Genomic Health

June 27, 2013

As the field of molecular diagnostics advances and new companies offering genomic-based breast cancer tests emerge, a number of you have approached us with questions about how these efforts compare to Onco*type* DX® and our work at Genomic Health. We'd like to take this opportunity to highlight the important distinctions that should be taken into consideration as you evaluate these companies and their products.

The Onco*type* DX Recurrence Score® was developed to answer the specific question of which estrogen receptor positive (ER+) breast cancer patients need chemotherapy in addition to hormonal therapy. To validate it for this specific purpose, Genomic Health and its collaborators obtained practice-changing results from landmark clinical studies that included patients randomized to treatment (so that both prognosis and prediction could be obtained) and followed for long term outcomes. To date, it is the only test validated to predict who benefits from chemotherapy, and the only test included in all major breast cancer guidelines (ASCO,NCCN) for treatment decision making. As a result, it has been broadly adopted by the physician community, widely reimbursed in the United States, and used to guide treatment in more than 350,000 breast cancer patients around the world.

Additionally, recent data presented at major medical meetings showed clinically meaningful differences between patient results generated by the Onco*type* DX breast cancer test and the Mammaprint test, which unlike Onco*type* DX was developed using a largely untreated patient population that did not reflect the established standard of care of hormone therapy for patients with estrogen receptor positive disease. Specifically, these results revealed that patients stratified as high-risk by Mammaprint with high ER expression may lead physicians to inappropriately offer treatment with chemotherapy.

We realize there is a lot of information in the market right now that can lead to confusion, and we encourage you to ask the following questions when talking to companies who claim to offer tests similar to Onco*type* DX.

- **What specific clinical question was the test developed to answer and is it relevant to current practice?**
- **Were multiple randomized studies, including treated and untreated patients, conducted to validate and reproduce the test's ability to answer this question?**
- **What comprises test volume – is it commercial or research use?**
- **Are they getting paid routinely by private payors without appeal?**
- **For tests in kit form, like the one Nanostring is developing, what measures are taken to ensure high, reproducible quality at local labs?**
- **Have they conducted prospectively designed, randomized trials with long term clinical outcomes (i.e., 10 years or longer)?**
- **What is the pipeline opportunity and how is the company investing in it to drive long-term growth?**

We would be happy to schedule a call to discuss this information in more detail.

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