



LABORATORY UPDATE

July 8th, 2015

The New PLAC test for Lp-PLA₂ Activity

Effective Monday, July 13th 2015, Enzo Clinical Labs, Inc. will be introducing the new FDA-cleared PLAC enzyme activity test by diaDexus, Inc.⁽¹⁾ This test will provide a more meaningful measurement of calcium-independent phospholipase A2 activity and its role in the formation of atherosclerotic plaques in coronary heart disease.

We will no longer offer the original PLAC ELISA test that simply determines the *mass* or *amount* of Lp-PLA₂ enzyme in the blood. Rather, the new and improved PLAC test measures the actual Lp-PLA₂ enzyme *activity*. It is a unique enzymatic lipoprotein-associated phospholipase A assay, with vascular specificity, demonstrating value in the detection and monitoring of cardiovascular risk in patients with no history of cardiovascular disease.

	<i>NEW</i>	<i>OLD</i>
	<i>PLAC Lp-PLA₂ Activity Test</i>	<i>PLAC Lp-PLA₂ Mass Test</i>
<i>Enzo Test Code</i>	6279 (remains the same)	6279 (remains the same)
<i>Test Name</i>	PLAC Test for Lp-PLA₂ Activity	PLAC Test for Lp-PLA ₂ Mass
<i>Specimen Collection</i>	Serum: SST or Red Top	Serum: SST or Red Top
<i>Specimen Integrity</i>	If hemolyzed, discard specimen and redraw	If hemolyzed, discard specimen and redraw
<i>Turn Around Time</i>	< 24 hours	< 24 hours
<i>Reference Range</i>	Reduced risk: < 225 nmol/min/ml Increased risk: ≥ 225 nmol/min/ml	Desirable < 200 ng/ml Borderline 200-235 ng/ml High > 235 ng/ml

We appreciate the continued opportunity to serve you and your patients and welcome any questions or concerns you may have. You can reach us at (631)755-5500 or speak with your Enzo Clinical Labs sales or service representative for more information.

Sincerely,

Dieter Schapfel, MD
Medical Director

1. PLAC Test for Lp-PLA₂ Activity Enzyme Assay for the Quantitative Determination of Lp-PLA₂ Activity. http://www.accessdata.fda.gov/cdrh_docs/pdf14/K141575.pdf.