

HE4 EIA Kit

A new biomarker for ovarian cancer

The HE4 EIA Assay is a solid phase, 2-step immunoassay using the 2H5 and 3D8 monoclonal antibodies. The assay is intended for use in the monitoring of patients with epithelial ovarian cancer. In addition, the assay can be used in combination with the CanAg CA125 EIA or the Abbott ARCHITECT CA125 assay to aid in estimating the risk of epithelial ovarian cancer in women who present with a pelvic mass. Results should be interpreted with other methods in accordance with standard clinical management guidelines.¹

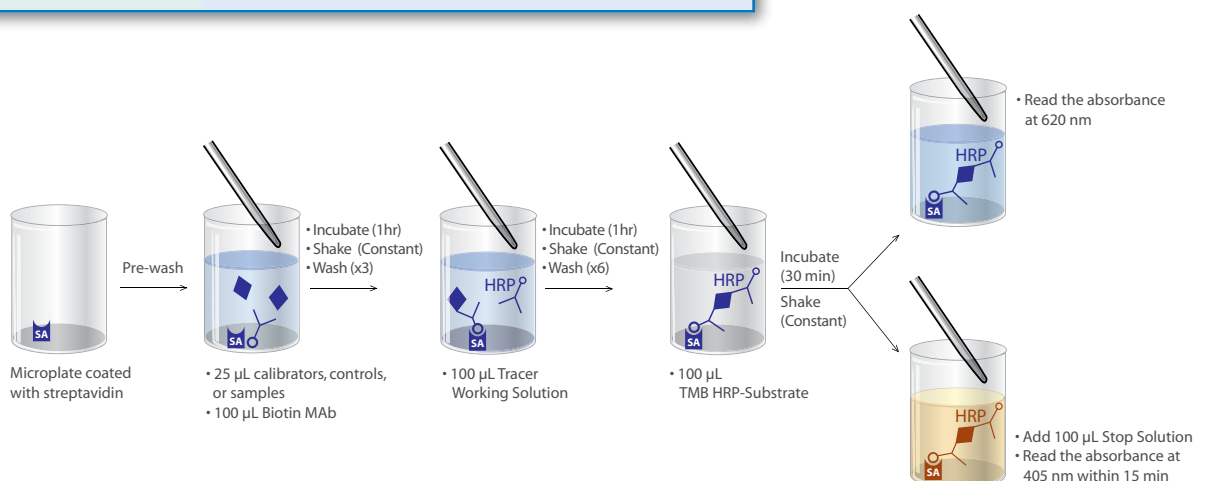
Benefits of the HE4 Assay

- The combination of HE4 + CA125 increases sensitivity over CA125 alone
- Increased sensitivity in women with early stage (I/II) disease compared with CA125
- Increased sensitivity in premenopausal women compared with CA125
- May be used alone or in combination with CA125 to monitor epithelial ovarian cancer.

Specifications

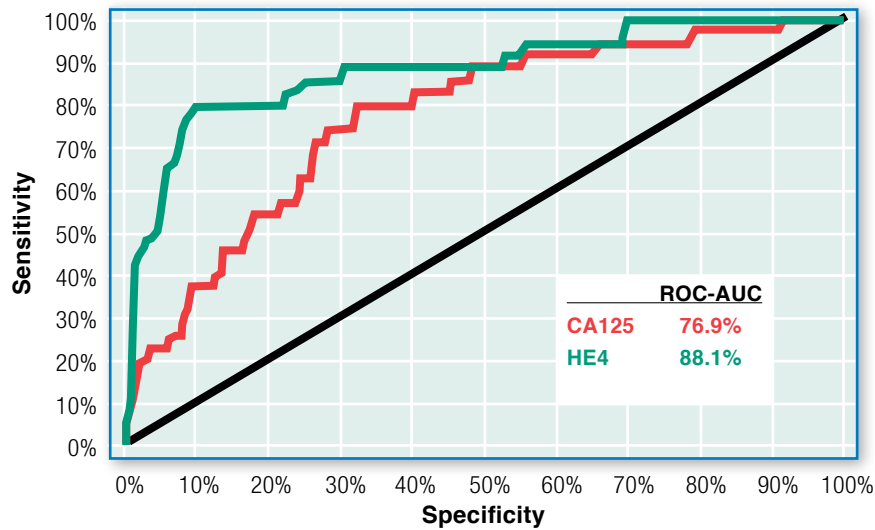
Product No: 404-10

Results within:	3 hours, two step procedure
Detection limit:	≤15 pM
Measuring range:	15 – 900 pM
Sample volume:	25 µL
Stability:	18 months at 2 – 8° C
Calibrator range:	0 – 900 pM
Incubation temp:	20 – 25° C
Detection:	620 nm or 405 nm
Precision:	≤15% total CV



Currently CA125 is the most widely used tumor marker in ovarian cancer, however it has limitations due to elevated levels in many benign gynecologic and non-gynecologic conditions. Based on recent studies investigating new biomarkers, adding the HE4 biomarker to CA125 resulted in an increased sensitivity and specificity compared with CA125 alone.² Below is an ROC curve that illustrates the increased sensitivity and specificity of the HE4 biomarker.

Ability of HE4 and CA125 to Differentiate Between Benign (N=351) and Stage I-II Epithelial Ovarian Cancers (N=35) in Pre- & Post-Menopausal Women



Kit Components			
Item	Quantity	Item	Quantity
Microplate, 96 wells streptavidin coated	1 plate, 12 x 8, breakable	Controls	
Calibrators		HE4 Control 1	1 x 1 mL, Lyophilized
HE4 Calibrator A	1 x 8 mL, Ready to Use	HE4 Control 2	1 x 1 mL, Lyophilized
HE4 Calibrator B	1 x 1 mL, Lyophilized	Biotin Anti-HE4	1 x 15 mL
HE4 Calibrator C	1 x 1 mL, Lyophilized	Tracer, HRP Anti-HE4	1 x 0.75 mL
HE4 Calibrator D	1 x 1 mL, Lyophilized	Tracer Diluent	1 x 15 mL
HE4 Calibrator E	1 x 1 mL, Lyophilized	TMB HRP Substrate	1 x 12 mL
HE4 Calibrator F	1 x 1 mL, Lyophilized	Stop Solution	1 x 15 mL
		Wash Concentrate	1 x 50 mL

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References: 1. HE4 EIA (Package Insert), Fujirebio Diagnostics, Inc. 2. Moore RG, Bast RC Jr. How do you distinguish a malignant pelvic mass from a benign pelvic mass? Imaging, biomarkers, or none of the above. *J Clin Oncol.* 2007;25(27):4159-4161. Trademarks are the property of their respective owners.
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