

NEW TEST ANNOUNCEMENT

NOTIFICATION DATE: September 16, 2013 **EFFECTIVE DATE:** September 24, 2013

HUMAN EPIDIDYMIS PROTEIN 4, SERUM

Test ID: HE4

USEFUL FOR: An aid in monitoring patients with treated epithelial ovarian cancer for recurrence or progression.

NOTE: This test is replacing the FHE4, HE4 (Human Epididymis Protein 4), Serum, which will become obsolete on October 17, 2013.

NOTE: The following referral test code will become obsolete.

Test Name	Test ID	Referral Lab Code	Referral Lab
HE4 (Human Epididymis	FHE4	FHE4	Women & Infants
Protein 4			Hospital

METHODOLOGY: Electrochemiluminescence Immunoassay

REFERENCE VALUES:

Females: < or = 140 pmol/L

Males: Not applicable

SPECIMEN REQUIREMENTS: Collection Container/Tube:

Preferred: Red top **Acceptable:** Serum gel

Submission Container/Tube: Plastic screw topped tube

Specimen Volume: 1.0 mL

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Serum	Refrigerated (preferred)	7 days
	Frozen	90 days

CAUTIONS:

Results cannot be interpreted as absolute evidence of the presence or absence of
malignant ovarian disease, because mild elevations of HE4 might also be present in
individuals with benign gynecologic conditions (ovarian cysts, cystadenomas,
leiomyomas, myomas, fibromas, and endometriosis), hypertension, congestive heart
failure, renal and liver disease.

- Serial testing for patient HE4 results should be used in conjunction with other clinical methods for monitoring ovarian cancer
- HE4 should not be used as a screening test for ovarian cancer.
- The use of this test in disease states other than ovarian cancer has not been clinically validated.
- Serum markers are not specific for malignancy and values may vary by method. Values obtained with different assay methods cannot be used interchangeably. Correlation studies between this method and the previous ELISA method (Test ID FHE4) show good correlation (correlation coefficient =0.92). However the new method will, on average, give 28% higher HE4 concentrations and individual patient results may vary more than would be calculated from the correlation equation.
- Ideally when changing methods, parallel testing using the old and new method will allow establishing the patient's HE4 baseline levels with the new method (re-baseline).
- In rare cases, interference due to extremely high titers of antibodies to analyte-specific reagents (human anti-mouse or heterophile antibodies, streptavidin, or ruthenium) can occur. The laboratory should be alerted if result does not correlate with the clinical presentation.
- Specimens should not be collected from patients receiving therapy with high biotin doses (ie. >5 mg/day) until at least 8 hours following the last biotin administration.

CPT CODE: 86305

DAY(S) SET UP: Monday through Friday; 5 AM- **ANALYTIC TIME:** 1 day

12 AM, Saturday; 6 AM- 6 PM

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or Greg Renkly, MML Laboratory Technologist Resource Coordinator Telephone: 800-533-1710