

**Fujirebio Diagnostics Receives FDA Clearance for the HE4 EIA Assay for the monitoring of patients with ovarian cancer.**

Fujirebio Diagnostics received the Food and Drug Administration (FDA) clearance for the HE4 EIA assay. HE4 is a simple blood test for use as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer. Fujirebio Diagnostics is the industry leader in biomarker assays and is the manufacturer of CA125, the gold standard test for monitoring ovarian cancer.

In a recent study, the value of HE4 was assessed in serial samples from 80 women diagnosed with ovarian cancer. 60% of patient samples had an increase in the value of HE4 of at least 25% greater than the previous value and correlated with progression of disease. In addition, 75% of serial samples showed no significant change in the HE4 value which correlated with no progression of disease in patients.

The HE4 assay is CE marked in Europe and will be available to US-based physicians in July. For more information on the HE4 assay please contact us at [info@fdi.com](mailto:info@fdi.com) or 1-800-342-9225.