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FDA CLEARS THE PATHWORK[®] TISSUE OF ORIGIN TEST FOR HARD-TO-IDENTIFY TUMORS

Pathwork Diagnostics' Gene Expression Test Is the First to Receive FDA Clearance for Diagnosis of Uncertain Tumors; Problem Affects 200,000 New U.S. Cancer Cases Annually

Sunnyvale, Calif. --- July 31, 2008 --- Pathwork Diagnostics, Inc., a molecular diagnostics company focused on oncology, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Pathwork[®] Tissue of Origin Test for use in determining the origin of uncertain tumors. The test analyzes a tumor's gene expression pattern to help pinpoint the source of hard-to-identify tumors and is the first test of its kind to receive FDA clearance. Up to an estimated 200,000 newly diagnosed cancer patients annually in the U.S. may have a tumor for which the site of origin is uncertain after the initial diagnostic workup.^{1,2,3,4} The FDA's clearance underscores the growing role that patients' genomic information can play in helping physicians make better decisions.

"Knowing the primary tumor site with greater certainty enables more appropriate cancer treatment. The growing trend in cancer care is the use of therapies that target specific tissues and their genomic components, rather than relying on a one-size-fits-all treatment approach," said Deborah J. Neff, President and Chief Executive Officer of Pathwork Diagnostics. "We believe the Pathwork Tissue of Origin Test will help provide more certainty in tumor diagnosis, which will enable more patients to realize the benefits of this new era in genomics-based diagnostics." The FDA-cleared Pathwork Tissue of Origin Test will be available as an in vitro diagnostic (IVD) kit, meaning that clinical laboratories can run the test themselves. The test is currently available as a service through Pathwork's CLIA-certified laboratory.

The Pathwork Tissue of Origin Test uses a microarray to measure the expression pattern, comprising more than 1,500 genes, in the uncertain tumor and compares it to expression patterns of a panel of 15 known tumor types, representing 60 morphologies overall, to help determine the tumor's origin. In the in vitro diagnostics clinical validation study submitted to the FDA, the test demonstrated 89 percent positive agreement (akin to sensitivity) with available diagnoses and 99 percent negative agreement (akin to specificity). The study consisted of 545 metastatic, poorly differentiated and undifferentiated tumors that had been identified as one of the 15 tumor types on the panel using existing methods.⁵ The test demonstrated an average 94 percent overall concordance across four laboratories in a cross-laboratory comparison study of 60 metastatic, poorly differentiated and undifferentiated tissue specimens.⁶

“Hard-to-identify tumors are a significant clinical problem,” said Dr. James Abbruzzese, Professor of Medicine at M.D. Anderson Cancer Center. “They are time-consuming and frustrating for both physicians and patients. Accurately identifying a tumor’s origin – and thus knowing what kind of cancer the patient has – is necessary for beginning standard-of-care, cancer-specific treatment per the National Comprehensive Cancer Network Clinical Practice Guidelines. Knowing the tumor’s origin can also enable patients to get into – and benefit from – appropriate clinical trials.”

Targeted cancer therapies can be effective even with metastatic tumors and are generally tumor-specific (e.g., Herceptin[®] for breast cancer), requiring identification of the primary tumor site or tissue of origin. Targeting therapy to specific tumor types can allow patients to avoid the toxicity of broader chemotherapy.

“Traditional tools used to identify tumors of uncertain origin include imaging studies, such as CT scans and MRIs, as well as a thorough pathological evaluation with immunohistochemistry and other techniques,” said Federico Monzon, M.D., Director of Molecular Diagnostics of The Methodist Hospital in Houston. “However, for difficult cases the use of these complex iterative techniques can often take weeks, and in some cases they still do not definitively identify the tissue of origin. A gene expression test like the Pathwork Tissue of Origin Test provides unique information and, based on this data, it is reasonable to expect that it will improve the diagnosis of uncertain primary tumors.”

About Pathwork Diagnostics

Pathwork Diagnostics, Inc., based in Sunnyvale, California, develops and commercializes high-value molecular diagnostics for oncology. The company delivers FDA-cleared, microarray-based tests to clinical laboratories and also provides diagnostic tests through its CLIA-certified laboratory. The company’s initial tests utilize Pathwork Diagnostics’ proprietary analytics and a companion Pathchip[®] microarray, which runs on the proven Affymetrix GeneChip[®] System. The company’s first test – the Pathwork Tissue of Origin Test – is now FDA-cleared as an in vitro diagnostic kit. A functionally equivalent version of the test is also available through Pathwork[®] Diagnostics Laboratory. The test aids in determining a tumor’s origin so that standard-of-care, cancer-specific treatment can begin. For more information, please call toll-free 1.877.808.0006 or visit www.pathworkdx.com.

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- ¹ Pavlidis N, Fizazi K. Cancer of unknown primary (CUP). *Crit Rev Oncol Hematol*. 2005;54(3):243-250.
- ² Tong KB, Murtagh KN, Hubert HB, et al. Incidence, costs of care and mortality of Medicare beneficiaries diagnosed with cancer of unknown primary origin. Poster presented at the annual meeting of the American Society of Clinical Oncology; June 2-6, 2006; Atlanta, GA.
- ³ Pathwork Diagnostics analysis.
- ⁴ American Cancer Society, *Cancer Facts & Figures 2008*. Atlanta: American Cancer Society; 2008.
- ⁵ Pathwork Tissue of Origin Test User Guide (P/N 72912).
- ⁶ Dumur CI, Lyons-Weiler M, Sciulli C, et al. *J Mol Diagn*. 2008;10:67-77.