

## The Pathwork<sup>®</sup> Tissue of Origin Test Fact Sheet

### Overview

The Pathwork<sup>®</sup> Tissue of Origin Test is the first FDA-cleared gene expression test to aid in diagnosing the origin of uncertain tumors. The test is available as a service through Pathwork Diagnostics' CLIA-certified laboratory and, with recent FDA clearance, will be available in a kit format to clinical laboratories so that they can run the test themselves.

Approximately 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.<sup>1,2,3,4</sup> Hard-to-identify tumors are time-consuming to work up, frustrating for both physicians and patients, and expensive to the healthcare system. Existing diagnostic technologies for such cases – including imaging and immunohistochemistry – are subjective and time-consuming, and often do not produce a definitive diagnosis. Knowing the primary tumor site – and thus what type of cancer the patient has – with greater certainty enables more appropriate cancer treatment, especially with the increased availability of new, targeted cancer therapies.

The Pathwork Tissue of Origin Test measures 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. It then provides a report with an objective, probability-based score for each potential tumor type. The test uses a proprietary Pathchip<sup>®</sup> microarray and runs on the proven Affymetrix GeneChip<sup>®</sup> System.

### Validation Data

The Pathwork Tissue of Origin Test is supported by extensive analytical and clinical validation data. The test demonstrated 89 percent positive agreement (akin to sensitivity) with available diagnoses and 99 percent negative agreement (akin to specificity) in the FDA in vitro diagnostic clinical validation study. 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.<sup>5</sup> Additionally, 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.<sup>6</sup>

### 15 Featured Tissue Types

The Pathwork Tissue of Origin Test provides a Similarity Score for each of the following 15 tumor types, representing 60 morphologies overall, uniquely enabling the physician to rule in or rule out specific tumor types:

- more -

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<sup>1</sup> Pavlidis N, Fizazi K. Cancer of unknown primary (CUP). *Crit Rev Oncol Hematol*. 2005;54(3):243-250.

<sup>2</sup> 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.

<sup>3</sup> Pathwork Diagnostics analysis.

<sup>4</sup> American Cancer Society, *Cancer Facts & Figures 2008*. Atlanta: American Cancer Society; 2008.

<sup>5</sup> Pathwork Tissue of Origin Test User Guide (P/N 72912).

<sup>6</sup> Dumur CI, Lyons-Weiler M, Sciulli C, et al. *J Mol Diagn*. 2008;10:67-77.

Bladder  
Breast  
Colorectal  
Gastric  
Hepatocellular

Kidney  
Melanoma  
Non-Hodgkin's Lymphoma  
Non-Small Cell Lung  
Ovarian

Pancreas  
Prostate  
Soft Tissue Sarcoma  
Testicular Germ Cell  
Thyroid

### When to Order the Test

The Pathwork Tissue of Origin Test must be ordered by a physician. Following are examples of scenarios in which the test may be beneficial:

- The cancer is found in multiple locations, demonstrating metastatic disease without a clear primary site.
- The tumor's cells are poorly differentiated or undifferentiated, making them difficult to interpret.
- The cancer is found in an unexpected location.

### How to Order the Test

The Pathwork Tissue of Origin Test is available through the CLIA-certified Pathwork<sup>®</sup> Diagnostics Laboratory, located in Sunnyvale, California. Qualified frozen tissue specimens may be provided to the laboratory for processing and analysis. A Pathwork staff pathologist interprets the results and provides a comprehensive report to the physician. Pathwork Diagnostics, Inc., provides extensive reimbursement support. To order a shipping kit, healthcare providers should call toll-free 1.877.808.0006 or e-mail [support@pathworkdx.com](mailto:support@pathworkdx.com). You can also visit [www.pathworkdx.com](http://www.pathworkdx.com). The FDA-cleared Pathwork Tissue of Origin Test will be available in a kit format to clinical laboratories.

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