



Roundtable with the Experts: Genomic Assays

Thursday, December 3, 2020 7:00 PM-8:30 PM ET

AGENDA

ASBrS Roundtable with the Experts is a series of product/technique focused webinars highlighting specific topics. These events are designed to provide members with the opportunity to learn about technologies available for specific procedures and surgical techniques. Our next event in the series focuses on genomic assays, featuring presentations from Agendia, Biotheranostics, Inc., Exact Sciences, and Myriad Genetics, Inc. Each company will provide information about their product(s) followed by an interactive and objective panel discussion led by society leaders. **Note: No CME will be provided.**

This webinar will focus on genomic assays and the different tests available.

Moderators: Susan K. Boolbol, MD, Eric R. Manahan, MD, Shawna C. Willey, MD

Speakers: Kristi Funk, MD, James V. Pellicane, Jr., MD, Christy A. Russell, MD, Thomas J. Slavin, Jr., MD **Panelists:** N. Craig Brackett, III, MD, Sean T. Canale, MD, Beth-Ann Lesnikoski, MD, Aye Moe Thu Ma, MD

7:00 PM-7:10 PM	Welcome and Introductions	Susan K. Boolbol, MD
7:10 PM-7:20 PM	Company 1 Presentation: Agendia	James V. Pellicane, Jr., MD
7:20 Pm-7:30 Pm	Company 2 Presentation: Biotheranostics, Inc.	Kristi Funk, MD
7:30 PM-7:40 PM	Company 3 Presentation: Exact Sciences	Christy A. Russell, MD
7:40 PM-7:50 PM	Company 4 Presentation: Myriad Genetics, Inc.	Thomas J. Slavin, Jr., MD
7:50 PM-8:30 PM	Panel Discussion/Q&A	All Speakers and Panelists
8:30 PM	Adiourn	





ASBrS ROUNDTABLE WITH THE EXPERTS GENOMIC ASSAYS DECEMBER 3, 2020 7:00 PM – 8:30 PM ET

Company Name: Agendia

Product Name: MammaPrint® and BluePrint® Website Address: https://www.agendia.com

Contact Name: Israel Madera

Contact Email/Phone: lsrael.madera@agendia.com / 510-871-0167

Agendia is a precision oncology company headquartered in Irvine, California, committed to bringing early-stage breast cancer patients and their physicians the information they need to make the most effective treatment decisions. The company currently offers two commercially-available genomic profiling tests, supported by clinical and real-world evidence. MammaPrint®, the 70-gene breast cancer recurrence assay, and BluePrint®, the 80-gene molecular subtyping assay, provide a comprehensive genomic profile and the data physicians need to make more informed decisions in the pre- and post-operative treatment settings. By developing evidence-based novel genomic tests and conducting groundbreaking research while building an arsenal of data that will help treat cancer, Agendia aims to improve patient outcomes and support the evolving clinical needs of breast cancer patients and their physicians every step of the way, from initial diagnosis.

CAPABILITIES	LIMITATIONS
Rapid turnaround time for results (average of 5 days)	
Both tests inform pre-operative treatment planning (NAC vs.	
NET vs. surgery)	
MP informs risk of recurrence/need for adjuvant	
chemotherapy	
MP informs need for endocrine therapy	
Most comprehensive genomic profile for ESBC	
BP augments standard pathology by identifying underlying	
pathways driving tumor growth	
Testing can be done successfully on core biopsies (and results	
are highly consistent from sample to sample)	

Company Name: Biotheranostics, Inc. Product Name: Breast Cancer Index™

Website Address: https://www.breastcancerindex.com Contact Name/Phone: Lisa Whitmyer / 216-513-7808

Breast Cancer Index is a genomic test that predicts benefit from extended endocrine therapy and the individual risk of recurrence beyond 5 years for HR+ early-stage breast cancer patients.

CAPABILITIES	LIMITATIONS
Predictive of response to extended endocrine therapy	Can't be run on more than 3 positive Lymph nodes
Prognostic of risk of recurrence	
Level 1B evidence	
Indicated for N- and N+ disease (1-3 + LN)	
HER+	

Company Name: Exact Sciences

Product Name: Oncotype DX Breast Recurrence Score® Test

Website Address: https://www.oncotypeig.com

Contact Name: Lei Lynn Lau

Contact Email/Phone: <u>llau@exactsciences.com</u> / 650-274-9649

The Oncotype DX portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumor in order to optimize cancer treatment decisions. In breast cancer, the Oncotype DX Breast Recurrence Score test is the only test that has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the Oncotype DX Breast DCIS Score test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. In prostate cancer, the Oncotype DX Genomic Prostate Score* test predicts disease aggressiveness and further clarifies the current and future risk of the cancer prior to treatment intervention, and the Oncotype DX AR-V7 Nucleus Detect™ test helps determine which patients with metastatic castration-resistant prostate cancer (mCRPC) are resistant to androgen receptor (AR)-targeted therapies. The Oncotype DX AR-V7 Nucleus Detect test is performed by Epic Sciences at its centralized, CLIA-certified laboratory in San Diego and offered exclusively by Exact Sciences. With more than 1 million patients tested in more than 90 countries, the Oncotype DX tests have redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.MyBreastCancerTreatment.org or www.MyProstateCancerTreatment.org or

CAPABILITIES	LIMITATIONS
The Oncotype DX Breast Recurrence Score® test is a precision diagnostic test for personalized adjuvant treatment decisions in early-stage HR+, HER2- breast cancer that translates the specific individual's tumor biology into clinically meaningful information.	A minimum linear length of 2 mm of invasive carcinoma is required to render a Recurrence Score® result.
The Oncotype DX® test is validated as prognostic biomarker to provide an individual's risk of distant recurrence.	Rare histological subtypes of breast cancer are poorly represented in the clinical validation studies.
The Oncotype DX test is validated as predictive biomarker to identify patients who will benefit from the addition of chemotherapy to standard endocrine therapy.	
The Oncotype DX test has been validated for use in women with lymph node-negative and lymph node-positive breast cancer. Additionally, the test has been validated in the neoadjuvant setting.	

Company Name: Myriad Genetics, Inc.

Product Name: EndoPredict®

Website Address: https://www.myriad.com

Contact Phone: 800-469-7423

Myriad Genetics Inc., is a leading personalized medicine company dedicated to being a trusted advisor transforming patient lives worldwide with pioneering molecular diagnostics. Myriad discovers and commercializes molecular diagnostic tests that: determine the risk of developing disease, accurately diagnose disease, assess the risk of disease progression, and guide treatment decisions across six major medical specialties (autoimmune, dermatology, neuroscience, oncology, urology and women's health) where molecular diagnostics can significantly improve patient care and lower healthcare costs. For more information on how Myriad is making a difference, please visit the Company's website: www.myriad.com.

CAPABILITIES	LIMITATIONS
Great head to head data	Little market share in the US
Uses clinical AND molecular features for prognostication	Even with published chemopredictive data, there remains a lack of category 1 status/Chemopredictive labeling in NCCN guidelines
Solid >5 year and node positive performance	5-15 year data is late recurrence only, more data is needed to quantify EET benefit
Easy high or low answer	