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PATHWORK TISSUE OF ORIGIN TEST SHOWS POTENTIAL TO AID IN THE DIAGNOSIS OF CANCER OF UNKNOWN PRIMARY

Data Presented at AMP Indicates Potential New Application of Tissue of Origin Test

SUNNYVALE, Calif. --- October 31, 2008 --- Pathwork Diagnostics, a molecular diagnostics company focused on oncology, will present three studies involving the gene expression based Pathwork® Tissue of Origin Test at the Association for Molecular Pathology (AMP) Annual Meeting.

In a poster entitled, “Gene Expression Microarray-Based Diagnostic Test May Identify Primary Tumor Site in Patients with Carcinoma of Unknown Primary (CUP),” Fabiola Medeiros, MD, Assistant Professor of Laboratory Medicine and Pathology at the Mayo Clinic, found that the Pathwork Tissue of Origin Test indicated a probable origin of metastatic CUP in 73 percent of the tumors tested.

CUP cases account for approximately three percent of all malignancies, representing one of the 10 most frequent cancer diagnoses. The CUP samples from the Mayo Clinic consisted of 11 fresh-frozen tumor specimens, whose origin could not be determined after full clinical and imaging workup, including immunohistochemistry. The cases where the tissue of origin was identified have treatment options that show increased survival compared to standard therapies used for the treatment of CUP.

“Identifying the tumor’s origin can allow oncologists to prescribe more appropriate, targeted therapy and avoid the toxicity of less-specific chemotherapies. They may also be able to enroll these patients in new therapeutic clinical trials which otherwise would not be available without a defined tissue of origin,” said David Henner, MD, PhD, Chief Medical Officer of Pathwork Diagnostics.

Since the test was validated and FDA-cleared using metastatic tumors for which the primary site was known, the purpose of this study was to examine the diagnostic performance of this test using CUP specimens. Analysis of the accuracy of these results is limited, since there is no reference diagnosis for comparison with CUP specimens where by definition the primary site is unknown. The test uses a microarray to measure the expression pattern, comprising more than 1,500 genes, in the tumor and compares it to the expression patterns of a panel of 15 known tumor types, representing 60 morphologies overall, to help determine the tumor’s origin.

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Additional AMP Presentations

Two additional research studies on the Pathwork Tissue of Origin Test were presented at AMP by Catherine Dumur, Ph.D., Director of Molecular Morphology Genomics for the Department of Pathology, Virginia Commonwealth University School of Medicine: “Clinical Verification of the Pathwork TOO Test on Poorly Differentiated Metastases” and “Assessing the Impact of Tumor Devitalization Time on Gene Expression-based Tissue of Origin Testing.”

In the first study, Dr. Dumur performed a clinical verification comparing the results from the Pathwork Tissue of Origin Test to the original pathology report diagnoses in 23 poorly differentiated and undifferentiated tumors, including 1 CUP specimen. Overall the Tissue of Origin Test demonstrated 94.7 percent accuracy. In cases of disagreement, Tissue of Origin Test results were compared to IHC and imaging results. Upon further review of the IHC and CT scans results, four of the five cases that initially showed a disagreement between the original diagnosis and the Pathwork Tissue of Origin Test revealed that that Tissue of Origin Test was correct. This study supports the hypothesis that the Pathwork test can be effectively used to complement existing diagnostic technologies for tissue of origin analysis.

In the second study, Dr. Dumur assessed how variations in clinical specimen acquisition impacted the test’s accuracy and reproducibility. Her results demonstrated that with proper sample handling and rigorous quality control procedures for RNA extraction and microarray analysis, tumor classification utilizing the Tissue of Origin Test will not be adversely affected.

About Pathwork Diagnostics

Pathwork Diagnostics, Inc., based in Sunnyvale, Calif., develops and commercializes high-value molecular diagnostics for oncology. The company’s first test to market – the Pathwork® Tissue of Origin Test – utilizes proprietary analytics and a companion Pathchip® microarray, which runs on the proven Affymetrix GeneChip® System. The test aids in determining a hard-to-identify tumor’s origin so that standard-of-care, cancer-specific treatment can begin. The test is FDA cleared as an in vitro diagnostic kit, while a functionally equivalent version of the test is also available through the CLIA-certified Pathwork® Diagnostics Laboratory. For more information, call 1.877.808.0006 or visit www.pathworkdx.com.

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