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 alone[2]
- ROMA is used to calculate the pelvic mass patient's risk of malignancy[5]
- Referring patients to the appropriate physician can significantly help reduce morbidity, mortality, and care-related costs[2,4]

CA125+HE4 = RISK STRATIFICATION

"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, please contact Fujirebio Diagnostics, Inc.

Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355

Toll Free: +1 877.861.7246
Tel: +1 610.240.3800
Fax: +1 610.240.3803

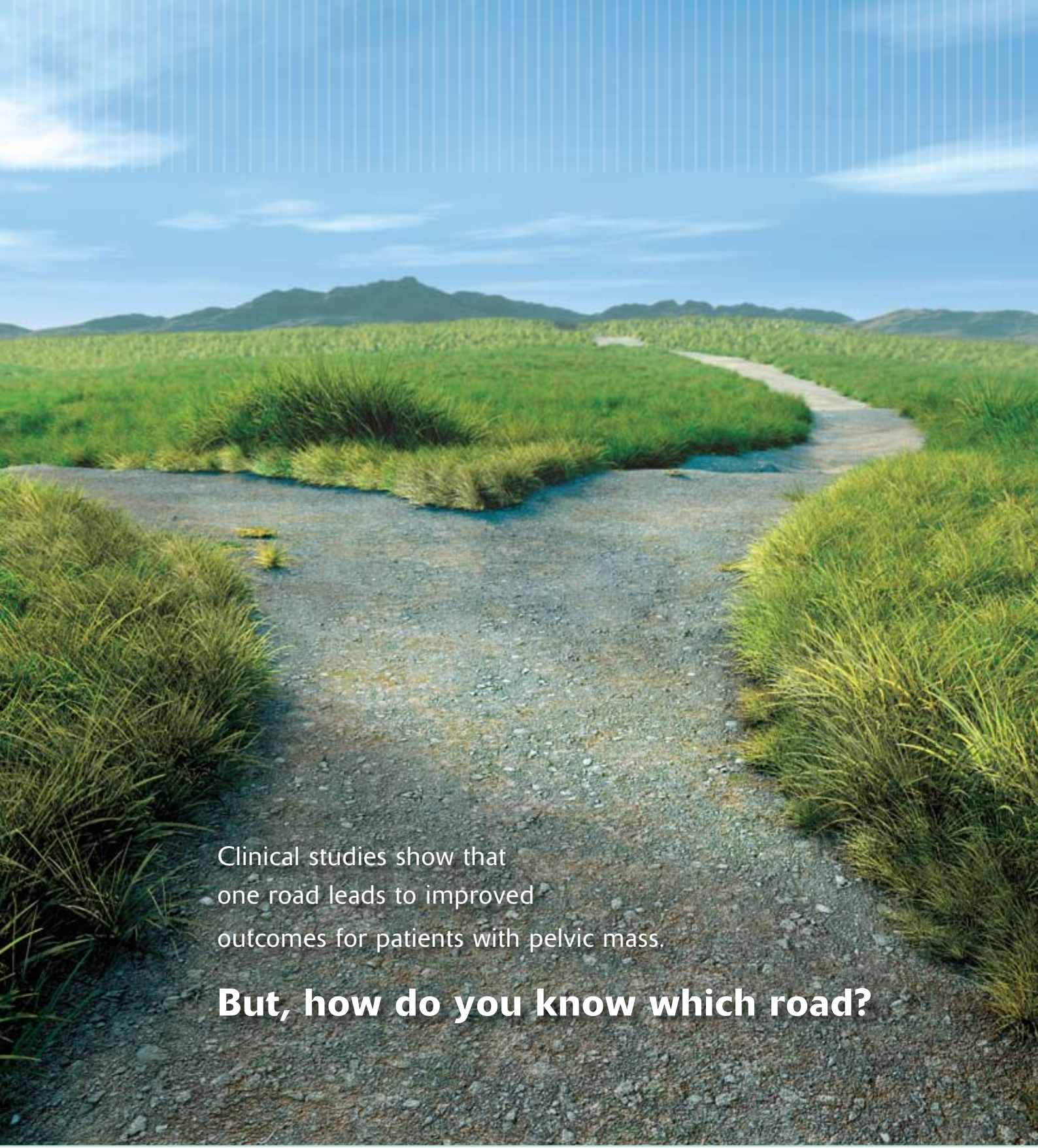
Fujirebio Diagnostics AB
Majnabbeterminalen
414 55 Göteborg
Sweden

Tel: +46 31 85 74 30
Fax: +46 31 85 70 40
info@fdab.com
www.fdab.com

FUJIREBIO™ Diagnostics, Inc.

www.FDI.com

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.



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.

*This product is not available in the US.

Diagnostic Dilemma of Pelvic Mass

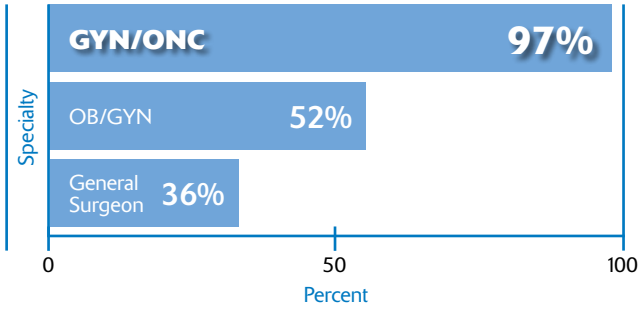
Approximately 1 in 5 women will develop a pelvic mass in their lifetime; however, the majority of women will not have malignant disease and many do not require surgery[1,2]:

- 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 not[1]

Risk stratification helps ensure optimal patient care by the appropriate physician

GYN/ONCs are best trained for complete management of ovarian cancer[3]:

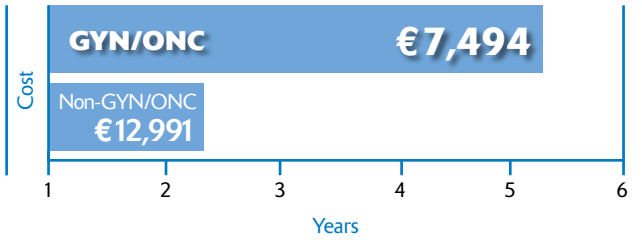
Percent of Pelvic Mass Patients Who Received Comprehensive Surgical Evaluations per Specialty[3]



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

- Reduced need for second surgeries[2]
- More accurate staging[3]
- Retained fertility[3]
- More economical use of imaging[3]

Cost of Comprehensive Care per Patient Quality-adjusted Life Years[4]



FUJIREBIO™
Diagnostics, Inc.

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

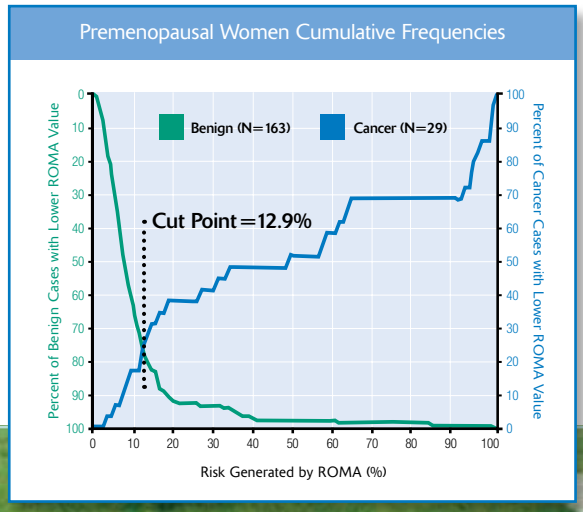
CA125 + HE4 combination accurately determines risk of malignancy[2,5]:

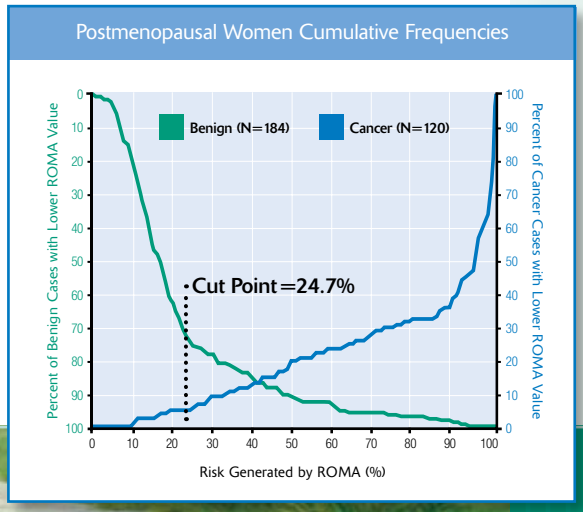
- Many markers have been studied, but the CA125 + HE4 combination has proven to be a more accurate predictor of malignant disease than either marker alone[2]
- Patients classified as being at increased risk for ovarian cancer can be referred to a GYN/ONC for optimal care[2]
- In a prospective, multi-center 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 disease[5]:

- 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.