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Boston Heart Granted New York Laboratory Permit for Diagnostic Testing

New Yorkers Can Now Benefit from a Personalized Cardiovascular Disease Wellness Program

FRAMINGHAM, Mass. – April 17, 2014 – Boston Heart Diagnostics Corporation, a pioneer in integrating next-generation diagnostics into personalized nutrition and lifestyle programs for patients with or at risk for heart disease, today announced that the company can serve patients from all 50 states now that it has successfully completed the New York State Department of Health (NYSDOH) clinical laboratory permitting process. The first state in the nation to establish a licensing program, New York is recognized worldwide as setting a gold standard in quality for laboratory testing.

“This is another critical milestone for the company as we work to fulfill our mission of enabling patients to prevent disease and improve overall heart health,” said Boston Heart President and CEO, Susan Hertzberg. “Cardiovascular disease (CVD) is complex, so we have assembled a focused test menu addressing the key areas of CVD risk including: lipids, metabolics, inflammation and genetics. Lifestyle choices are paramount to preventing and reversing CVD and we can use each person’s test results to create a personalized nutrition plan to help with those choices. There’s a significant unmet need in New York State. We’re delighted that New Yorkers can now have access to the full complement of next-generation diagnostics and individualized patient reports that Boston Heart offers.”

According to [New York State Department of Health vital statistics](#), 50,116 New Yorkers died of heart disease and stroke in 2011. It was the leading cause of death for both men and women, as well as for all races. Residents of New York State were 25 percent more likely to die of heart attack and stroke than the next leading cause of death (other), and 43 percent more likely than cancer (the third leading cause of death). [The 2011 Behavioral Risk Factor Surveillance System](#), NYSDOH’s annual statewide telephone survey of adults, found that among New Yorkers who have had their cholesterol checked, nearly 40 percent report being told they had high cholesterol. Adults with diabetes have a significant higher rate (68 percent), compared with 35 percent of those without diabetes. However, cholesterol levels are only a small part of the puzzle when it comes to each person’s specific risk for heart attack or stroke.

“The New York statistics are a sobering illustration of why we’ve taken a fresh, deep-dive approach to individualized risk assessment and tailored treatment plans to improve health outcomes,” said Boston Heart’s Chief Medical Officer, Ernst J. Schaefer, M.D. “We believe our test menu is unparalleled, harnessing the best science available to deliver clinically relevant and actionable results that help healthcare providers and patients better manage, prevent, and control cardiovascular disease.”

Requirements for a New York State permit include certification of a director and/or assistant directors for each test category; an on-site inspection to ensure that the premises, laboratory practices, equipment, personnel and record-keeping meet the state’s exacting requirements; successful performance of proficiency testing or alternate requirements for each test category; and review and approval of any in-house developed or non-FDA approved methods to assure the accuracy, validity, and clinical utility of the test.

(more)

Boston Heart is a leader in the science of chronic disease risk assessment and patient management. More than lab results, Boston Heart gives healthcare providers the tools they need to identify risk, individualize treatment plans, and engage patients in preventing and reversing cardiovascular disease.

About Boston Heart Diagnostics (BostonHeartDiagnostics.com)

Boston Heart is re-inventing the role of diagnostics in cardiovascular disease (CVD), the number one cause of death in the United States. There's much more to CVD than "good" and "bad" cholesterol – that's why traditional cholesterol screens often miss those at significant risk for heart attack or stroke. In fact, individuals can still have up to a 75% residual risk for serious cardiac events after successfully lowering LDL. We work with healthcare providers to engage individuals in their own well-being and give them the tools they need to prevent or reduce their CVD risk and improve health outcomes. Applying the latest clinical research and advances in laboratory science, we integrate results from our exclusive tests and health history information with an individual's food and exercise preferences – all transformed into practical nutrition, lifestyle, and support strategies tailor-made for each person. We help people make meaningful and lasting change through the use of easy-to-understand reports, one-on-one coaching, and sustained support. Boston Heart is leading the charge to turn the promise of personalized medicine into a reality.