



A Gene Expression Profile Test for the Differential Diagnosis of Ovarian Versus Endometrial Cancers

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BACKGROUND

Carcinomas that are either metastatic or involve both the ovary and endometrium can present a diagnostic dilemma. For example, endometrial cancers metastatic to the ovary can often mimic ovarian primaries on gross and microscopic examination. We have developed a gene expression profile test (Pathwork Tissue of Origin Endometrial Test) that distinguishes ovarian and endometrial cancers in formalin-fixed, paraffin-embedded (FFPE) specimens.

METHODS

The Test was developed using a 316–gene classification model and was validated in a blinded study using a pre-specified algorithm and microarray data files for 75 metastatic, poorly differentiated or undifferentiated FFPE tumor specimens that had either a known ovarian or endometrial diagnosis.

RESULTS

Measures of test performance include overall agreement with the available diagnosis of 94.7% (95% CI, 87% to 99%), an area under the ROC curve (AUC) of 0.997 and a diagnostics odds ratio (DOR) of 406 for both ovarian and endometrial cancers. Ovarian cancers (N=30) gave an agreement with reference diagnosis of 96.7% and endometrial cancers (N=45) gave an agreement of 93.3%. In a precision study, concordance in test results for adjacent FFPE sections from the same specimen processed in the same run was 100% (95% CI, 92% to 100%). Reproducibility in test results between two laboratories had a concordance of 96.6% (95% CI, 82% to 100%).

CONCLUSIONS

The Tissue of Origin Endometrial Test can aid in resolving this important differential diagnostic question in gynecologic oncology.

For information about the Pathwork® Tissue of Origin Test, please contact Pathwork Diagnostics at info@pathworkdx.com or call 1-877-808-0006