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.
The new formula for increased diagnostic clarity
Now Add HE4 to CA125
To Better Assess Pelvic Mass

- Late-stage diagnosis of ovarian cancer greatly decreases a woman’s chance of survival
- Early-stage diagnosis significantly increases a woman’s chance of surviving ovarian cancer

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.

What is ROMA?
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
When the focus is on improved monitoring of ovarian cancer, 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

<table>
<thead>
<tr>
<th>Markers</th>
<th>Accuracy,%</th>
<th>ROC-AUC,%</th>
<th>Sensitivity,%</th>
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<tbody>
<tr>
<td>Ovarian Cancer vs Ovarian Endometriosis⁷</td>
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<tr>
<td>CA125 + HE4</td>
<td>94.0</td>
<td>91.3</td>
<td>78.6</td>
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<tr>
<td>CA125</td>
<td>92.8</td>
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<tr>
<td>HE4</td>
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<td>91.9</td>
<td>71.4</td>
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</table>

When the focus is on improved monitoring of ovarian cancer, Now Add HE4 to CA125⁴,⁷

- Use serial testing of CA12S and HE4⁴,⁷
- 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 cancer⁴,⁷

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

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A vast body of multi-national 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., 2011

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., 2011

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., 2011

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., 2011

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

REFERENCES:

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