

Fact Sheet

For Information Contact:
Barbara Sullivan, Sullivan & Associates
714/374-6174, bsullivan@sullivanpr.com

Christina Andrian, diaDexus, Inc.
650/246-6476, candrian@diadexus.com

The PLAC[®] Test

Introduction

- The PLAC test, developed by diaDexus, Inc., is a simple blood test that measures levels of a novel risk factor for coronary heart disease and ischemic stroke, lipoprotein-associated phospholipase A₂ (Lp-PLA₂).
- The PLAC test is cleared for marketing by the U.S. Food & Drug Administration as an aid in predicting an individual's risk for coronary heart disease and ischemic stroke associated with atherosclerosis.
- Measurement of Lp-PLA₂ with the PLAC test enables physicians to identify patients at increased risk for heart disease and stroke to drive more aggressive treatment programs, such as lifestyle modification or therapeutic intervention, including statins and daily aspirin.
- Risk factor identification remains one of the most important approaches to preventing cardiovascular disease, but cholesterol tests and analysis of traditional risk factors fail to identify many people at risk.
- Nearly half of all coronary events occur in individuals who have low-to-moderate low-density lipoprotein (LDL) cholesterol levels. Cholesterol is not a reliable indicator of an individual's risk for stroke.
- The PLAC test is the only available test to measure Lp-PLA₂.

What Is Lp-PLA₂?

- Lp-PLA₂ is a cardiovascular-specific inflammatory enzyme that is a proven predictor of heart disease and stroke risk.
- Lp-PLA₂ associates in the blood primarily with LDL, the "bad" cholesterol. It is carried to the walls of coronary arteries by LDL, where it can activate an inflammatory response, making plaque prone to rupture. As a result, Lp-PLA₂ serves as a specific indicator of vascular inflammation.

- Lp-PLA₂ is a strong risk factor for heart disease and stroke, statistically independent of traditional risk factors, as well as markers of system inflammation, such as C-reactive protein and fibrinogen.
- Studies show that the risk of stroke is twice as great for individuals with elevated levels of Lp-PLA₂ compared with individuals with low levels of Lp-PLA₂. For those with the highest levels of Lp-PLA₂ and high systolic blood pressure, the risk increases sixfold.

Clinical Studies Supporting Lp-PLA₂ as a Cardiovascular Risk Factor

- More than 20 epidemiological studies have confirmed that elevated levels of Lp-PLA₂ increase the risk of coronary heart disease and ischemic stroke.
- An analysis from the West of Scotland Coronary Prevention Study (WOSCOPS), a five-year trial of 6,595 men with elevated cholesterol and no history of heart attack, showed that Lp-PLA₂ was the most powerful predictor of cardiovascular events among four candidate biomarkers. Patients with the highest levels of Lp-PLA₂ had twice the risk of an event compared with patients with the lowest levels, even after adjusting for traditional risk factors and the other biomarkers.
- The Atherosclerosis Risk in Communities (ARIC) coronary heart disease study evaluated Lp-PLA₂ to determine its ability to predict heart disease. Results showed that in individuals with normal LDL, Lp-PLA₂ levels were associated with heart disease, independent of traditional risk factors and C-reactive protein (CRP).
- The ARIC study also found that Lp-PLA₂ levels were associated with ischemic stroke, even after adjustment for traditional risk factors, body mass index, and CRP.
- Findings from another recent study verified the role of Lp-PLA₂ in the formation and progression of unstable arterial plaque. Rupture of unstable arterial plaque is the most common cause of heart attack and stroke.

How the PLAC Test Measures Lp-PLA₂

- The PLAC test is a “sandwich” enzyme immunoassay that uses two highly specific monoclonal antibodies for the direct measurement of Lp-PLA₂ concentration in human plasma and serum.
- Specifically, the test is an enzyme-linked immunosorbent assay (ELISA), a biochemical technique used by clinical labs to detect and quantify the presence of an antibody or antigen in a sample.
- Values of Lp-PLA₂ are provided in ng/mL. Recently published recommendations propose that Lp-PLA₂ \geq 235 ng/mL should be used to decide whether patients should be moved to a higher risk category, helping clinicians to incorporate this specific marker of unstable plaque into everyday practice.

- Fasting is not required for accurate results, and the PLAC test reports consistent and reliable values that typically do not fluctuate during acute systemic inflammation.
- The PLAC test is performed by Clinical Laboratory Improvement Act-certified high-complexity diagnostic laboratories throughout the United States, including Quest Diagnostics Incorporated, LabCorp, Mayo Medical Laboratories, ARUP Laboratories, and Berkeley HeartLab.
- Results are available to physicians in approximately 5–7 days.

About diaDexus

- diaDexus, based in South San Francisco, Calif., is a privately held biotechnology company focused on the discovery, development, and commercialization of novel, patent-protected diagnostic products with high clinical value.
- For more information, visit www.diaDexus.com or www.plactest.com.

###