

OVA1™

Now you'll know more before surgery.



Introducing OVA1™, the first blood test FDA cleared to help assess the likelihood that an ovarian mass is malignant before it's removed.

21,550 women will be diagnosed with ovarian cancer this year, and many more will undergo evaluation to determine if their ovarian tumor is malignant.¹ With results from the new OVA1 test, you'll have additional information to create an informed treatment plan as early as possible.

Test Code: 16991

Specimen Requirements: 2.2 mL red top tube refrigerated serum or SST tube

CPT Code*: 84999

5 biomarkers provide a unitless result between 0.0 and 10.0 by the OvaCalc™ software.

What is OVA1?

- **CA125**
 - **Beta Microglobulin**
 - **Transthyretin**
 - **Apolipoprotein A1**
 - **Transferrin**
- Pre-menopausal**
Low probability of malignancy OVA1 < 5.0
High probability of malignancy OVA1 ≥ 5.0
- Post-menopausal**
Low probability of malignancy OVA1 < 4.4
High probability of malignancy OVA1 ≥ 4.4

OVA1 More Sensitive

OVA1 is significantly more sensitive than CA 125-II at identifying early stage ovarian malignancies.⁷

For EOC and non-EOC combined, the sensitivities were as follows:

- **Early stage – OVA1 = 94%, CA125-II = 61%**⁷

For EOC only, the sensitivities were:

- **Early stage – OVA1 = 98%, CA125-II = 66%**⁷

Make a more informed treatment plan; use OVA1 as part of your comprehensive ovarian cancer diagnostic protocol.

* The CPT code provided is based on AMA guidelines and is for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

Why OVA1?

OVA1 is a blood test that uses results of 5 biomarkers, with an algorithm to indicate the likelihood of malignancy of an ovarian mass. It is not a screening or standalone test, but when used in conjunction with a standard pre-surgical evaluation, this test:

- **Assesses the likelihood that an ovarian mass is malignant before it's removed**
- **Helps to identify patients for referral to a gynecologic oncologist**
- **May enable improved patient outcomes**

Who benefits from OVA1?

OVA1 has been cleared for use in women who meet the following criteria:

- **Are over 18 years of age**
- **Have an ovarian mass**
- **Have surgery planned**
- **Have not yet been referred to an oncologist**
- **Have not had cancer in the past five years**
- **Have a rheumatoid factor of less than 250 IU/mL**

Clinical proof

The OVA1 test was validated using blood samples from 269 women, 72 of whom had a pathology-determined malignancy. When pre-surgical assessment was combined with results from the OVA1 test, the following results were concluded:⁴

- **Sensitivity for malignancy increased by 20%, from 72% to 92%, in all women, and is as high as 96% in postmenopausal women.⁵**
- **Approximately 70% of the malignancies missed by pre-surgical assessment alone were identified by OVA1.**
- **A high negative predictive value (NPV=93%) strengthened the prediction that cancer is absent.⁶**
- **NPV was similar in pre- and postmenopausal women.**

REFERENCES/NOTES

1. American Cancer Society. Cancer Facts and Figures 2009. http://www.cancer.org/docroot/STT/stt_0.asp. Accessed March 11, 2010.
2. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Management of adnexal masses. *Obstet Gynecol.* 2007;110:201-214.
3. Junor EJ, Hole DJ, McNulty L, et al. Specialist gynecologists and survival outcome in ovarian cancer: a Scottish national study of 1866 patients. *Br J Obstet Gynecol.* 1999; 106:1130-1136.
4. OVA1™ [package insert]. Fremont, CA: Vermillion, Inc. 2010.
5. The improvement in detection rate achieved with OVA1 may vary, based on the effectiveness of the initial clinical assessment.
6. Although specifically decreased to 42%, the negative predictive value (NPV) increased to 93%.
7. *International Journal of Gynecological Cancer*, Vol. 20 Supplement 2, October 2010.