Beaumont HEALTH

Beaumont Laboratory
Clinical Pathology
Royal Oak

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Supersedes:

PLAC® Activity on Abbott Architect

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Principle

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.

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.

Specimen Collection and Handling

Fasting is not required.

- Serum collected with or without gel is acceptable
- Un-centrifuged specimens are stable 4 hours at 20-22℃ or up to 30 hours at 2-8℃
- Centrifuged samples stable:
  -24 hours at 20-26℃
  -2 weeks at 2-8℃
  -18 months at -20℃
  -2 years at -70℃
- Samples can be frozen and thawed up to 5 times

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 barcoded and must be placed in User defined spots for testing. Ensure that reagents do not contain bubbles before placing on the instrument.

Calibration

The assay is calibrated using a 5-point calibration curve. The calibration is stable for 4 weeks. Calibrators are packaged with each reagent lot ready to use and **may not** be interchanged between different kit lots. Recalibrate as necessary up to the expiration date of the opened reagent if controls fall outside of the acceptable range. Calibrators should be well mixed before testing. 200µL of each calibrator is required per calibration. Calibration is required with each new lot of reagent.

Quality Control

2 levels of controls are tested each day. Controls packaged with the reagent are lot specific and **may not** be interchanged between different kit lots. In house control pools are available frozen for testing. Controls should be well mixed before testing. Pipette 200µL of each manufacturer control to position programed on the Architect. The in house control pools are tested with each new lot of reagent and as needed to supplement limited control supplied by the manufacturer. In house controls will be tested as patients and compared for acceptability with the posted ranges for each pool.

Special Safety Precautions

Follow Universal Precautions when handling specimens and quality control materials.

Procedure

1. 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.
2. Select System at the top of the screen, Configuration, Assay Categories.
3. Select Reagent Settings, PLAC, F-6 Configure.
4. The Configure reagent window displays.
5. Select the New Lot option under lot number. Enter the Lot Number, expiration and Serial Number. (Note: the serial number is required but can be any number)
6. Define the cartridge sizes for both R1 and R2. Select Done.
7. Select the Reagents button at the top of the screen. Select F-6 Assign Location. Highlight the reagent and select the location. Select Done.
8. 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.
9. Samples should be well mixed before testing. Testing is performed on Tuesday and Friday 6:30 to 15:00.

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.

Expected Values

< 225 nmol/min/mL

Reportable Range

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

Interfering Substances

Hemolyzed samples are not acceptable.

References

diaDexus PLAC® Test for Lp-PLA² Activity IFU

Authorized Reviewers

Section Medical or Technical Director

Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S: /AutoChem/DocCont/CSL/ARC
Master printed document stored in the Abbott Architect Chemistry Procedure Manual Core Lab
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 0
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Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
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