New Study Shows Cleveland HeartLab Inflammation Testing can Prevent Thousands of Heart Attacks and Strokes, Averting $187 Million in Healthcare Costs for Cardiovascular Disease—The Number One Killer of Men and Women in the U.S.

_The American Heart Association estimates 50 percent of all heart attacks and strokes occur in individuals with normal cholesterol. Cleveland HeartLab’s inflammation testing identifies at-risk patients cholesterol testing alone often fails to find_

Cleveland, OH and Boca Raton, FL, (April 21, 2015) – Cleveland HeartLab Inc. (CHL), the premier cardiovascular disease management company, and MDVIP, the leader in personalized, preventive medicine, are pleased to announce the publication of a seminal peer review study in the _Journal of Medical Economics_. The study shows that by improving cardiovascular disease risk (CVD) assessment, CHL’s inflammation testing could reduce heart attacks and strokes by nearly 10 percent.

The risk assessment, treatment and economic model—published by the _Journal of Medical Economics_ and based on the risk reduction achieved among patients enrolled in the MDVIP wellness program—showed that for a typical population of 1 million Americans, the addition of CHL’s inflammation testing could reduce the average heart attack and stroke rate by approximately 10%. In this study, this reduction results in $187.7 million in cost savings over five years, or $3.13 per member per month (PMPM) for the typical U.S. commercial payer compared to current standard of care. This savings could dramatically impact the system as approximately 15 percent ($450 billion per the Centers for Disease Control and Prevention) of the $3.8 trillion spent on healthcare in the U.S. went to treating heart attacks and strokes.

“This study shows that by more accurately measuring CVD risk with tools that detect arterial inflammation, we can decrease the overall number of heart attacks and strokes, allowing clinicians and health plans to deploy resources more strategically in order to better manage patient outcomes and costs,” said Marc Penn, M.D., Ph.D., FACC, Director of Research at Summa Cardiovascular Institute and Chief Medical Officer of CHL. “Even small reductions in heart attacks and strokes lead to enormous cost savings because these events are so traumatic and so costly to treat. Furthermore, we’re at a major crossroads in our focus on cholesterol testing to predict heart attack and stroke. As clinicians and researchers eagerly seek ways to improve the efficacy of cholesterol lowering in cardiovascular disease, there is still a great need to better assess near-term CVD risk in order to determine which patients need therapy and which patients on therapy still have excessive risk.”

The publication titled: _The Economic Impact of Implementing Multiple Inflammatory Biomarker-Based Approach to Identify, Treat and Reduce Cardiovascular Risk_ looked at the impact of inflammation testing, in addition to cholesterol testing, on the health outcomes of a typical U.S. health plan with one million members. Patients with evidence of decreased levels of inflammatory markers for CVD—as measured with tests offered by CHL—have consistently been shown to have better outcomes.
"MDVIP physicians routinely use CHL’s inflammation testing and, as a result, are identifying more patients at risk in clinical practice,” said Andrea Klemes, D.O., F.A.C.E., Chief Medical Officer, MDVIP.

“It's rewarding to see the results that our physician network achieves through the MDVIP model by decreasing inflammation and clinical events. It’s also exciting to think about the impact of these results extrapolated to a larger population. Inflammation has been proven to identify hidden risk in real-world clinical practice giving us a more complete picture of risk beyond our current arsenal of diagnostic tools.”

An important and novel component of this study is the inclusion of real world data used as model inputs for the effects of a multi-marker approach to create a tiered patient risk profile and the treatment success of lowering inflammatory markers. Specifically, the measurement of Myeloperoxidase (MPO), Lp-Pla2 and hsCRP were used to generate tiered risk. These data were extrapolated onto a patient population of 1 million by a team of biostatisticians, healthcare economists and clinicians. The research model strongly suggests that by implementing routine testing with CHL inflammation testing and a multi-tiered approach to cardiovascular risk, a decrease in non-fatal MI events and non-fatal IS events can be achieved.

“While I served as Secretary of Health and Human Services a decade ago, it was already clear that the way we managed CVD in the U.S. was financially unsustainable—a reality that has only worsened,” said Tommy Thompson, former U.S. HHS Secretary and a member of CHL’s Board of Directors. “By controlling the costs of CVD with these advanced tests, we can materially control the cost of the healthcare system because CVD patients—a relatively small number of patients as compared to the entire population—are the most costly to treat.”

Routine inflammation testing helps identify individuals with previously unidentified risk so that steps can be taken to decrease vascular inflammation, improve their state of wellness and lower their risk of a heart attack and death. This study demonstrated a significant savings in healthcare spending for 1 million patients. Applied nationally, the true savings is likely much greater. According to the Centers for Disease Control and Prevention, over 100 million Americans have at least one major risk factor for heart attack and stroke (1).

The study was conducted in collaboration with MDVIP and a team of expert economists from the Analysis Group, a leading health economics consultancy. Data from MDVIP and CHL supported the economic analysis using real-world data from over 100,000 patients who were monitored and managed using CHL’s inflammation testing.

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 reduce serious cardiovascular events by approximately 10% and the cost of care by $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 www.clevelandheartlab.com. For more information on CVD visit www.knowyourrisk.com

About MDVIP

MDVIP, Inc. is the national leader in affordable personalized healthcare offered by over 800 affiliated primary care physicians across the United States. These carefully chosen MDVIP-affiliated physicians limit the size of their practices in order to provide each patient with a comprehensive preventive care program with more time and attention which includes a customized wellness plan. With prevention at the center of its program, MDVIP has proven that its affiliated physicians offer excellent care and achieve impressive patient outcomes. Published results include lower hospitalization rates which yield significant cost savings to patients, employers, insurers and the healthcare system. MDVIP, Inc. was founded in 2000 and is headquartered in Boca Raton, Florida. For more information, visit www.MDVIP.com.

About Analysis Group

With more than 500 professionals with advanced degrees and expertise in health outcomes research, epidemiology, strategy, biostatistics, economics, and other quantitative disciplines, Analysis Group (www.analysisgroup.com) has established a leadership role in the science, economics, and business strategy of the global health care industry. The firm’s 11 offices are located in Boston, Chicago, Dallas, Denver, Los Angeles, Menlo Park, New York, San Francisco, and Washington, DC; and internationally in Montreal and Beijing.

***

Contacts:

Cleveland HeartLab, Bethany Hilt (330) 338-6633

For more information on MDVIP or to interview Dr. Andrea Klemes, please contact:

Nancy Udell, MDVIP, at 561-310-5455, nudell@mdvip.com or Deborah Kohan at 212-593-5885, Deborah.Kohan@finnpartners.com

Ref. CDC, Million Hearts: Strategies to Reduce the Prevalence of Leading Cardiovascular Disease Risk Factors --- United States, 2011.