



CA125 + HE4

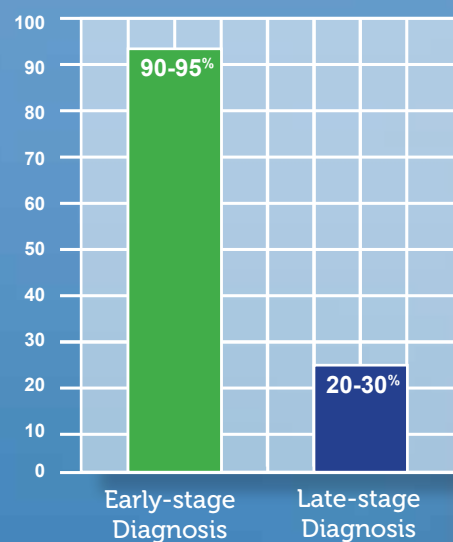
The
new formula
for
diagnostic clarity
of ovarian cancer

From the company that brought you CA125, Fujirebio Diagnostics introduces HE4, the first new biomarker in 25 years for ovarian cancer management.¹

 **FUJIREBIO**[®]
Diagnostics, Inc.

The new formula for increased diagnostic clarity Now Add HE4 to CA125 To Better Assess Pelvic Mass²⁻⁴

5-Year Survival Rate^{5,6}



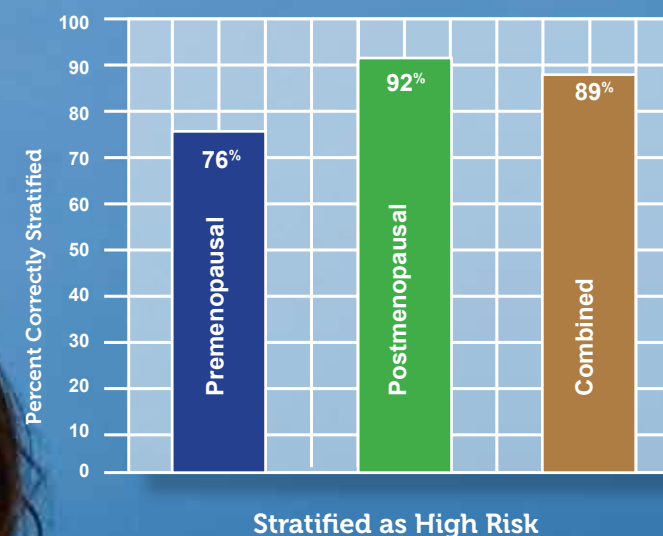
- Late-stage diagnosis of ovarian cancer greatly decreases a woman's chance of survival⁵
- Early-stage diagnosis significantly increases a woman's chance of surviving ovarian cancer⁵

What is HE4?

Human epididymis protein 4 (HE4), a novel serum biomarker, is normally expressed in epithelial tissue. HE4 is detected in high levels in the serum of ovarian cancer patients.

- ROMA™ correctly stratified 89% of women with epithelial ovarian cancer and low malignant potential tumors into a high-risk group²
- ROMA correctly stratified 75% of women with benign disease into a low-risk group²
- The combination of CA125 + HE4 has been shown to be the most accurate predictor of disease than either marker alone²

CA125 + HE4 = Improved Stratification²



What is ROMA⁴?

Risk of Ovarian Malignancy Algorithm. A risk stratification tool that combines CA125 + HE4 to compute risk of malignancy.

You can input
CA125 + HE4
online at:
www.he4test.com



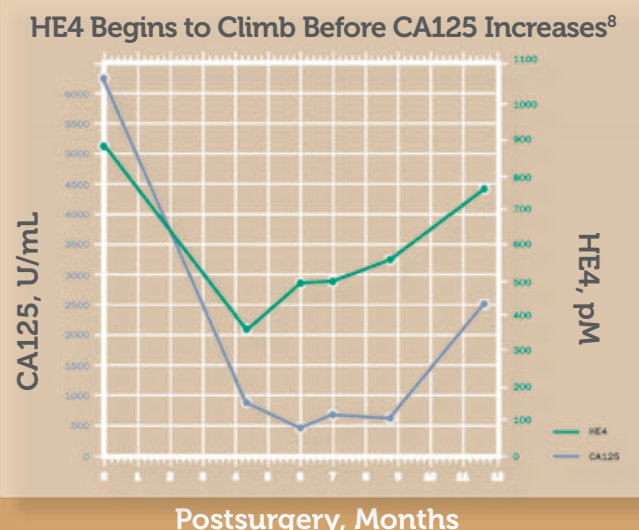
For a clear picture of ovarian cancer differentiation,
Now Add HE4 to CA125
 and Differentiate Ovarian Endometriotic Cysts²⁻⁴

- HE4 is significantly higher in endometrial and ovarian cancers, but not in endometriosis⁷
- CA125 is elevated in ovarian cancer and endometriosis, but not in endometrial cancer⁷
- Taken together, CA125 + HE4 differentiates ovarian tumors from endometriosis⁷

Markers	Accuracy,%	ROC-AUC,%	Sensitivity,%
Ovarian Cancer vs Ovarian Endometriosis⁷			
CA125 + HE4	94.0	91.3	78.6
CA125	92.8	77.0	64.3
HE4	91.6	91.9	71.4

When the focus is on improved monitoring of ovarian cancer,
Now Add HE4 to CA125^{4,7}

- Use serial testing of CA125 and HE4^{4,7}
- Monitor response to therapy in invasive epithelial ovarian cancer⁴
- Correlates with disease progression⁴
- HE4 increases by 25% or greater in 60% of patients with disease⁴
- HE4 remains constant in 75% of patients without progression of disease⁴
- HE4 may be used alone or in combination with CA125 to monitor epithelial ovarian cancer^{2,4}



A vast body of multi-national peer-reviewed and published clinical evidence supports the use of HE4

Since 2008, there have been over 40 peer-reviewed publications regarding the use of HE4 for ovarian cancer detection and management.

Evaluation of the Diagnostic Accuracy of the Risk of Ovarian Malignancy Algorithm in Women with a Pelvic Mass

"The use of the serum biomarkers HE4 and CA125 with the Risk of Ovarian Malignancy Algorithm (ROMA) has a high sensitivity for the prediction of ovarian cancer in women with a pelvic mass."

"... HE4 and CA125 provided the greatest level of discrimination between benign and malignant cases."

-Richard G. Moore, MD, et al., 2011¹

Prognostic Impact of Prechemotherapy Serum Levels of HER2, CA125, and HE4 in Ovarian Cancer Patients

"High levels of serum HE4 is a strong and independent indicator of worse prognosis in epithelial ovarian cancer patients."

"From the present study, it appears that HE4, aside from its usefulness as a diagnostic tool, is also an independent prognostic marker."

-Karina Dahl Steffensen, MD, PhD, et al., 2011²

Human Epididymis Protein 4 Offers Superior Specificity in the Differentiation of Benign and Malignant Adnexal Masses in Premenopausal Women

"We found that serum HE4 levels were elevated in only 8% of premenopausal women with benign disease while CA125 was elevated in 41% of these patients."

"Taken together, HE4 shows the most utility in correctly classifying benign cases where CA125 shows poor performance (endometriosis, dermoid cysts, PID)."

-Kevin Holcomb, MD, et al., 2011³

Prognostic Significance of Human Epididymis Protein 4 in Epithelial Ovarian Cancer

"The serum HE4 level is a promising indicator for the progression of cancer as well as a biomarker for the detection of epithelial ovarian cancer."

"... HE4 is less frequently elevated in patients with benign gynecologic disease compared with CA125."

-Jiheum Paek, MD, et al., 2011⁴

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When the focus is on
improved
ovarian cancer management

The formula is:
CA125 + HE4

Get FREE Practice Tools and Clinical Information at:
www.he4test.com



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