



1196 Borregas Avenue
Suite 200
Sunnyvale, CA 94089

www.pathworkdx.com

FOR IMMEDIATE RELEASE
CONTACT: Ed Stevens
727-327-3396
Estevens3@tampabay.rr.com

STUDIES INVESTIGATE DIAGNOSTIC PERFORMANCE AND REPRODUCIBILITY OF PATHWORK DIAGNOSTICS' TISSUE OF ORIGIN TEST

Sunnyvale, CA, November 8, 2007 – Pathwork Diagnostics, a genomics-based diagnostics company focused on oncology, announced that its Pathwork™ Tissue of Origin Test is the focus of two studies featured in poster presentations at this week's 12th Annual Meeting of the Association for Molecular Pathology (November 7-10, Los Angeles). The new genomics-based test is designed to help determine a tumor's origin so that tissue-specific management can begin.

There are an estimated 200,000 cancer patients each year in the United States who may benefit from diagnostic information to determine the tissue of origin for their cancer. One study showed that, in some 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's proprietary analytics are designed to measure the expression of more than 1600 genes and compare a tumor's genetic "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 instrument system.

"This test has the potential to be an effective aid in the diagnosis of cancer patients presenting with poorly differentiated and undifferentiated tumors," concluded Federico Monzon, M.D., Methodist Hospital, Houston, TX, (Poster #ST102, Friday, November 9, 1:00-3:00 PM, Constellation and Olympic Ballroom).

Dr. Monzon's clinical validation study ("Validation of a gene expression-based tissue of origin test applied to poorly differentiated and undifferentiated cancers") evaluated the performance of the Pathwork Tissue of Origin Test in a clinical setting. In the study, specimens of 477 metastatic and poorly differentiated and undifferentiated primary human tumors were obtained. All samples were of known origin (termed reference diagnosis).

Frozen tissue specimens were processed in two laboratories with a recommended protocol for gene expression with the Affymetrix platform. Data were analyzed with the Pathwork Tissue of Origin algorithm and a Tissue of Origin report was generated for each sample. The result was compared to the reference diagnosis to establish the performance characteristics of the Pathwork test. The Tissue of Origin Test results matched the reported origin in 89% of samples tested and provided greater than 92% agreement for at least 8 tissues of origin.

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In the second study, Catherine I. Dumur, Ph.D., Virginia Commonwealth University, Richmond, VA, led a group which examined the analytical performance characteristics and reproducibility of the Tissue of Origin Test, “Analytic performance of a microarray-based gene expression test to determine tissue of origin in uncertain primary cancers” (Poster #ST01, Thursday, November 8, 2:30-4:30 PM, Constellation and Olympic Ballroom).

In Dr. Dumur's 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. In addition, an average of 93.8% overall concordance between laboratories in terms of final tissue of origin calls was obtained.

“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 Dr. Dumur.

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.

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