

# Performance of the American College of Obstetricians and Gynecologists' Ovarian Tumor Referral Guidelines With a Multivariate Index Assay

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## Overview

In this study, 516 women with an ovarian mass on pelvic imaging were evaluated with the American College of Obstetricians and Gynecologists' (ACOG) Ovarian Tumor Referral Guidelines. It was demonstrated that replacing CA-125 serum testing of the ACOG guidelines with OVA1 increased the overall sensitivity to cancer and negative predictive value.

ACOG guidelines recommend preoperative consultation with a gynecologic oncologist for one or more of following criteria:

### Premenopausal women

1. Very elevated CA-125 (more than 200 units/mL)
2. Ascites
3. Evidence of abdominal or distant metastasis
4. Family history of one or more first-degree relatives with ovarian or breast cancer.

### Postmenopausal women

1. Any elevated CA-125 (more than 35 units/mL)
2. Nodular or fixed pelvic mass
3. Ascites
4. Evidence of abdominal or distant metastasis
5. Family history of one or more first-degree relatives with ovarian or breast cancer.

## Key Results

- ACOG guidelines with OVA1 identified 27 malignancies missed by ACOG guidelines with CA-125 (161 total malignancies in cohort)
- Replacing CA-125 with OVA1 in the ACOG guidelines increased detection of early stage ovarian cancer from 73% to 96%
- The improvement in cancer detection was most notable for premenopausal women
- Using ACOG guidelines with OVA1 led to an increase in sensitivity (94%) and negative predictive value (93%), and decrease in the specificity (35%) and positive predictive value (40%)

## Conclusion

Using OVA1 instead of CA-125 in the ACOG guidelines will identify more malignancies before surgery, particularly for premenopausal women and early-stage disease.

	ACOG Guidelines with CA-125		ACOG Guidelines with OVA1	
Premenopausal	Early Stage	Late Stage	Early Stage	Late Stage
Sensitivity	47%	100%	88%	100%
Specificity	77%	77%	43%	43%
Postive Predictive Value	16%	19%	12%	9%
Negative Predictive Value	94%	100%	98%	100%
Postmenopausal	Early Stage	Late Stage	Early Stage	Late Stage
Sensitivity	88%	98%	100%	100%
Specificity	56%	56%	26%	26%
Postive Predictive Value	28%	37%	21%	26%
Negative Predictive Value	96%	98%	100%	100%