Cleveland HeartLab Receives Internationally Recognized Quality Designation ISO 13485 and Achieves CE Mark for it’s New Universal CardioMPO Assay; Opening New Global Markets for Valuable and Proprietary MPO Testing

Recognized in over 100 peer-reviewed publications as a key measure of vascular inflammation, the new Universal CardioMPO test will now enable clinicians globally to utilize this important test for patient care

CLEVELAND, OH (APRIL ##, 2015) – Cleveland HeartLab Inc. (CHL), the premier cardiovascular disease management company, announced today that its newly launched Universal CardioMPO test has received CE marking in Europe and has been certified to the standards and requirements of both ISO 13485 and the Canadian Medical Device Conformity Assessment System (CMDCAS). These benchmarks achieved by CHL will dramatically increase access to MPO cardiovascular disease testing and benefit patients with cardiovascular disease (CVD) risk around the globe.

The new Universal CardioMPO assay is a TIA (turbidimetric immunoassay) that provides high quality and automated results on various laboratory chemistry analyzers. For the first time, this allows international laboratories the ability to offer this state-of-the-art technology within their current laboratory systems making it easier to adopt of this valuable technology in broader markets.

A recent publication in the Journal of Medical Economics demonstrated that the use of MPO testing along side of LP-PLA2 and hsCRP and in combination with standard lipid testing could reduce heart attacks and strokes by approximately 10% vs traditional cholesterol testing alone, not only saving lives but also hundreds of millions of healthcare dollars. MPO within the bloodstream is a vascular-specific marker for vulnerable plaque formation. Vulnerable plaque occurs when arterial narrowing is exacerbated by inflammation, the body’s natural response to injury. Inflammation can occur anywhere in the body, including within arteries. In 2001, researchers at the Cleveland Clinic were the first to document the association between MPO levels and risk of coronary artery disease. MPO has been licensed exclusively from the Cleveland Clinic to Cleveland HeartLab and there are now over 30 issued and pending patents globally.

“The new availability to measure MPO in Europe will catalyze further research into cardiovascular health,” said Stephan Baldus, MD, Professor of Medicine at The Heart Center of the University Hospital of Cologne. “CVD is a global health threat of enormous concern and MPO testing can have a meaningful positive effect.”

Dr. Baldus has published several studies on the role of inflammation in heart disease and the potential value of MPO in diagnosing arterial inflammation. A recent study showed that CVD is the single greatest cause of death among Europeans, killing more people each year than any other disease. In some regions of Europe, CVD kills twice as many people as cancer.
“Expanding the use of MPO could not come at a better time,” according to Stephen Nicholls, MBBS, PhD, Professor of Cardiology, University of Adelaide and Cardiologist at the Royal Adelaide Hospital. According to the World Health Organization, CVD is the leading cause of death worldwide, responsible for an estimated 17.5 million deaths in 2012, or 31 percent of all fatalities worldwide. As obesity and diabetes are reaching epidemic levels in developing regions of the world, CVD has become a global crisis with dramatic increases in China, India and Latin America.” Dr. Nicholls is the lead author of the IVUS study, Myeloperoxidase levels predict accelerated progression of coronary atherosclerosis in diabetic patients: insights from intravascular ultrasound.

“As a demonstration of our continuous commitment to innovation, quality and patient care, CHL achieved ISO 13485 and CMDCAS certifications after completing a rigorous audit of our quality and management system,” said Jake Orville, CEO of CHL. “Both certifications set global standards for quality. Achieving both of these certifications, as well as launching the next generation CE-mark Universal CardioMPO assay is another example of our ability to bring high value advanced diagnostics to market. Achieving ISO and CMDCAS certification not only demonstrates that our organization adheres to the highest standards of quality and excellence, it also allows us to expand access into global markets—another vital distinction for CHL.”

The International Organization of Standardization (ISO) 13485 is the globally accepted standard for the implementation of comprehensive quality management systems applied to all facets of the medical technology industry, including the development, manufacture, quality control and sale of medical devices. According to the U.S. Dept. of Health and Human Services, Americans suffer 1.5 million heart attacks and strokes each year. CVD—including heart disease and stroke—is the leading cause of death in the U.S. Every day, 2,200 people die from CVD—that's nearly 800,000 Americans each year, or 1 in every 3 deaths. According to the American Heart Association, half of those who suffer heart attacks and strokes have “normal” cholesterol levels, so new tools are desperately needed to improve our ability to assess CVD risk in patients whose risk is not revealed by cholesterol testing alone. The U.S. spends approximately $4 trillion on healthcare annually, one-sixth of which is spent treating CVD, according to the Centers for Disease Control and Prevention.

About Cleveland HeartLab

Cleveland HeartLab Inc. is the premier cardiovascular disease (CVD) Management Company with a comprehensive array of propriety tests focused on improving the early identification of those with CVD risk. In addition to its industry leading approach to inflammation testing, CHL manages a robust R&D program to accelerate the clinical use of scientifically proven and medically relevant biomarkers. CHL’s biomarkers have been validated in more than 100 peer-review studies published in leading medical and scientific journals. Formed in 2009 as a spin-off from the Cleveland Clinic, CHL offers its testing to thousands of leading clinicians focused on health and wellness as well as corporate wellness plans through its CAP-accredited and CLIA-certified clinical lab. Half of all patients who suffer from heart attack have normal cholesterol. With the goal of improving CVD risk assessment, CHL’s unique testing provides a more complete picture of CVD risk allowing clinicians to deploy personalized medical programs and interventions to reduce the overall risk of CVD, with a specific focus on reducing the risks
of inflammation. In a 2015 Journal of Medical Economics study on the economic impact of CHL’s core inflammation tests, CHL’s CVD management protocol demonstrated the potential to avoid nearly 4,000 heart attacks and strokes per 1 million patients of average health. The cost of care averted was estimated to exceed $187 million. CHL holds over 20 issued and 30 pending global patents and has been recognized for its innovation with the prestigious Nortech Innovation Award, The Ohio Venture of the Year Award and the Edison Crystal Award for Excellence. CHL was also named an “Inc. 5,000” company in recognition of its innovation and growth. For more information about CHL visit us at www.clevelandheartlab.com. For more information on CVD visit www.knowyourrisk.com

Contact: Bethany Hilt, Baker & Yorke Healthcare Communications, (330) 338-6633.