Breast cancer prognostic gene-signature assay, 11/13

NanoString Technologies has received FDA 510(k) clearance for its Prosigna breast cancer prognostic gene signature assay. Based on the PAM50 gene signature, Prosigna is the company's first FDA-cleared in vitro diagnostic assay and uses the gene-expression profile of cells found in breast cancer tissue to assess a patient's risk of distant recurrence of disease. The Prosigna assay is performed using the nCounter Dx analysis system, which can be placed in qualified laboratories throughout the U.S.

The Prosigna assay is intended for use as a prognostic indicator for distant recurrence-free survival at 10 years and is indicated for postmenopausal women with stage I/II lymph node-negative or stage II lymph node-positive hormone receptor-positive breast cancer who have undergone surgery in conjunction with locoregional treatment consistent with standard of care. For each patient, the Prosigna assay provides a risk category and numerical score to assess distant recurrence of disease.

Other key features of the Prosigna assay include all-in-one assay consumables, including RNA extraction kits, allowing laboratories to test as little as a single section of formalin-fixed, paraffin-embedded tumor tissue; high-throughput workflow, allowing each nCounter Dx analysis system to process up to 30 patient samples per eight-hour work day; and automated generation of personalized full-color patient reports that can be quickly and easily shared electronically.

Prosigna is not intended for diagnosis, to predict or detect response to therapy, or to help select the optimal therapy for patients in the U.S. The assay has been CE-marked and is available for use by health care professionals in the European Union and other countries.

***NanoString Technologies**, 888-358-6266*