

Lp-PLA₂ Enzyme Activity Assay (EAA)

Lp-PLA₂, also known as platelet-activating factor acetylhydrolase (PAF-AH), is a phospholipase A2 enzyme produced by inflammatory cells. Lp-PLA₂ is involved in the development of atherosclerosis and serves a specific marker of cardiac disease. Studies found that Lp-PLA₂ levels were positively correlated with increased risk of developing coronary disease, stroke, and mortality. Lp-PLA₂ Activity Assay is an enzymatic assay. Lp-PLA₂ in a sample hydrolyzes the acetyl group at the sn-2 position of phospholipids, 1-myristoyl-2-(4-nitrophenylsuccinyl)-sn-glycero-3-phosphocholine (MNP) to generate 4-nitrophenyl group, a colorful product, which can be monitored spectrophotometrically at 405-415 nm.

SJK Product Improvements over Existing Lp-PLA₂ Reagents

Improvements	Benefits
SJK Global made a break-through in bulk production of key raw materials	SJK can offer Lp-PLA ₂ EAA substrate at a significantly reduced cost
Assay may be used with auto-analyzer instruments	Savings in processing costs over microplate assays
Lp-PLA ₂ EAA produces results in Units/L	Recommended by MML over existing Lp-PLA ₂ immunoassays

Mayo Clinic Endorsement of Lp-PLA₂ activity assay over concentration assays:

"Mayo Medical Laboratories (MML) offers the recently Food and Drug Administration (FDA)-cleared test PLACA / Lipoprotein-Associated Phospholipase A2 Activity, Serum. This test is for Lp-PLA2 activity and should not be confused with the Lp-PLA2 concentration assay (immunoassay) that has several known limitations including significant reagent lot variation and specimen instability. The results could be up to 50 percent falsely elevated simply because the specimen was not tested immediately. Therefore, MML decided not to perform the concentration assay."

Use of Lp-PLA₂ Testing in Life Insurance Underwriting

In 2011 Lp-PLA₂ assay was described in a Society of Actuaries' Committee publication, they found that an individual with elevated serum Lp-PLA₂ level, "is twice as likely to suffer ischemic stroke as similar individuals without such elevation." They also stated that "Lp-PLA₂ was found to be significantly related to incident cardiovascular disease and cardiovascular death but not to non-cardiovascular deaths." Finally they concluded that "with the estimated cost of \$25, this test would be considered cost-justified for [policy] amounts beginning at \$100,000, depending on the age and gender of the applicant."

Source:

Kelvin, A., Rudolph, K., "New Medical Markers in Life Insurance Underwriting", Society of Actuaries, December 30, 2011