

## Distinguishing between recurrent breast cancer or a new primary adenocarcinoma

*Tipton Hospital, Tipton, IN*

**Provisional Diagnosis:** Uncertain metastatic adenocarcinoma

**Final Confirmed Diagnosis:** Colorectal cancer (intestinal)

### Initial Staining/Scan History:

- Ultrasound of abdomen: three masses in liver suspicious for metastasis
- CT scan dx: extensive liver metastases
- CEA: 471 (elevated)
- CA 27 29: 36.1 (wnl)
- CA 19-9: 522.6 (elevated)
- CA 125: 25.4 (wnl)
- Chromogranin A: 36 (wnl)
- Neuron Specific Enolase: 17.8 (elevated)
- New anemia at time of diagnosis

### Case Summary:

An elderly female with two previous primary breast cancers presented at Tipton Hospital complaining of abdominal pain. Bloodwork revealed elevated liver enzymes; a CT scan performed shortly after showed extensive liver metastases.

Treatment for the previous primary cancers comprised of:

- Chemotherapy and hormone treatment for the first breast cancer (diagnosed in 1993). The patient's medical team stopped hormone therapy when uterine cancer developed. They subsequently treated the uterine cancer with surgery and radiation.
- Mastectomy to address the second primary cancer, ductal carcinoma in situ (DCIS), diagnosed in 2002.

Following the DCIS, the patient had a variety of other illnesses and health issues, but there was no further indication of cancer until she appeared at the Tipton Hospital emergency room in late 2008.

Susan Kirby, RN, OCN and oncology program coordinator says, *“Of course, the question was: is this recurrent breast cancer?”*

Due to the time lapse and the results of patient follow-up monitoring over the interceding years, the patient’s oncologist felt strongly that the current metastatic disease was from a new primary cancer—not metastasis from the previous breast cancers.

To help obtain a more definitive diagnosis, the hospital next performed a guided liver biopsy, which resulted in a diagnosis of metastatic adenocarcinoma.

Kirby had recently obtained information about the THEROS CancerTYPE ID test; she placed it on the oncologist’s desk a few weeks prior to this case presentation. The oncologist felt the THEROS CancerTYPE ID test could be helpful for the current case and asked that the tissue sample be ordered. One week later, the THEROS CancerTYPE ID test results were back, predicting a primary intestinal cancer. A colonoscopy performed that week revealed a colon mass that the CT had missed. Biopsies of masses from the cecum revealed a high-grade, invasive adenocarcinoma.

Clinically, a definitive diagnosis in this case enabled the oncology professionals to begin treatment with FOLFOX 6 plus Avastin as treatment for metastasized colon cancer.

*“Oncologists can’t treat without a diagnosis,”* said Kirby. *“And we certainly weren’t going to start treating this patient for breast cancer without more certainty that this is what she was fighting.”* While the breast cancer treatment for this patient would have varied depending on IHC and FISH study results and other diagnostic features, Kirby says that *“the treatment would definitely not have been FOLFOX.”*

From the patient’s perspective, the definitive diagnosis *“helped her tremendously because we could assure her we were treating her appropriately,”* said Kirby. *“Once we told her the results of the THEROS CancerTYPE ID test and explained the course of treatment, she said, ‘You’ve given me some hope - and that’s all I needed.’”*



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: Cerebellum  
Date of Collection:  
Date Reported:

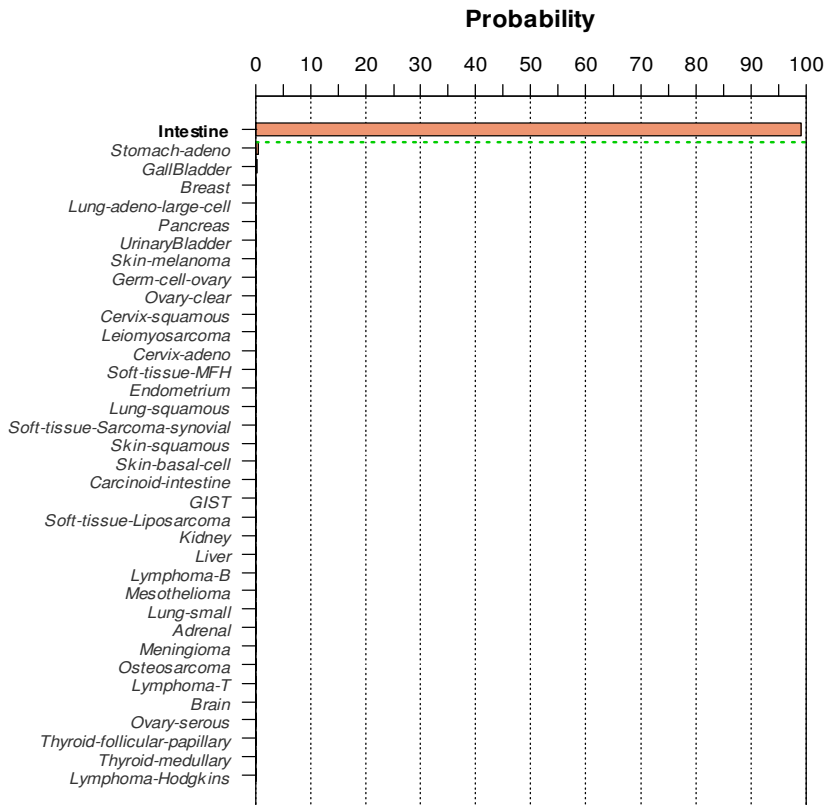
## THEROS CancerTYPE ID<sup>®</sup> Molecular Cancer Classification Test

<b>Sample quality:</b>	<b>Sufficient</b>
<b>Microdissection:</b>	<b>No</b>
<b>Cancer Type</b>	<b>Probability</b>
<b>Intestine</b>	<b>98.9%</b>

### Additional Test Information

The test sample is most similar to the cancer type 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, bioTheragnostics, Inc.

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

This test was developed and its performance characteristics determined by bioTheragnostics, 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.