PreludeDx Receives New York State CLEP Approval for the DCISionRT® DCIS Test

Laguna Hills, CA—May 22, 2019—Prelude Corporation (PreludeDx), the leading molecular diagnostics and personalized medicine provider for early stage breast cancer, announced today that the State of New York Clinical Laboratory Evaluation Program (CLEP) has approved the proprietary DCISionRT® test. This test is used for patients diagnosed with ductal carcinoma *in situ* (DCIS), the most common type of non-invasive breast cancer. DCISionRT is the only DCIS test that assesses recurrence risk and can predict radiation therapy benefit, a critical decision point in the management of DCIS.

CLEP, established by the New York State Department of Health (NYSDOH), ensures the accuracy and reliability of tests performed for residents of New York. The program has meticulous evaluation standards and requires on-site inspections. Following CLEP's approval, PreludeDx's DCISionRT test is available in all 50 US states. Prior to this approval, DCISionRT was available in New York through a waiver program requiring a restricted permit be issued on a patient-by-patient basis from CLEP. The PreludeDx laboratory is also accredited by the College of American Pathology (CAP) and has CLIA certification.

According to PreludeDx President and CEO Daniel Forche, "New York has a rigorous evaluation process, and this CLEP approval further supports the robustness of DCISionRT. We are pleased to be able to offer DCISionRT to the women of New York and appreciate all the professionals working at NYSDOH and CLEP to ensure the well-being of their residents."

He continued, "DCISionRT is the only predictive DCIS test and marks an important leap forward for delivering precision medicine to women diagnosed with DCIS in the State of New York. We believe it is important for every woman with DCIS to Know Her Risk."

Initially through a provisional waiver program, Dr. Lauren Cassell, Chief of Breast Surgery at Lenox Hill Hospital, was able to access DCISionRT, enabling her to offer the latest innovation to her patients. She commented about DCISionRT and CLEP's approval saying, "The New York approval of DCISionRT is great news for the women of this state as well as the physicians that care for them. DCISionRT represents a new paradigm for the management of DCIS. Plus, my patients love it."

About DCISionRT for Breast DCIS
DCISionRT is the only radiogenomic risk assessment test for patients with ductal carcinoma *in situ* (DCIS), which affects over 60,000 women in the US each year. The test was developed by PreludeDx and built on research that began with funding from the National Cancer Institute to better understand the biology of DCIS. DCISionRT assesses a woman's individual tumor biology and other risk factors to provide a personalized Decision Score™ that identifies a woman's risk as low or elevated. DCISionRT's intelligent reporting provides a woman's recurrence risk after breast conserving surgery alone and with the addition of radiation therapy, effectively allowing patients and their physicians to make more informed treatment decisions.

About PreludeDx
PreludeDx is a leading personalized breast cancer diagnostics company dedicated to serving

breast cancer patients and physicians worldwide. Founded in 2009 with technology licensed from University of California San Francisco, PreludeDx focuses on developing precision breast cancer tools that will impact a patient's treatment decision. Our mission is to improve patient outcomes through innovative technology and reduce the overall cost burden to the healthcare system. Before making a treatment decision, Know Your Risk™.

For more information on how PreludeDx is making a difference for patients, please visit the Company's website: https://preludedx.com and follow us on Twitter @PreludeDx, Facebook and LinkedIn.

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https://www.prnewswire.com/news-releases/preludedx-receives-new-york-state-clep-approval-for-the-dcisionrt-dcis-test-300854897.html