

## Resolving a differential diagnosis of colorectal or pancreatic adenocarcinoma

*Medical Oncology, LLC, Baton Rouge, LA*

**Provisional Diagnosis:** Uncertain small bowel cancer

**Final Confirmed Diagnosis:** Pancreatic cancer

### Initial Staining/Scan History:

- CT scan Dx: jejunitis (Nov 2007)
- Ultrasound Dx: pelvic cyst (Dec 2007)
- CA 125: 70 (elevated; Jan 2008)
- Esophagogastroduodenoscopy (EGD): negative polyps (Jan 2008)
- Immuno stains: Positive vilium stain, CK7 and CK20

### Case Summary:

A 60-year-old female presented at the Our Lady of the Lake Regional Medical Center emergency room with abdominal pain in fall 2007. A CT scan resulted in a diagnosis of jejunitis, for which the patient was prescribed antibiotics. One month later, an ultrasound performed by a gynecologic surgeon identified a pelvic cyst. At that time the surgeon ordered a CA 125 blood test.

In January 2008, the patient returned to the emergency room complaining of abdominal pain. An esophagogastroduodenoscopy (EGD) revealed several negative polyps; after which a gynecologic surgeon performed a laporoscopic procedure and identified masses in the omentum that hadn't appeared on the initial CT scan.

This surgeon took tissue for biopsy and, given the existing masses, performed a colon resection in February 2008.

Based on tissue taken from the laparoscopic biopsies as well as a number of immuno stains, the Our Lady of the Lake Regional Medical Center pathology laboratory rendered a diagnosis of metastatic adenocarcinoma (small bowel primary). The patient was referred to the office of oncologist M. Patrick Stagg, where she underwent a PET scan that revealed carcinomatosis in the abdomen with an additional site directly behind the pancreas.

The oncologist's office then made plans to start the patient on a FOLFOX and Avastin regimen as treatment for primary small bowel or colon cancer. During this time, the team ordered a THEROS CancerTYPE ID test to provide additional diagnostic confirmation. Days before the patient was slated to begin her first chemotherapy cycle, the THEROS CancerTYPE ID test provided a probable match of pancreatic or stomach cancer.

Based on the THEROS CancerTYPE ID report, the oncologist ordered a CA 19-9 antigen marker for pancreatic cancer. In March 2008, the test came back at 2,066 (a normal result is 0-35), confirming the THEROS CancerTYPE ID result's prediction. After six cycles of chemotherapy with FOLFOX (oxaliplatin, fluorouracil, leucovorin) and Avastin, this antigen had dropped to 602.

*"While the ultimate diagnosis for this patient was more dire than the original and did not significantly alter the therapeutic regimen, the THEROS CancerTYPE ID test did give us a much more realistic prognosis,"* said nurse practitioner Aileen Brassard. *"The test is very easy to order, the turnaround is fast, and the results are presented in a way that's easy to read. It provides an important piece of the puzzle in cases where the primary cancer is uncertain."*



Molecular Diagnostics in Oncology

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## Patient & Order Information

Order ID:  
Patient Name:  
DOB:  
Medical Record #:  
Sample ID:  
Date Received:

Sex: Female  
Site of Biopsy: Ileum  
Date of Collection:  
Date Reported:

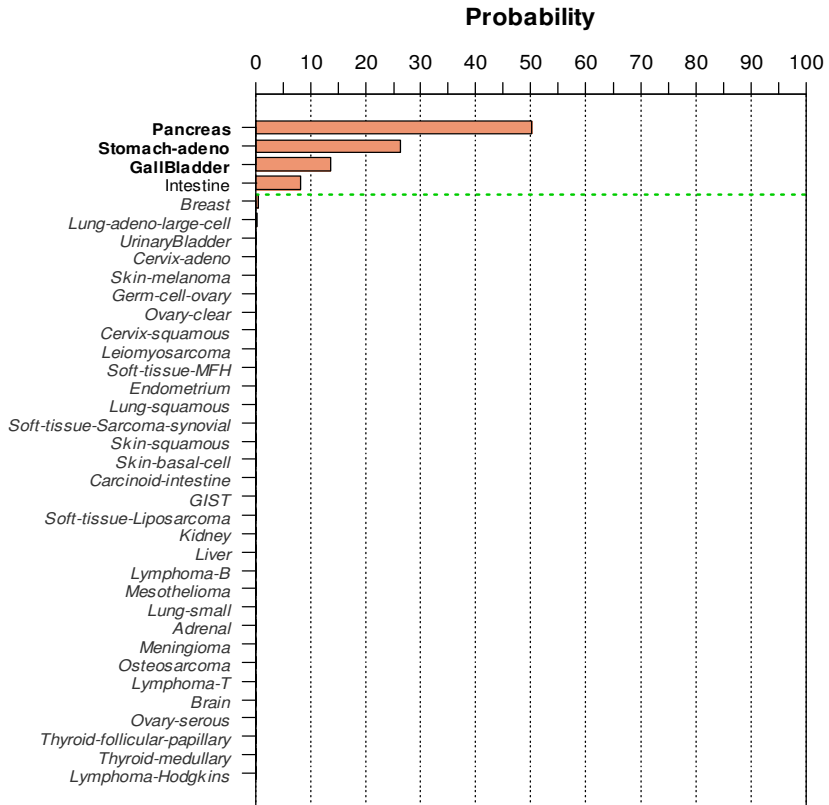
## THEROS CancerTYPE ID<sup>®</sup> Molecular Cancer Classification Test

<b>Sample quality:</b>	<b>Sufficient</b>
<b>Microdissection:</b>	<b>No</b>
Cancer Type	Probability
<b>Pancreas</b>	<b>50.2%</b>
<b>Stomach-adeno</b>	<b>26.3%</b>
<b>GallBladder</b>	<b>13.8%</b>
<b>Cumulative Probability</b>	<b>90.3%</b>

### Additional Test Information

The test sample is most similar to the three cancer types listed in the table above. The probability is a direct measure of the confidence for the prediction.

**How it works.** The probability for each cancer type is based on the 92-gene expression profile of the test sample. The probability scores for all cancer types sum to 100%. The cancer type with the highest probability represents the most likely type. When the difference between the highest and the second highest probability is small, the top two or three types are listed as predictions to reach >80% cumulative probability.



**Note: cancer types below the horizontal dashed line are ruled out with 95% confidence. Clinical correlation is recommended for cancer types above this line.**

### Intended Use

THEROS CancerTYPE ID<sup>®</sup> is a molecular test that is recommended to guide the process of cancer classification.

### Test Description and Methodology

This test identifies the most likely tumor origin based on the expression profiles of 92 genes analyzed by RT-PCR and is capable of classifying up to 39 tumor classes. The 92-gene expression profile is obtained by extracting mRNA from tumor-enriched sections of formalin-fixed paraffin embedded (FFPE) tissue and performing real-time quantitative RT-PCR using Taqman<sup>™</sup> technology. This RT-PCR based test has been shown to have an accuracy of 86% in classifying 39 cancer types[1,2]. However, cancer types outside of these 39 types may be unclassifiable or potentially misclassified.

1. Ma et al. *Molecular Classification of Human Cancers Using a 92-Gene Real-Time Quantitative Polymerase Chain Reaction Assay.* *Archives of Pathology and Laboratory Medicine.* 2006;130:465-473
2. Data on File, Technical Report 051909, bioTheranostics, Inc.

**Laboratory Director:** Bernard S. Chang, M.D.      **CLIA #** 05-D1065725      **CA #** CLF334843

This test was developed and its performance characteristics determined by bioTheranostics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. How this information is used to guide patient care is the responsibility of the physician. This molecular cancer classification predictive testing should be interpreted in the context of additional clinical and/or histopathological findings and not in lieu of such studies.