



NEWS RELEASE

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Study Presented at San Antonio Breast Cancer Symposium Demonstrates Strong Performance of Biotheranostics' 92-gene Assay in the Diagnosis of Triple Negative Breast Cancer

FOR IMMEDIATE RELEASE...Dec. 12, 2016...SAN DIEGO...A study showing the strong performance of an optimized version of Biotheranostics' 92-gene assay to accurately identify both primary and metastatic triple negative breast cancer was presented Friday, Dec. 9, at the 2016 San Antonio Breast Cancer Symposium.

Triple negative breast cancers (TNBC) are often poorly differentiated tumors that may confound the initial pathology workup because TNBC lacks typical protein markers used to distinguish breast tumors from other tumor types that can be histomorphologically similar to TNBC. Accurate and early diagnosis of TNBC is important for individualizing a patient's treatment plan, which may include neoadjuvant and/or adjuvant chemotherapy to treat this aggressive form of breast cancer.

First author Peggy Sullivan, M.D., Associate Professor of Pathology and Laboratory Medicine at the David Geffen School of Medicine at UCLA, said, "There is a strong need for a molecular classifier for TNBC because of its diagnostic difficulty in the setting of metastatic disease. Given the limited treatment options for TNBC and the associated poor prognosis, more refined tumor characterization is important for developing optimal chemotherapy regimens or clinical trial therapies for patients. As a result, biomarkers that can aid in the diagnosis of TNBC are essential."

The study included 160 tumor samples from TNBC (57%) and non-breast tumors (43%) that were tested in a blinded manner. For performance in TNBC, the optimized 92-gene assay demonstrated an overall sensitivity of 88% (95% CI, 81-92), and sensitivities of 96% (95% CI, 89-99) and 80% (95% CI, 52-96), in primary and metastatic tumors, respectively. The overall sensitivity for non-breast tumors such as gastrointestinal, gynecological, and lung tumors that can have pathology overlap with TNBC was 89% (95% CI, 75-96).

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“These initial study results are important because triple negative breast cancer is an aggressive disease for which accurate and timely diagnosis is critical to treatment selection,” said Nicolas Barthelemy, President and CEO of Biotheranostics. “With this new algorithm for triple negative breast cancer developed in collaboration with a team of pathologists, our goal is to establish a higher level of accuracy, and these results show we are on the right pathway. We will continue to leverage our expertise in molecular diagnostics to develop new ways to help improve the care and outcomes for all cancer patients.”

“Triple negative breast cancer is an aggressive form of breast cancer with only a few treatment options,” said Elena Brachtel, M.D., Assistant Professor of Pathology at Harvard Medical School, and Assistant Pathologist at Massachusetts General Hospital. “These study results show high sensitivity to identify both primary and metastatic triple negative breast cancer, which is an important first step in establishing the clinical utility of molecular cancer classification and its ability to inform clinical decision making for patients with this challenging disease.”

To access the study abstract, titled An Optimized 92-gene Assay for the Molecular Diagnosis of Triple-Negative Breast Cancer (Poster No. P5-03-01), click [here](#).

About Biotheranostics

Biotheranostics, Inc., is a leader in helping physicians improve the care of cancer patients, offering a suite of proprietary genomics-based molecular diagnostics that allow treatment to be tailored to individual patients. The company's CancerTYPE ID[®] is the most rigorously validated gene expression test for metastatic patients with diagnostic ambiguity, helping physicians determine optimal site-directed treatment regimens with the goal of improving patient outcomes. Its Breast Cancer IndexSM helps oncologists make difficult decisions about extended endocrine therapy for ER+ breast cancer patients based on its unique ability to predict risk of late disease recurrence and identify which patients are likely to benefit from continuing therapy beyond five years. Biotheranostics operates a CLIA-certified, CAP-accredited diagnostic laboratory in San Diego. Learn more at biotheranostics.com.

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