LSUHealth
Neuroendocrine Tumor Clinic Healthcare Network

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To Whom It May Concern:

I have been utilizing CancerType ID in my Neuroendocrine Tumor Clinic for several years. I feel that it is a critically important tool to accurately localize the primary tumor in patients who present with an unknown primary NET and liver/nodal metastases. In these patients, CancerType ID can be used in place of many other expensive and time consuming diagnostic tests. This test has been very valuable in planning out surgical procedures by accurately directing us towards the correct region to explore. The abstract below has been submitted to ASCO and details our experience with CancerType ID. Based on our experience in about 75 patients we believe that CancerTypeID is a significant improvement in our ability to predict the location of tumors that have urknown primary locations

Thank you,

Eugene Woltering MD, FACS
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Gene Expression Profiling (GEP) Accurately Predicts the Primary Site of Metastatic Neuroendocrine Tumors (NETs) Presenting with an Unknown Primary

Background: NETs often present as liver metastasis with an unknown primary. Accurate subtyping of NETs has important clinical implications for staging and site-specific targeted therapy. Traditionally, the work-up to identify a primary NET as being lung, pancreatic or gut-based can be challenging and time-consuming.

Methods: GEP was performed on formalin-fixed, paraffin-embedded tumor samples using a 92-gene RT-PCR assay (CancerTYPE ID, bioTheranostics Inc.) as part of the clinical work-up for patients diagnosed with NETs and unknown primaries.

Results: Results were categorized by level of agreement:

Level of Agreement	Criteria	92-gene assay results (N=39)
1	GEP result concordant with surgical results	12
1a	GEP result concordant with histology, IHC, imaging/radiolcgical findings, and clinical impression	11
2	GEP result provided additional information that was inconsistent with histology, IHC, imaging/radiological findings, and clinical impression	4
3	GEP result discordant with histology, IHC, imaging/radiolcgical findings, and clinical impression	3
	Insufficient information on additional work-up	9

Of the 39 patients tested with the assay, 82% presented with liver metastasis. Assay results from those patients with adequate work-up were concordant with clinical data in 77% (23/30) of cases. Surgery was performed in 12 of these cases and 100% accuracy of the molecular assay was confirmed, resulting in 75% of primary tumors being found in the gut and 25% in the pancreas or duodenum. Assay predictions were clinically plausible but inconsistent in 13% (4/30) of cases and were discordant with histology, IHC, imaging/radiological findings, and clinical impression in 10% of the cases.

Conclusions: The 92-gene assay accurately predicted tumor subtype in patients presenting with NETs and an unknown primary. These findings have clinical utility for appropriate treatment selection, particularly where targeted therapies are available (everolimus, sun tinib). We believe the 92-gene assay can be useful in clinical management, and that our approach will lead to effective diagnosis and treatment algorithms to streamline extensive pre-operative work-up.