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Document Contact: *Colette Kessler: Mgr Laboratory*
Area: *Laboratory-Chemistry*
Key Words:
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PLAC® Activity on Abbott Architect - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The PLAC® Test for Lp-PLA2 (lipoprotein-associated phospholipase A2) Activity is an enzyme assay used for the *in vitro* determination of Lp-PLA2 activity in serum. Lp-PLA2 in serum hydrolyzes the sn-2 position of the substrate, 1-myristoyl-2-(4-nitrophenlysuccinyl) phosphatidylcholine, producing a colored reaction product, 4-nitrophenol. The rate of formation is calculated from the rate of change in absorbance and is proportional to the Lp-PLA2 activity in nmol/min/mL.

II. CLINICAL SIGNIFICANCE:

Lp-PLA2 activity is 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.

III. SPECIMEN COLLECTION AND HANDLING:

A. Fasting is not required.
B. Serum collected with or without gel is acceptable
C. Un-centrifuged specimens are stable 4 hours at 20-22°C or up to 30 hours at 2-8°C
D. Centrifuged samples stable:
    1. 24 hours at 20-26°C
    2. 2 weeks at 2-8°C
    3. 18 months at -20°C
    4. 2 years at -70°C
E. Samples can be frozen and thawed up to 5 times

IV. REAGENTS:

Reagents are provided ready to use. Reagents are stable up to 4 weeks once opened. Assay uses R1 (buffer) and R2 (substrate) reagents. Reagents are not bar-coded and must be placed in User defined spots for testing. Ensure that reagents do not contain bubbles before placing on the instrument.

V. CALIBRATION:

The assay is calibrated using a 5-point calibration curve. The Lot specific Calibrator values are provided with each lot number. The calibration is stable for 4 weeks. Recalibrate as necessary up to the expiration date of the opened reagent if controls fall outside of the acceptable range.

A. Reconstitute each vial with 1.0 mL deionized water.

B. Cap and leave at room temperature for 5 minutes. Mix gently by inverting and swirling to thoroughly dissolve the contents. Calibrators should be well mixed before testing.

C. After reconstitution calibrators are stable for 4 weeks when stored at 2-8°C.

D. 200µL of each calibrator is required per calibration.

E. Calibration is required with each new lot of reagent and every 4 weeks for kits of the same lot number.

VI. QUALITY CONTROL (QC):

Two levels of controls are tested each day.

A. Reconstitute each vial with 2.0 mL deionized water.

B. Allow to stand at room temperature for 5 minutes and mix gently by swirling until throughly dissolved. Controls should be well mixed before testing.

C. After reconstitution, the controls are stable for 4 weeks when stored at 2-8°C.

D. Pipette 200µL of each manufacturer control to position programed on the Architect.

VII. SPECIAL SAFETY PRECAUTIONS:

Follow Universal Precautions when handling specimens and quality control materials.

VIII. PROCEDURE:

A. PLAC® Activity testing is performed on the Architect Chemistry Analyzer using user defined settings. System must be in ADMIN to open a new lot of reagent.

B. Select System at the top of the screen, Configuration, Assay Categories.

C. Select Reagent Settings, PLAC, F-6 Configure.

D. The Configure reagent window displays.

E. Select the New Lot option under lot number. Enter the Lot Number, expiration and Serial Number. (Note: The serial number is required. Enter the date you load the reagent on the analyzer.)

F. Define the cartridge sizes for both R1 and R2. Select Done.

G. Select the Reagents button at the top of the screen. Select F-6 Assign Location. Highlight the reagent and select the location. Select Done.

H. Packs of the same lot can be replaced in the same location as the onboard pack by selecting Reagents, Highlighting the Reagent Pack and Selecting F-8 Reset.

I. Samples should be well mixed before testing. Testing is performed on Tuesday and Friday 6:30 to 15:00.

IX. CALCULATIONS AND INTERPRETATIONS:

Completed results will automatically upload to Instrument Manager. Results needing operator attention will remain in Held Status in Instrument Manager for further investigation.

X. EXPECTED VALUES:

< 225 nmol/min/mL

XI. REPORTABLE RANGE:

10-382 nmol/min/mL. Samples may not be diluted for testing.

XII. INTERFERING SUBSTANCES:

Hemolyzed samples are not acceptable.

XIII. REFERENCES:

diaDexus PLAC® Test for Lp-PLA² Activity IFU

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	3/2/2022
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr Laboratory [RC]	3/1/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	3/1/2022
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	3/1/2022
Lab Chemistry Best Practice Committee	Elizabeth Sykes: System Med Dir, Chemistry	2/28/2022
	Colette Kessler: Mgr Laboratory [RC]	2/28/2022

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