

Studies cite utility of molecular cancer classification test, 8/16

August 2016—A study published in Oncotarget (Brachtel EF, et al. Epub ahead of print March 28, 2016) demonstrates the high accuracy and success rate of Biotheranostics' CancerType ID molecular cancer classifier in the diagnosis of cancer for specimens with limited tissue. Results from the study support additional clinical utility for CancerType ID in small biopsy and cytology cases.

The accuracy of the test for molecular diagnosis of tumor type was evaluated in a blinded manner using 109 limited tissue samples representing a range of tumor types and grades at a variety of primary and metastatic sites. Analytical success rate and diagnostic utility were measured through a subsequent series of 644 cytology cases submitted for clinical testing.

The test predicted a molecular diagnosis in 95 percent of cases where a confirmed histopathologic diagnosis was available. It also demonstrated a 91 percent sensitivity for tumor classification; test performance was consistent across biopsy types and histologic grades. In the clinical case series, a molecular diagnosis was reported in 87 percent of 644 samples, identifying 23 different tumor types and allowing for additional mutational analysis in selected cases.

In another study, presented at the American Society of Clinical Oncology in June, more than 22,000 cases with unknown or uncertain cancer diagnosis submitted for clinical testing with the CancerType ID test were analyzed to assess differences in molecular diagnoses in patients under 40 years old and in patients 40 or older, and to evaluate potential impact based on expected treatment response to first-line therapies in specific tumor types.

Molecular diagnoses were categorized as either responsive or less-responsive tumors based on median overall survival of ≥ 12 months and

The test provided a single molecular diagnosis in 95.3 percent of cases. Predicted tumor types with significantly higher prevalence in young patients included intestine, sarcoma, germ cell, melanoma, thyroid, adrenal, sex cord stromal tumor, and meningioma. Fifty-four percent of patients under age 40 had molecular diagnoses more likely to respond to standard site-directed therapies, and 58 percent had molecular diagnoses with available targeted therapy. In patients 40 or older, these proportions were 55 percent and 60 percent, respectively.

[Biotheranostics](http://www.biotheranostics.com), 877-886-6739