

The Pathwork[®] Tissue of Origin Test Fact Sheet

Overview

The Pathwork[®] Tissue of Origin Test is an innovation in molecular diagnostics—a gene expression–based test that uses a tumor’s own genomic information to reliably pinpoint its origin. The test provides objective data previously unavailable to physicians for tissue of origin identification. The Tissue of Origin Test is part of a growing family of products that includes lab service tests for formalin-fixed, paraffin-embedded (FFPE) specimens and a FDA-cleared in vitro diagnostic (IVD) kit that will be available.

The American Cancer Society estimates that there are 1.4 million new cancer diagnoses annually in the United States. Of these new cases, up to 10 percent are of tumor types not readily classifiable in the course of the initial diagnostic workup.ⁱ Tumors with uncertain origins 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 1500 genes, in a tumor with an uncertain origin and compares it to expression patterns from 58 morphologies, consolidated into a panel of 15 known tumor types representing 90 percent of all solid tumors. It then provides a report with an objective score for each potential tumor type in the panel, uniquely enabling the physician to rule in or rule out specific tumor types. The test uses a proprietary Pathchip[®] microarray and runs on the proven Affymetrix GeneChip[®] System.

Validation Data

The Pathwork Tissue of Origin Test is supported by extensive analytical and clinical validation data.

- In 352 FFPE specimens, the test demonstrated 89% positive percent agreement (akin to sensitivity) with available diagnoses, and greater than 99% negative percent agreement (akin to specificity) in specimens that had previously been identified with existing methods as being among the 15 tumor types on the panelⁱⁱ
- In 487 frozen specimens, the test demonstrated 89% positive percent agreement and greater than 99% negative percent agreement^{2,iii}

15 Featured Tissue Types

Bladder	Breast	Colorectal
Gastric	Hepatocellular	Kidney
Melanoma	Non-Hodgkin’s Lymphoma	Non-small Cell Lung
Ovarian	Pancreatic	Prostate
Soft Tissue Sarcoma	Testicular Germ Cell	Thyroid

When to Order the Test

When there is uncertainty about a tumor’s origin, the Tissue of Origin Test can fill the information gap with accurate, objective, actionable information. The physician can order the test when:

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

How to Order the Test

1. Call Pathwork Diagnostics Laboratory Customer Support toll-free at 1.877.808.0006 to request a Specimen Collection and Shipping Kit.
2. Follow instructions in the Pathwork Tissue of Origin Specimen Collection and Shipping Kit to prepare, qualify and ship the specimen(s) and the completed Test Requisition Form to the Pathwork Diagnostics Laboratory. Use the Specimen Collection and Shipping Kit Checklist provided with the kit.
3. Pathwork Diagnostics Laboratory processes the specimen, runs the Pathwork Tissue of Origin Test and provides a report to the physician.

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Media contact: Maura Sieftring
215.928.2346
media@pathworkdx.com

ⁱ Pathwork market research data on file. Pathwork Diagnostics: 2008.

ⁱⁱ Data on file. Pathwork Diagnostics: 2008.

ⁱⁱⁱ Monzon FA, Lyons-Weiler M, Buturovic LJ, et al. Multicenter validation of a 1550-gene expression profile for identification of tumor tissue of origin. *J Clin Oncol*. In press.