595 Penobscot Drive
Redwood City, CA 94063

Phone: 650-366-1003
Fax: 650-599-9084
www.pathworkdx.com

Contact:
Andrew Noble
Media Relations Consultant
(415) 722-2129
andrew_noble@noblecomms.com

Pathwork® Tissue of Origin Test for FFPE Cleared by U.S. Food and Drug Administration

Molecular profiling test utilizes common clinical specimen type to help identify cancers

REDWOOD CITY, Calif., June 15, 2010 – Pathwork Diagnostics Inc., a molecular diagnostics company focused on oncology, today announced the U.S. Food and Drug Administration (FDA) cleared the Pathwork® Tissue of Origin Test for formalin-fixed, paraffin-embedded (FFPE) tissues. The FDA clearance allows the Tissue of Origin Test to be broadly utilized on common clinical FFPE tumor specimens from both community and research hospitals and paves the way for additional FFPE-based cancer tests on the Pathwork platform.

With some metastatic and poorly differentiated tumors, identifying the tumor's origin is complex and can make diagnosis and treatment difficult. The Pathwork Tissue of Origin Test uses microarray-based RNA profiling to compare the patient's specimen to a database of known tumor types. The highly accurate and reproducible results are evaluated by the physician in the context of the patient's clinical history and complementary diagnostics, such as immunohistochemistry. Pathwork has the only FDA-cleared molecular classification tests for tissue of origin.

"When there is uncertainty about the identity of the tumor, we are challenged to provide the best treatment," said Gauri Varadhachary, M.D., associate professor, Department of Gastrointestinal Oncology, M.D. Anderson Cancer Center. "With the molecular information provided by the Pathwork Tissue of Origin Test, we have the opportunity to be better equipped to define preferred therapeutic approaches for our patients."

"Pathologists can consider using molecular profiling to help classify the cancer when existing methodologies may not be sufficient to provide a definitive diagnosis," said Marina Nikiforova, M.D., director, Molecular Anatomic Pathology Laboratory, University of Pittsburgh. "Since the performance of the Pathwork Tissue of Origin Test is cleared by the FDA, we can use this test and resulting information with more confidence."

"Over the past two years, we have seen significant adoption for our Tissue of Origin Test from leading oncologists and pathologists at major academic medical centers and top cancer clinics across the country," said Deborah J. Neff, CEO, Pathwork Diagnostics. "The FDA clearance demonstrates our ability to develop and commercialize robust FFPE diagnostics, and opens the door for future tests to be offered on the Pathwork platform."

Pathwork Diagnostics
595 Penobscot Drive
Redwood City, CA 94063
Phone: 650-366-1003
Fax: 650-599-9084
www.pathworkdx.com

The Pathwork Tissue of Origin Test measures the degree of similarity between the RNA expression patterns in a patient's tumor and the RNA expression patterns in a database of 15 tumor types (metastatic, poorly differentiated and undifferentiated cases) that were diagnosed according to then current clinical and pathological practice. The test uses microarray technology from Affymetrix Inc. (Nasdaq: AFFX) to measure the expression levels of more than 2,000 genes.

Pathwork will transition its Tissue of Origin Test for FFPE offered through its CLIA-certified laboratory from a Laboratory Developed Test (LDT) to an in vitro diagnostic (IVD). The company also plans on making an IVD kit available to customers who want to run the test in their own clinical laboratory. For more information on how to order the Tissue of Origin Test, please visit: http://www.pathworkdx.com/OrderOrigin.

About Pathwork Diagnostics

Pathwork Diagnostics Inc. is a privately held company based in Redwood City, Calif., that develops and commercializes high-value molecular diagnostics for oncology. The company's flagship Tissue of Origin Test is the only FDA-cleared molecular test of its kind. For more information, please call toll-free 1.877.808.0006 or visit www.pathworkdx.com.