

The new CA125 + HE4 risk stratification tool improves differential diagnosis of pelvic mass

Risk stratification ensures the right patient sees the right physician^{2,4,5}:

- CA125 + HE4 is a more accurate predictor of malignant disease than either marker alone²
- ROMA is used to calculate the pelvic mass patient's risk of malignancy⁵
- Referring patients to the appropriate physician can significantly help reduce morbidity, mortality, and care-related costs^{2,4}



“Clinically, the multiple marker assay consisting of CA 125 and HE4 will be useful to triage patients to gynecologic oncologists and centers specializing in the treatment of ovarian cancer.”⁶

**For more information,
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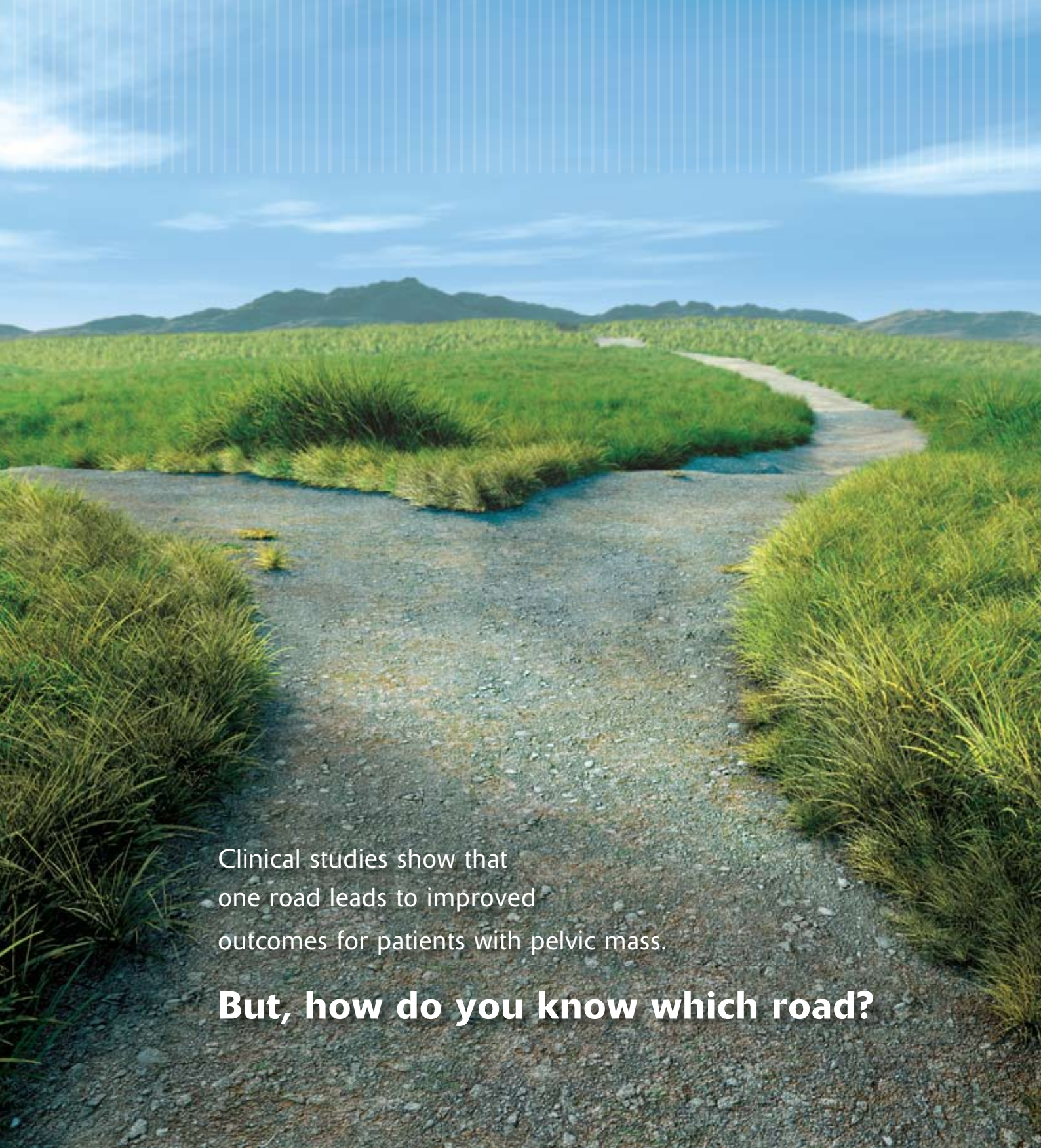
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References: 1. Moore RG, Bast RC Jr. How do you distinguish a malignant pelvic mass from a benign pelvic mass? Imaging, biomarkers, or none of the above. *J Clin Oncol.* 2007;25(27):4159-4161. 2. Moore RG, Brown AK, Miller CM, et al. The use of multiple novel serum tumor markers for the detection of ovarian carcinoma in patients with a pelvic mass. *Gynecol Oncol.* 2008;108(2):402-408. 3. Guidelines for referral to a gynecologic oncologist: rationale and benefits. The Society of Gynecologic Oncologists. *Gynecol Oncol.* 2000;78(3 Pt 2):S1-S13. 4. Bristow RE, Santillan A, Diaz-Montes TP, et al. Centralization of care for patients with advanced-stage ovarian cancer: a cost-effectiveness analysis. *Cancer.* 2007;109(8):1513-1522. 5. Data on File [Clinical data report], Fujirebio Diagnostics, Inc. 6. Data on File. Fujirebio Diagnostics, Inc.

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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.



*This product is not available in the US.

Diagnostic Dilemma of Pelvic Mass

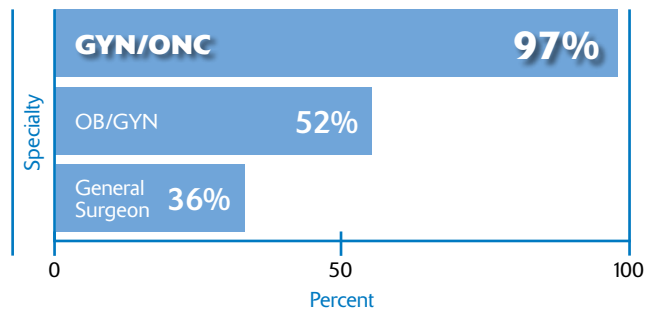
Approximately 1 in 5 women will develop a pelvic mass in their lifetime; however, the majority of women will not have malignant disease and many do not require surgery^{1,2}:

- An ovarian cancer patient's outcome will be better when her surgery is performed by a surgeon specialized in gynecologic oncology (GYN/ONC)²
- A tool is needed to stratify patients who have a high risk of malignancy from those who do not¹

Risk stratification helps ensure optimal patient care by the appropriate physician

GYN/ONCs are best trained for complete management of ovarian cancer³:

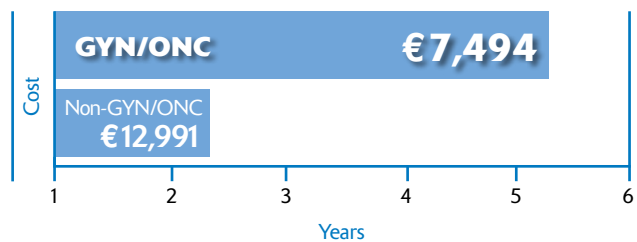
Percent of Pelvic Mass Patients Who Received Comprehensive Surgical Evaluations per Specialty³



Ovarian cancer patients cared for by a GYN/ONC experience improved clinical outcomes and reduced care-related costs^{2,3}:

- Reduced need for second surgeries²
- Retained fertility³
- More accurate staging³
- More economical use of imaging³

Cost of Comprehensive Care per Patient Quality-adjusted Life Years⁴



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

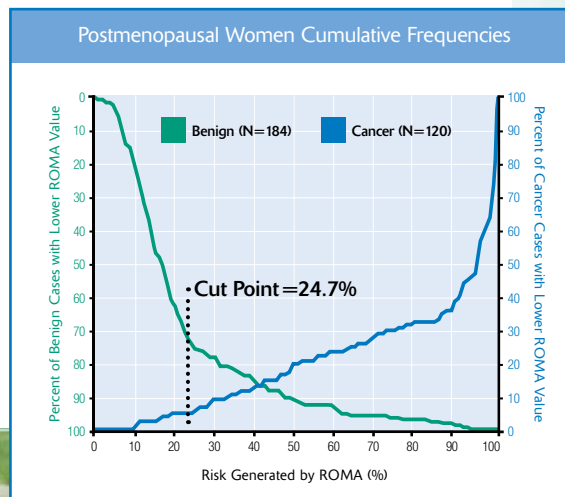
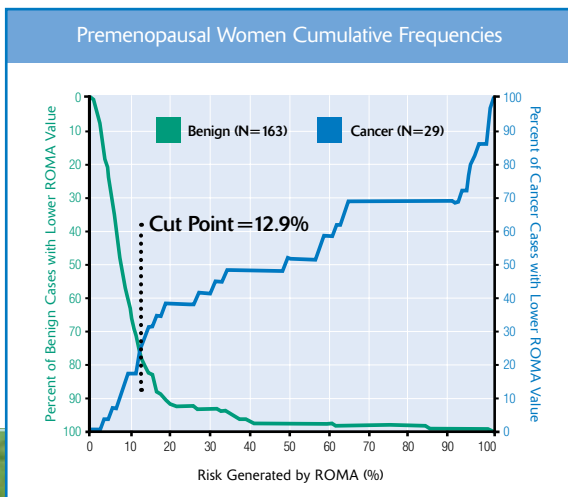
CA125 + HE4 combination accurately determines risk of malignancy^{2,5}:

- Many markers have been studied, but the CA125 + HE4 combination has proven to be a more accurate predictor of malignant disease than either marker alone²
- Patients classified as being at increased risk for ovarian cancer can be referred to a GYN/ONC for optimal care²
- In a prospective, multi-center study, the combination assay yielded a sensitivity of 91%, with a fixed specificity of 75%⁵

ROMA (Risk of Ovarian Malignancy Algorithm) classifies patients as being at low or high risk for malignant disease⁵:

- ROMA calculates a risk of finding ovarian cancer during surgery
 - Classifies patients as being at low or high risk for malignant disease
 - Cut points were determined by setting specificity at 75%
- Premenopausal group: 76% of all epithelial ovarian cancers are stratified as high risk, and 75% of all benign cases are stratified as low risk
- Postmenopausal group: 94% of all epithelial ovarian cancers as high risk and 75% of all benign cases as low risk
- Combined patient groups: 91% of all epithelial ovarian cancers as high risk and 75% of all benign cases as low risk

Cumulative Frequency of the CA125 + HE4 Combination to Stratify Into Low- and High-risk Groups*



*Cut points were determined using the Fujirebio Diagnostics HE4 EIA and the Abbott ARCHITECT® CA 125II assay combination. Use of CA 125 assays from other manufacturers may result in different cut points.