clinical interpretation of a multivariate index assay. Am J Obstet Gynecol. 2014 Jul;211(1):65.e1-65.e11. doi: 10.1016/j.ajog.2014.02.010. **7.** DePriest PD, DeSimone CP. Ultrasound screening for the early detection of ovarian cancer. J Clin Oncol. 2003 May 15;21(10 Suppl):194s-199s. **8.** Timmerman D et al., Subjective assessment of adnexal masses with the use of ultrasonography: an analysis of interobserver variability and experience. Ultrasound Obstet Gynecol. 1999 Jan;13(1):11-6. **9.** Wallace AH, et al., Projecting the need for gynecologic oncologists for the next 40 years. Obstet Gynecol. 2010 Dec;116(6):1366-72. **10.** Havrilesky LJ, et al., Costs, effectiveness, and workload impact of management strategies for women with an adnexal mass. J Natl Cancer Inst. 2014 Dec 16;107(1). pii: dju322.

OVA1 is a qualitative serum test that combines the results of 5 immunoassays into a single numerical result. It is indicated for women who meet the following criteria: over age 18, ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist. OVA1 is an aid to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy.

PRECAUTION: 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 surgery, and/or delayed diagnosis.