THE DOCTORS LABORATORY

TEST UPDATE

HE4

CA125, HE4 and ROMA (Risk of Ovarian Malignancy Algorithm)

Approximately 6,800 women in the UK are diagnosed with ovarian cancer each year. This makes it the 5th most common cancer in women, after breast, bowel, lung and womb cancer. 5 out of every 100 cancers diagnosed in women (5%) are ovarian cancers. There is no one screening test considered reliable enough to use to look for ovarian cancer in the general population, and the two main tests used in screening trials are serum tumour marker CA125 and transvaginal ultrasound.

Ovarian cancer is often detected at an advanced stage, which generally results in a poor prognosis and poor survival rate. Early detection is the key to improved survival among women with ovarian cancer.

CA125 is, to date, the best known test for ovarian cancer diagnosis. It is the serum marker most widely used to monitor therapeutic response, and to detect disease or disease recurrence in patients treated for epithelial ovarian cancer. However, only about 85% of all women with ovarian cancer have raised CA125, only 50% of women with early stage ovarian cancer have raised CA125, approximately 20% of ovarian cancers lack expression of CA125, and women with other, or benign, conditions can also have raised CA125 levels.

HE4 is a new marker for ovarian carcinoma, which is over-expressed in patients with ovarian, and some other cancers. Normal ovarian tissue has minimal production of HE4. When combined with CA125, HE4 significantly raises the level of sensitivity for the detection of ovarian cancer. HE4 is consistently expressed in patients with ovarian cancer and has demonstrated an increased sensitivity and specificity over that of CA125 alone.

A **Risk of Ovarian Malignancy Algorithm (ROMA)** classifies patients as being at low or high risk for malignant disease using both the CA125 and HE4 results and a woman's menopausal status. This risk is given as an adjunct to the test results for both CA125 and HE4. ROMA calculates a risk of finding ovarian cancer during surgery. ROMA classifies patients as being at low or high risk for malignant disease.

HE4 complements CA125 measurement in patients with ovarian cancer by providing improved sensitivity at fixed levels of specificity. This enhancement in sensitivity has been used to develop the ROMA algorithm that helps triage of women with adnexal mass to appropriate clinical/surgical management.

Test information

Test	Code	Sample type	Turnaround Time
HE4	**HE4**	**1 x SST/Serum**	**3 days**

*ROMA = Risk of Ovarian Malignancy Algorithm

HE4 is CE marked as an aid in estimating the risk of epithelial ovarian cancer in premenopausal and postmenopausal women.

Report format

CA125	U/mL	normal range (0–35)
HE4	pM	normal range (less than 150 pM)

Pre-menopausal	ROMA* %	High Risk > 13.1% for pre-menopausal
Post-menopausal	ROMA %	High Risk > 27.7% for post-menopausal

To order postal pathology packs for HE4 testing, please contact HE4@tdlpathology.com or Annette Wilkinson on 020 7307 7343.

For further information, please contact:

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