New Study: Blood Test Offers Improved Breast Cancer Detection, New Tool to Reduce Use of Breast Biopsy

Study of Videssa® Breast shows “liquid biopsy” after abnormal mammogram and other imaging can help rule out breast cancer, reduce breast biopsy by up to 67 percent in women under age 50

New York – A new study published in Clinical Breast Cancer demonstrates that Videssa® Breast, a multi-protein biomarker blood test to detect breast cancer, can help inform better decision-making after abnormal mammogram or other breast imaging results and potentially reduce use of biopsy by up to 67 percent. The study evaluated the performance of Videssa Breast among women under age 50.

“With about 1.6 million breast biopsies performed each year,¹ the implications of a blood test that can help clinicians confidently rule out breast cancer and avoid a potentially unnecessary biopsy are tremendous,” said Judith K. Wolf, MD, Chief Medical Officer of Provista Diagnostics, Inc. “We know imaging has limitations, especially among women under age 50 who, because of confounding factors, are more difficult to image. This research shows that Videssa Breast can be a powerful new tool in the diagnostic toolbox for clinicians.”

The study, “A Non-Invasive Blood-Based Combinatorial Proteomic Biomarker Assay to Detect Breast Cancer in Women Under the Age of 50 Years” (http://dx.doi.org/10.1016/j.clbc.2017.05.004) demonstrated the performance of Videssa Breast from two prospective trials that enrolled 545 women, ages 25-50, with abnormal or difficult-to-interpret imaging (BI-RADS 3 and 4). The overall performance of Videssa Breast in women with a breast cancer prevalence of 5.87 percent, resulted in a sensitivity of 87.5 percent, specificity of 83.8 percent, positive predictive value (PPV) of 25.2 percent and a negative predictive value (NPV) of 99.1 percent.

The study notes that the high NPV helps clinicians identify patients who are highly unlikely to have breast cancer. Depending on age, approximately 70 to 90 percent of breast biopsies are benign.¹² The improved PPV of Videssa Breast over imaging – 25.2 percent vs. 8.8 percent – can increase the percentage of biopsies that yield a breast cancer diagnosis from one in 11 to one in four.

“When a mammogram yields an abnormal result, the challenge for every clinician is to decide which patients need follow-up, further imaging or biopsy,” said Josie R. Alpers, MD, a radiologist specializing in mammography and diagnostic radiology at Avera McKennan Hospital & University Health Center and a study co-author. “A test that is well-validated in a prospective trial means clinicians have a new way to accurately identify which patients may or may not need additional follow-up.”

² Data on file, Provista Diagnostics
Videssa Breast has been studied in two prospective, randomized, multi-center and blinded clinical trials, in more than 1,350 patients ages 25-75. It is the first prospective study of a proteomic assay composed of serum protein biomarkers and tumor-associated autoantibodies being used to detect breast cancer in women with abnormal imaging results. The data featured in the current Clinical Breast Cancer publication is taken from the first study and cohort one of the second study. Data from the over 50 cohort will be featured in upcoming publications. Videssa Breast is currently in limited clinical use through an early access program.

About Videssa® Breast
Videssa® Breast is the first blood-based proteomic test of its kind to provide early and accurate detection of breast cancer. In women who present with abnormal or difficult-to-interpret mammography results, the decision whether to order additional imaging or biopsy can be difficult. With a simple blood draw, Videssa Breast can help guide further diagnostic procedures or provide assurance that the patient does not have breast cancer. Videssa Breast transforms the breast cancer detection paradigm and applies proteomic testing to bring clarity to imaging results. When used in combination with imaging, Videssa Breast improves diagnostic accuracy and provides greater confidence and clarity when clinical assessment is challenging.

About Provista
Provista Diagnostics is a privately held molecular diagnostics company focused on developing and commercializing a new generation of proprietary blood-based proteomic diagnostic, prognostic and monitoring tests designed to address the unmet needs in women’s cancer, such as breast and gynecologic cancers. Provista Diagnostics’ state-of-the-art, high-complexity clinical laboratory is accredited by the College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA). Additional information about Provista Diagnostics is available at ProvistaDx.com. Information about Provista Diagnostics’ clinical trials is available at ClinicalTrials.gov.

About Clinical Breast Cancer
Clinical Breast Cancer is a peer-reviewed bimonthly journal that publishes original articles describing various aspects of clinical and translational research of breast cancer. Clinical Breast Cancer is devoted to articles on detection, diagnosis, prevention, and treatment of breast cancer. The main emphasis is on recent scientific developments in all areas related to breast cancer.

Notes for editors
The article is “A Non-Invasive Blood-Based Combinatorial Proteomic Biomarker Assay to Detect Breast Cancer in Women Under the Age of 50 Years” (http://dx.doi.org/10.1016/j.cbc.2017.05.004), by David E Reese, Ph.D. et al. It appeared online ahead of print May 23, 2017 in Clinical Breast Cancer, published by Elsevier. Copies of this paper are available to credentialed journalists upon request; please contact Elsevier’s Newsroom at newsroom@elsevier.com or +31 20 485 2492.

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