

Progress of Biomarker Development for Breast Cancer

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In my upcoming presentation, I am excited to share the advancements made in our laboratory regarding our state-of-the-art diagnostic tools based on genomic analysis. These innovative tools have the potential to revolutionize the field of cancer diagnostics and treatment. Allow me to elaborate on two key assays that have emerged from our research.

Firstly, I will introduce the HER2DX assay, a breakthrough in the management of early-stage HER2+ breast cancer. This assay incorporates a comprehensive analysis of 27 genes, encompassing four distinct gene signatures: immune, HER2, luminal, and proliferation. The primary goal of HER2DX is to predict prognosis and treatment response, enabling us to tailor systemic therapy for each patient. By utilizing this assay, we can accurately determine whether de-escalation or escalation of systemic therapy is appropriate. The robustness of HER2DX has been validated through extensive studies involving over 2,000 patients over the past three years. Consequently, this test has gained recognition and has recently been incorporated into the esteemed Spanish Breast Cancer Clinical Guidelines.

Next, I will delve into our groundbreaking DNADX assay, which harnesses the power of DNA Next-Generation Sequencing (NGS) data. This cutting-edge tool surpasses the scope of single gene alterations, focusing instead on capturing intricate tumor phenotypes found within both tumor tissue and plasma. DNADX provides valuable insights into crucial characteristics such as endocrine sensitivity and proliferation. Our rigorous validation process has established DNADX as an invaluable asset in advanced breast cancer cases. Notably, this assay plays a pivotal role in identifying patients with HR+/HER2- advanced breast cancer who exhibit aggressive behavior and derive no benefit from endocrine-based treatments such as CDK4/6 inhibitors. Moreover, DNADX opens doors for further exploration of multi-feature genomic predictors derived from circulating tumor DNA (ctDNA) in breast cancer as well as other cancer types.

Lastly, I will address the significance of gene expression tests in the context of early-stage HR+/HER2- breast cancer. Specifically, I will emphasize the potential of these tests when analyzing residual tumors following endocrine-based therapy. By examining gene expression patterns, we can refine and personalize therapeutic strategies for these patients, leading to improved treatment outcomes.

In summary, this presentation will provide a comprehensive overview of our novel diagnostics genomic-based tools. The HER2DX assay offers a predictive approach to prognosis and treatment response, while the DNADX assay goes beyond single gene alterations to identify aggressive tumor phenotypes. Together, these assays represent significant advancements in cancer diagnostics and pave the way for further discoveries in the realm of genomic predictors. By tailoring therapy through phenotypic characterization tests, we can optimize treatment strategies and improve outcomes in both early-stage and metastatic breast cancer.