



Cleveland HeartLab Launches Only Clinical Test for Measuring TMAO, an Important Measure of Gut Dysfunction that is Associated with Cardiovascular Disease Risk

Innovative new test published in The New England Journal of Medicine detects levels of TMAO – which, when elevated, correlates with a two-fold increased risk of heart attack or stroke

February 16, 2016, CLEVELAND: Cleveland HeartLab Inc., the premier cardiovascular disease management company, announced it has successfully developed, validated and launched a new clinical test for the assessment of TMAO (trimethylamine-N-oxide), a dietary-derived metabolite that is produced by gut bacteria and is strongly associated with cardiovascular disease. This compound may explain the link between the high incidence of heart disease and diets rich in red meat and dairy products.

Licensed from the Cleveland Clinic, TMAO has received widespread scientific and public attention since its discovery. In 2013, the American Heart Association and the American Stroke Association selected the discovery of the connection between gut flora, TMAO, and cardiovascular disease risk as one of that year's "Top 10 advances in heart disease and stroke science." TMAO has also been featured in the leading medical and scientific publications including *The New England Journal of Medicine* and *Nature*, as well as reported by [NPR](#), [Time](#), [The New York Times](#), and most recently in the *PBS* documentary "[In Defense of Food](#)."

Discovered by researchers in Cleveland Clinic's Lerner Research and Heart & Vascular Institutes, Cleveland HeartLab's new blood test measures levels of TMAO, which is a powerful indicator of future risk for heart attack, stroke, and death in patients who may otherwise appear healthy, according to Cleveland Clinic research. TMAO offers physicians insight into whether the gut is contributing to vascular inflammation present in those patients with positive risk markers from Cleveland HeartLab.

"This is an exciting discovery," said Nina Radford, MD, Director of Clinical Research and a cardiologist at Cooper Clinic. "Prevention is our primary focus at Cooper Clinic and we've known for decades that diets rich in animal and saturated fats are associated with increased risk of heart disease. TMAO testing has the potential to help us connect the dots between diet and cardiovascular disease for each patient. This test may identify additional targets for risk factor modification to reduce a patient's risk of serious cardiovascular disease events."

Additional research recently published in *Cell* investigates how the negative cardiovascular effects of TMAO can be prevented. The compound DMB (3,3-Dimethyl-1-butanol) was found to inhibit production of TMAO from the gut bacteria of laboratory animals. Many heart-healthy foods are rich in DMB, including cold-pressed olive oil, balsamic vinegars and red wines. This breakthrough may potentially lead to a dietary-based therapy through which individuals eat foods rich in DMB to prevent TMAO production in order to reduce their risk of CVD. Last year, [Procter & Gamble](#) announced it is working to develop an over-the-counter product to help people manage their TMAO levels.

"TMAO could be a major missing piece in the puzzle of our understanding of cardiovascular disease," according to Michael F. Roizen, MD, Chief Wellness Officer at the Cleveland Clinic Foundation. "For some patients, diets rich in saturated fats dramatically increase the risk of cardiovascular disease. While in others, the same diet has a marginal impact on risk. With this new information, we can better assess the heart attack risk and overall heart health of each individual patient and help guide them to make the specific lifestyle changes best suited for their unique risk."



"Launching TMAO testing in our world-class clinical lab is another example of Cleveland HeartLab's ability to bring a great clinical discovery from a leading medical institution to the market. Clinicians have come to rely on us for breakthrough innovations such as these and we are pleased that we have been able to translate world-class science into actionable results for patients with heart disease or who are at risk for heart disease or stroke," said Jake Orville, CEO of Cleveland HeartLab Inc.

For more information on this groundbreaking test, or to order, please call **866.358.9828**, option **1**, email customersupport@clevelandheartlab.com or visit <http://www.clevelandheartlab.com/new-tests/>.

About Cleveland HeartLab

Cleveland HeartLab Inc. (CHL) 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 10% of heart attacks and strokes for 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.

About Cooper Clinic

Cooper Clinic is a multi-specialty practice focused on prevention in order to add both quality and quantity to patients' lives. Cooper Clinic provides patients with an individualized, in-depth picture of their health, action plans to improve and same-day test results – all in less than a day. Areas of specialization include cardiovascular screening, imaging procedures, breast health, medical screenings, gastroenterology, preventive and cosmetic dermatology and nutrition services. Cooper Clinic is housed on Cooper Aerobics Center in Dallas, the headquarters for Cooper Aerobics' seven health and wellness companies and a research and education nonprofit, The Cooper Institute®, founded in 1970 by Kenneth H. Cooper, MD, MPH. Recognizing the need for irrefutable research on fitness and activity, the Cooper Center Longitudinal Study was established. Today it remains one of the most highly-referenced databases in the world, containing more than 275,000 records from more than 105,000 people. Through the array of services Cooper offers, millions have been inspired to make good health a habit, helping improve their quality and quantity of life. Cooper Aerobics challenges people to *Get Cooperized™* by adopting a healthy living mindset and following eight health guidelines developed by Dr. Cooper. For more information, call 866.906.2667 (COOP) or visit cooperaerobics.com. Get the latest updates on the [Cooper Aerobics Facebook page](#).

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