

Provista

DIAGNOSTICS®

Precision Diagnostics to Enhance  
Women's Health



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## **Provista Diagnostics Announces Positive Trial Results Assessing the Use of Videssa® Breast to Detect Breast Cancer**

*Findings from Trial's Second Cohort Replicate Prior Results*

**New York, NY** – June 2, 2016 – Provista Diagnostics, a company developing and commercializing proteomic-based diagnostic, prognostic and monitoring tests for cancers affecting women, today announced positive results from Provista 002, a large, multi-center trial for its diagnostic test, Videssa® Breast. Representing over 500 patients, results from samples analyzed in the second cohort of the Provista 002 trial replicate findings from the first cohort, providing a strong clinical validation for the diagnostic assay.

“For clinicians, the validity of any diagnostic assay rests in the ability to produce replicable results. We are extremely excited that samples analyzed from Provista 002 Cohort 2 are consistent with the first cohort, as well as previously reported findings from Provista 001,” said David E. Reese, PhD., President and Chief Executive Officer of Provista Diagnostics. “For clinicians, these results demonstrate that they can look to Videssa® Breast to aid in the early detection of breast cancer and also to reduce both the overall number of biopsies used in women and the number of benign biopsies.”

The prospectively collected, randomized, blinded, multi-center study, Provista 002, enrolled a total of 1,005 patients, split across two cohorts. Prior results from the first 500 patients demonstrated highly accurate detection of early breast cancers independent of breast density status. These results showed that, when compared between the two cohorts, Videssa® Breast provided consistent results, regardless of variations in sample source, including the age, race, geography or clinical history of the patient or clinical trial site.

“The consistency of performance across those variations validates the generalizability of Videssa® Breast,” said Reese. “With a robust clinical validation set in place, we’ve achieved an important data milestone and looking ahead to the next six months, our focus will be on publishing results from both Provista 001 and 002, building on the commercial availability of Videssa® Breast and launching a registry trial that will serve to further validate the clinical use of Videssa®.”

Videssa® Breast is a non-invasive blood test designed to address current diagnostic challenges in breast cancer. Women with dense breasts or those who present with abnormal or difficult-to-interpret mammography results often face, with their healthcare professionals, a difficult decision whether to proceed with additional imaging or biopsy. The impact of clinical uncertainty can hold important implications, with approximately 30 to 40 percent of all early breast cancers going undetected in women with dense breasts.

“Each year, countless women and their clinicians navigate a maze of uncertainty and tough decisions in their efforts to accurately detect breast cancer,” said Reese. “These clinical findings show that Videssa® Breast will be an important ally in supporting clearer, more confident decision-making.”

### **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 with the Clinical Laboratory Improvement Amendments (CLIA).

Additional information about Provista Diagnostics is available at [ProvistaDx.com](http://ProvistaDx.com)

Information about Provista Diagnostics' clinical trials is available at [ClinicalTrials.gov](http://ClinicalTrials.gov)

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