

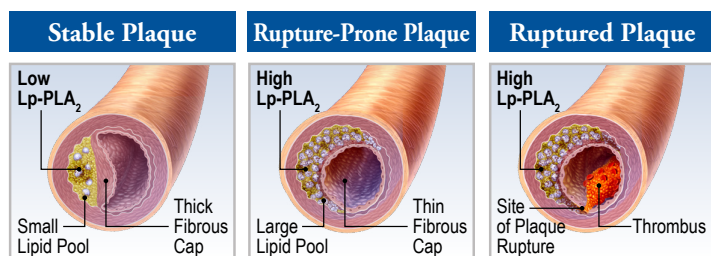
PLAC[®] Facts

Can a simple blood test help predict which patients are at a greater risk for heart attack or stroke? Yes. The PLAC Test can.

The PLAC[®] Test is the **only blood test cleared by the FDA** to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk of coronary heart disease (CHD) in patients with no prior history of cardiovascular events.

WHAT IS THE PLAC TEST?

The PLAC Test is a simple blood test that measures Lp-PLA₂, an enzyme highly specific to vascular inflammation and implicated in the formation of rupture-prone plaque.



75% of heart attacks and most strokes are caused by plaque rupture and thrombosis, not stenosis.

WHY IS THE PLAC TEST DIFFERENT FROM OTHER TESTS?

Lp-PLA₂ is independent of traditional cardiovascular risk factors.

- Lp-PLA₂ is a vascular specific inflammatory enzyme, therefore it is not as affected by systemic inflammation (infections, obesity, smoking) compared to other inflammatory markers such as hs-CRP.
- Because elevations in Lp-PLA₂ are independent of traditional risk factors, including obesity, the results of the PLAC Test provide valuable additive information to help determine the appropriate care for your patients.

WHO SHOULD BE TESTED?

The PLAC Test may be used as a management tool in patients at moderate to high risk for coronary heart disease or ischemic stroke events. Suitable patients may include patients with two or more risk factors, such as family history of cardiovascular disease or hypertension, even if their overall lipid profile looks normal.

WHAT DO PLAC TEST RESULTS MEAN?

Analyte	Units	Reduced Risk	Increased Risk
Lp-PLA ₂ Activity	nmol/min/mL	< 225	≥ 225

The PLAC Test for Lp-PLA₂ Activity provides information on the risk of coronary heart disease (CHD) events. In the Clinical Validation Study (see below), the overall population rate of CHD events at 5-year follow-up was 4.1% (95% CI 3.8 - 4.38%), prior to consideration of subject PLAC Activity values. Using a PLAC Activity cut-point value of 225 nmol/min/mL, subjects were then classified into a high PLAC Activity group (Lp-PLA₂ activity ≥ 225 nmol/min/mL) or a low PLAC Activity group (Lp-PLA₂ activity < 225 nmol/min/mL). The following absolute rates of CHD events at 5-year follow-up were observed (including 95% CI):

- **High PLAC Activity group CHD event rate 7.0% [6.2% - 7.8%]**
- **Low PLAC Activity group CHD event rate 3.3% [3.0% - 3.6%]**

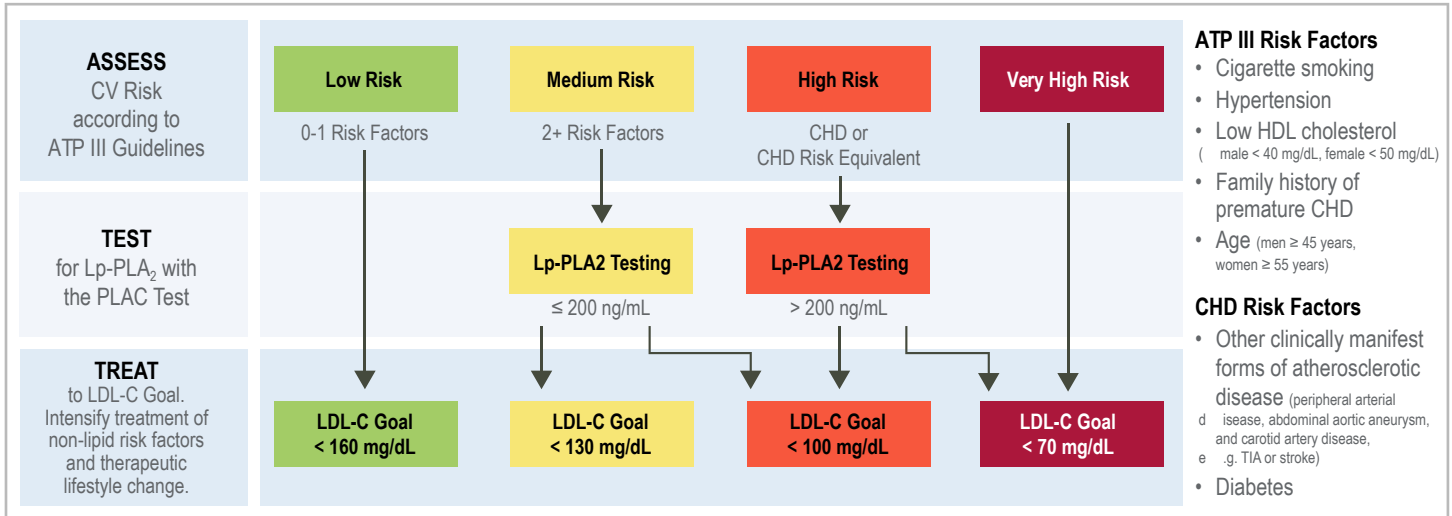
The high PLAC Activity group was found to have a 5-year absolute rate for CHD events that was over twice that of the low PLAC Activity group. The difference in absolute rates between the two PLAC Activity groups is both statistically significant ($p < 0.001$) and clinically important given the continuing lifetime risk of CHD events. The finding that an individual with no prior history of cardiovascular events has high PLAC Activity would suggest that they are at higher than average risk. Similarly, the finding that such an individual has low PLAC Activity would suggest that they are at lower than average risk.

Additional analyses showed that high PLAC Activity was a significant predictor of CHD events relative to low PLAC Activity, even after adjustment for other demographic and cardiovascular risk factors including age, race, gender, smoking, hypertension, diabetes, LDL-cholesterol and HDL-cholesterol.

Use of PLAC Activity results in conjunction with the other clinical parameters (e.g., age, life expectancy, etc.) and traditional risk factors (e.g., LDL-cholesterol, total cholesterol, blood pressure, etc.) may be used to refine risk assessment in primary prevention.

For more information on the PLAC[®] Test, please visit www.diazyme.com or call 1-888-DIAZYME.

RECOMMENDATION FOR USE OF LP-PLA₂ TESTING¹



HOW WILL THE PLAC TEST HELP IMPROVE PATIENT MANAGEMENT?

The PLAC Test helps identify patients who have “hidden” cardiovascular risk due to the formation of rupture-prone plaque.

- 1/2 of all heart attacks occur in patients with low to moderate cholesterol levels.
- While cholesterol is a useful tool in coronary heart disease, it is not a reliable predictor of stroke.
- 1/3 of all strokes affect individuals between 45 and 65 years of age.
- The PLAC Test enables you to gain additional information to identify patients in need of more aggressive treatment. High Lp-PLA₂ can be a wake-up call to your patients to help improve compliance to therapy.

HOW DOES THE PATIENT PREPARE FOR THE PLAC TEST?

There is no preparation required; it requires a simple venous blood draw. The patient does not have to be fasting and can be on medications. The test results are highly specific for inflammation associated with atherosclerosis, and are not likely to be falsely elevated from infections, rheumatologic disorders or obesity.

PAYMENT FOR THE PLAC TEST

- Medicare currently reimburses \$47.77* for the PLAC Test when medically necessary.
- CPT Code: 83698.
- Many health plans reimburse for the PLAC Test. However, some insurance companies may deny payment because the test is fairly new.

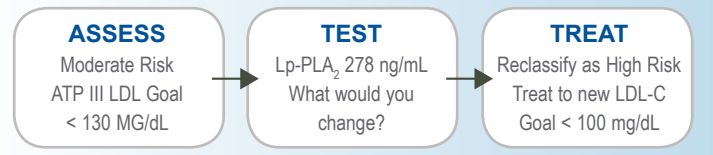
CONSIDER THIS CASE STUDY



Miranda
Age 45

Clinical Information

- Smoker
- Total Cholesterol 200 mg/dL
- HDL Cholesterol 49 mg/dL
- Systolic BP 138 mm/Hg
- On blood pressure medications
- Family history of premature CVD
- LDL 121 mg/dL
- BMI 31 kg/m², waist 40 in.
- Triglycerides 150 mg/dL
- Fasting Blood Glucose 98 mg/dL



References

- Davidson, MH, et al. *Am J Card Suppl* 2008
- * In most states, please visit www.plactest.com for a complete list.

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