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## HE4 in serum – New Biomarker for Ovarian Cancer Available now at FML

Ovarian cancer is the 4<sup>th</sup> leading cause of cancer death worldwide and responsible for 5% for all cancer deaths in women. More than 200,000 women are annually diagnosed with ovarian cancer and fewer than 30% of these ovarian cancers are diagnosed in stages I/II.

The **gene encoding HE4 is amplified in ovarian carcinomas**, whereas its expression in normal tissues, including ovary, is low. The function of the HE4 protein (human epididymis protein 4) is currently unknown, but compared to CA 125 its specificity for malignant disease is higher. As a biochemical marker, HE4 has a higher potential than CA 125 in detecting early tumor stages and is found in 93% of serous and 100% of endometrioid epithelial ovarian cancers, also in the early stages. HE4 expression is highly restricted to the reproductive tracts and a low expression is found in normal tissue and benign tumors as well as in mucinous ovarian carcinomas; however, it is not found in the majority of non-ovarian cancers.

**The combination of testing for HE4 and CA 125 significantly increases the diagnostic sensitivity and specificity** for epithelial ovarian carcinomas. However, for detection in the early stage (I) HE4 is the best single marker with no increase in sensitivity when combined with CA 125 or any other marker (according to the study by Moore et al.).

Another advantage of HE4 is that it only shows higher concentrations in women with endometrial and ovarian cancer, however not with ovarian endometriomas or other types of endometriosis. Measuring the combination of both markers can be used to classify women with tumors into high and low risk groups and to estimate the risk of epithelial ovarian cancer in premenopausal and postmenopausal women presenting with pelvic mass (using the ROMA™ - Risk of Ovarian Malignancy Algorithm).

- Indication: Monitoring of therapy, recurrence and progressive disease in patients with epithelial ovarian carcinoma (not as primary screening test)
- Material: 1 ml serum
- Method: CLIA
- TAT: Germany, up to 10 days
- Dimension: pmol/l
- Ref.- range: a change of  $\geq 25\%$  is considered significant in disease progression
- Note: Results should be interpreted only in conjunction with other investigations and procedures in the diagnosis of disease and management of patients and the HE4 test should not replace any established clinical examination.
- Literature: Moore et al., Gynecologic Oncology, 2008, 108, p.402-408.