



Clinical studies show that  
one road leads to improved  
outcomes for patients with pelvic mass.

**But, how do you know which road?**

**Introducing the new CA125 + HE4 risk stratification tool\***

A new differential diagnostic for women presenting with pelvic mass  
to help determine the most appropriate course of care.

 CA125+HE4 = RISK STRATIFICATION

 **FUJIREBIO™**  
Diagnostics, Inc.

\*Pending approval for commercial distribution.

## Diagnostic Dilemma of Pelvic Mass

**Of the considerable number of women who present annually with a suspicious pelvic mass, only a small percent will have ovarian cancer<sup>1</sup>:**

- An ovarian cancer patient's outcome will be better when her surgery is performed by a GYN/ONC<sup>1</sup>
- A tool is needed to stratify patients who have a high risk of malignancy from those who do not<sup>2</sup>

## The path to more optimal patient outcomes begins with the new CA125 + HE4 risk stratification tool

**CA125 + HE4 combination accurately determines risk of malignancy<sup>1</sup>:**

- Many markers have been studied, but the CA125 + HE4 combination has proven to be a more accurate predictor of malignant disease than either marker alone
- The combination of CA125 and HE4 resulted in the highest sensitivity relative to any other dual combination of markers
- The combination of CA125 and HE4 added 33.1% to the sensitivity of CA125 alone and 3.5% to the sensitivity of HE4 alone
- As an individual marker, serum CA125 had a sensitivity of 43.3% at 95% specificity
- Individually, serum SMRP and HE4 had the highest sensitivities for detecting a malignancy

## Tumor Marker Sensitivities for All Types and Stages of Ovarian Cancers<sup>1</sup>

Marker Combination	Benign Disease vs Ovarian Cancer		
	ROC-AUC (95% CI)	Average Sensitivity at 95% Specificity	P-value for Comparison of AUC-ROC to CA125 + HE4
CA125	83.6% (77.7-89.5)	43.3%	0.0021
SMRP	82.4% (75.9-89.0)	53.7%	0.0041
HE4	90.8% (86.0-95.4)	72.9%	0.5953
<b>CA125 + HE4</b>	<b>91.4% (86.7-96.0)</b>	<b>76.4%</b>	<b>N/A</b>
CA125 + SMRP	86.3% (80.7-92.0)	56.8%	0.0176
CA125 + CA72-4	86.2% (81.2-91.3)	45.1%	0.0103
CA125 + Osteopontin	83.4% (77.5-89.4)	43.2%	0.0019
CA125 + Activin	81.7% (75.2-88.3)	44.5%	0.0004
CA125 + Inhibin	82.1% (75.6-88.6)	42.3%	0.0027

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References: 1. Moore RG, Brown AK, Miller CM, et al. The use of multiple novel serum tumor markers for the detection of ovarian carcinoma in patients with a pelvic mass. *Gynecol Oncol.* 2007. In press. 2. Moore RG, Bast RC Jr. How do you distinguish a malignant pelvic mass from a benign pelvic mass? Imaging, biomarkers, or none of the above. *J Clin Oncol.* 2007; In press.  
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