

Clinical Report Tissue of Origin Testing Service

PATIENT AND ORDER INFORMATION

Name: DOE, JANE DoB: 22 Apr 1968 Age: 43 Sex: Female Biopsy Site: Lung Date Specimen Collected: 05 Aug 2011 Date Specimen Received: 08 Aug 2011	Pathwork Case ID: TOO11-987654 Pathwork ID: 41040 Test Report Date: 15Aug2011 5:45PDT Version: TOO v5.0 Specimen ID: AE11_10087P13K
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PATHOLOGIST'S INTERPRETATION

MOST LIKELY TISSUE OF ORIGIN:

BREAST

DEGREE OF CONFIDENCE:

HIGH

TISSUES RULED OUT:

Colorectal	Gastric	Pancreas
Non-Small Cell Lung	Kidney	Sarcoma
Bladder	Non-Hodgkin Lymphoma	Prostate
Hepatocellular	Melanoma	Thyroid
Testicular Germ Cell		

TISSUE OF ORIGIN ANALYSIS

TISSUE TYPE	SS	≤ 5	100
Breast	68.9		
Ovarian	18.3		
Colorectal	2.7		
Gastric	1.9		
Pancreas	1.3		
Non-Small Cell Lung	1.1		
Kidney	1.1		
Sarcoma	1.0		
Bladder	0.7		
Non-Hodgkin Lymphoma	0.6		
Prostate	0.6		
Hepatocellular	0.5		
Melanoma	0.5		
Thyroid	0.5		
Testicular Germ Cell	0.3		

PATHOLOGIST'S COMMENTS:

The Tissue of Origin Test classified this tissue as Breast with a high degree of confidence. While an origin of Ovarian cannot be ruled out, it is highly unlikely that the origin for this tissue is Ovarian. All other tissues have been ruled out with > 99% confidence.

Specimen preparation: The specimen was macro-dissected.

TISSUE OF ORIGIN TEST GUIDE TO REPORT INTERPRETATION

The Similarity Score (SS) is a measure of the similarity of the RNA expression pattern of the specimen to the RNA expression pattern of the indicated tissue. Similarity Scores range from 0 (very low similarity) to 100 (very high similarity) and sum to 100 across all the tissues on the panel for both tests. For each test, the highest Similarity Score indicates the most likely tissue of origin.

For the Tissue of Origin Test:

- In a male patient with a highest SS for Ovarian, followed by a second highest SS for Testicular Germ Cell, the most likely tissue of origin corresponds to Testicular Germ Cell cancer.
- A Similarity Score of less than or equal to 5 rules out that tissue type as the likely tissue of origin greater than 99% of the time.
- Performance has not been established for results where the highest SS is less than 20.
- Performance characteristics for the Tissue of Origin Test were established in a clinical validation study that included 462 specimens. Results matched corresponding available diagnoses 89% of the time.

TISSUE OF ORIGIN TEST LIMITATIONS

The Pathwork Tissue of Origin Test is not intended to establish the origin of tumors (e.g., cancer of unknown primary) that cannot be diagnosed according to current clinical practice. It is not intended to subclassify or modify the classification of tumors that can be diagnosed by current clinical and pathological practice, nor to predict disease course or survival or treatment efficacy, not to distinguish primary from metastatic tumor. Tumor types not in the Pathwork Tissue of Origin Test database may have RNA expression patterns that are similar to patterns in the database. Therefore, results cannot be used to distinguish tumor types in the database from tumors not in the database.

CLIA Number: 05D1080859	Meredith Halks Miller, M.D.	15 Aug 2011
Laboratory Director: Meredith Halks Miller, M.D.	Electronic Signature of Pathwork Staff Pathologist	Date

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