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For Immediate Release

New Study Integrating Multiple Types of Protein Biomarkers Increases Accuracy of Early Breast Cancer Detection

To tackle diagnostic challenges associated with breast imaging, Provista's study compares diagnostic strength of protein biomarkers when used alone or in combination

New York – August 10, 2016 – A first-time study published in *PLOS ONE* shows that a combined assessment of multiple types of protein biomarkers in the blood offers an important advancement for detecting early breast cancer. The study – conducted by Provista Diagnostics, compared the ability of (Serum Protein Biomarkers (SPBs) and Tumor-Associated Autoantibodies (TAAbs), either alone or in combination, to detect breast cancer.

"The study contributes critical understanding about the sensitivity and specificity advantage gained by integrating SPBs and TAAbs, to accurately detect breast cancer," said David E. Reese, Ph.D., President and CEO of Provista Diagnostics. The study entitled "Integration of Serum Protein Biomarker and Tumor Associated Autoantibody Expression Data Increases the Ability of a Blood-based Proteomic Assay to Identify Breast Cancer" is part of the broader pipeline of research studies slated for publication in 2016, exploring the use of SPBs and TAAbs in Provista's blood-based diagnostic test, Videssa® Breast.

The retrospective study evaluated 210 samples, collected prior to biopsy. Samples from a single site (Mercy Women's Center, which was renamed Mercy Breast Center in June 2016) were used including specimens from 18 participants with no evidence of breast disease, 92 participants diagnosed with benign breast disease and 100 participants diagnosed with breast cancer (both invasive breast cancer and ductal carcinoma *in situ*).

Study results show that when SPB data were used independently, clinical sensitivity and specificity for detection of breast cancer were 74.7% and 77.0% respectively. When TAAb data were independently used, clinical sensitivity and specificity for detection of breast cancer were 72.2% and 70.8% respectively. However, when TAAb and SPB data were used together, clinical sensitivity and specificity for detection of breast cancer improved to 81.0% and 78.8% respectively, demonstrating that a combined proteomic biomarker assay is an important avenue for developing new approaches for detecting breast cancer.

"Mercy Breast Center is proud to partner with Provista Diagnostics on this important study and contribute to the scientific understanding needed to support the development of technologies that help improve the ability to detect breast cancer and simplify decision-making for clinicians and their patients," said Alan B. Hollingsworth, M.D., Mercy Breast Center.

The new data affirms the role of protein biomarkers in addressing the diagnostic challenges associated with imaging, particularly for women whose imaging results fall into Category 3 (probably benign finding), Category 4 (suspicious finding) on the American College of Radiology's BI-RADS® (Breast Imaging – Reporting and Data System) scale. When women present with abnormal mammography results and/or have dense breasts, clinicians and patients often face a difficult decision whether to proceed with additional imaging or biopsy.

Reese added, "This study demonstrates clearly that we can offer better diagnostic technologies to not only detect breast cancer at its earliest, most treatable stage, but also reduce the rate of benign biopsies, which is important in improving care for women who do not have breast cancer."

Upcoming publications of results from Provista's large, prospectively collected, blinded, randomized, multi-center clinical trials will further elucidate the clinical utility of SPBs and TAAbs included in Videssa Breast to aid in the early detection of breast cancer.

About Videssa® Breast

Videssa® Breast is the first protein-based blood 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 brings

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 with the 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

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