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STUDY OF PATHWORK DIAGNOSTICS' TISSUE OF ORIGIN TEST PUBLISHED IN THE JOURNAL OF MOLECULAR DIAGNOSTICS

Investigates Test Reproducibility in Multiple Labs to Determine Primary Tumor in Cancer Cases

Sunnyvale, CA, December 14, 2007 – Pathwork Diagnostics, a genomics-based diagnostics company focused on oncology, announced that its Pathwork[®] Tissue of Origin Test is the focus of a study published in the January issue of *The Journal of Molecular Diagnostics*. Pathwork's genomics-based test is designed to help determine a tumor's origin so that tissue-specific management can begin. The study, performed by principal investigator Federico A. Monzon, M.D., and colleagues from the University of Pittsburgh, Virginia Commonwealth University and Stanford University, examined the analytical performance characteristics and reproducibility of the Tissue of Origin Test.

There are an estimated 200,000 cancer patients with an uncertain primary diagnosis on their cancers each year in the U.S.^{1,2,3} These people may benefit from additional diagnostic information to determine the tissue of origin for their cancer. One study showed that, in such cases, the primary tumor site is identified only 25 percent of the time using traditional diagnostic tools. National Comprehensive Cancer Network guidelines emphasize the importance of identifying the tissue of origin so that management specific to the primary cancer can begin.

The Pathwork Tissue of Origin Test measures the expression of more than 1600 genes and compares a tumor's gene expression "signature" against those of 15 known tissue types. The test uses microarray technology, which enables large numbers of genes to be evaluated at the same time, using the proven, commercially available Affymetrix microarray platform.

In the study, 60 archived tissue specimens from poorly and undifferentiated tumors (metastatic and primary) were analyzed at four laboratories representing a wide range of pre-analytical conditions. Reproducibility was analyzed by cross-wise comparisons of all 4 sites. Cross-laboratory comparisons, performed using a variety of measures, showed highly reproducible results between laboratories. Overall concordance between laboratories in terms of final tissue of origin calls was 93.8%.

"As a result of the study, we concluded that the Pathwork Tissue of Origin Test is a robust assay that produces consistent results in diverse laboratory conditions reflecting the pre-analytical variations found in the everyday clinical practice of molecular diagnostics laboratories," explained Catherine I. Dumur, Ph.D., of Virginia Commonwealth University, lead author of the manuscript.

"This test has the potential to be an effective aid in the diagnosis of cancer patients presenting with poorly differentiated and undifferentiated tumors," commented Dr. Monzon, now at The Methodist Hospital in Houston, TX.

Note: The Pathwork Tissue of Origin Test is not cleared by the FDA for sale in the U.S. It is for Investigational Use Only.

About Pathwork Diagnostics

Pathwork Diagnostics, based in Sunnyvale, California, develops and delivers genomics-based diagnostics that advance cancer care. The company solves unmet clinical needs in oncology by using innovative technology to harness the power of genomics information and apply it in a robust, reproducible and reliable manner. Pathwork Diagnostics plans to deliver FDA-cleared microarray-based diagnostic tests for oncology to the clinical laboratory. The company's initial tests will consist of Pathwork Diagnostics' proprietary analytics and a companion Pathchip™ microarray, which runs on the proven Affymetrix instrument system. The company's first test – the Pathwork® Tissue of Origin Test – is designed to be an aid in the diagnosis of the tissue of origin in patients with poorly or undifferentiated tumors or metastases.

1. Pavlidis, Fizazi. Cancer of unknown primary. *Critical Reviews in Oncology Hematology* 54 (2005) 243-50.
2. Tong et al. Incidence, costs of care and survival of Medicare beneficiaries diagnosed with carcinoma of unknown primary. Abstract presented at ASCO 2006.
3. Pathwork Diagnostics analysis.

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