

PLAC[®] Test Reagent Kit

Abbott ARCHITECT Chemistry Analyzer Application Sheet



This procedure is to be used in conjunction with the package insert for the PLAC Test Reagent Kit. Read and follow the package insert instructions and the Specimen Handling Best Practices carefully. Failure to follow the instructions may result in inaccurate results. Reagent barcode labels are not provided. For ordering information, contact Customer Service at 1-877-752-2837 or visit www.plactest.com. For further information, see the analyzer operator's manual.

PROCEDURE:

1. Program a user defined test with the parameters listed below. For more detailed instructions refer to the Abbott User Instructions.
2. Transfer Auto PLAC reagents into appropriate Abbott reagent bottles.
3. Load the reagent bottles as described in the User Operating Instructions.
4. Calibrate with PLAC calibrator set (**REF** 90108 or **REF** 10-0108).

NOTE:

- Do not report samples with results greater than 360 ng/mL.
- Do not dilute and retest.
- See PLAC Test turbidimetric immunoassay method package insert for further information. Refer to the sections: *Warnings & Precautions, Procedural Notes and Limitations.*

USER DEFINED PARAMETERS:

Test Name: PLAC	
Reaction Type: Photometric	No. of Calibrators: 5
Units: ng/mL	Calibrator #1: 0.0
Decimal Precision: X.X	#2: 50.0
Reaction Direction: End Up	#3: 100.0
Calculation Factor: 0.0	#4: 250.0
Math Model: Spline	#5: 500.0
Correlation Factor: 1.0	#6: --
Intercept: 0.0	Replicates: 2
Primary Wavelength: 572 nm	Water Blank: Not used
Reagents: R1 Vol. 185 µL	Secondary Wavelength: None
R2 Vol. 60 µL	
Sample Volume: 6 µL	
Reagent Blank:	Reaction:
Start Read: 19	Start Read: 32
End Read: 20	End Read: 33
Error Detection Limits: --	Reaction: Low ABS Limit: 0.0
Reagent Blank: Low ABS Limit: -0.1	High ABS Limit: 2.0
High ABS Limit: 2.0	Expected cal factor: 0.0
Usable Range: Lower Limit: 0	Expected cal factor tolerance %: 0.0
	Upper Limit: 500

PERFORMANCE CHARACTERISTICS

Performance characteristics were established using the Architect.

On-Board Analyzer Reagent Storage

Open bottles of reagents stored in the refrigerated compartment on the Abbott ARCHITECT analyzer should be stable for up to 2 weeks. Laboratories should verify on-board reagent stability on their own analyzers, under typical laboratory conditions.

Sensitivity

The clinical sensitivity of the assay is 9.8 ng/mL as determined by the limit of quantitation (the lowest concentration with acceptable precision).

The analytical sensitivity of the assay is 2.4 ng/mL, as calculated by interpolation of the mean plus two standard deviations of 20 replicates of the 0 ng/mL Lp-PLA₂ calibrator from the standard curve.

Assay Precision

Intra-assay and inter-assay variability were determined by testing two human serum samples with Lp-PLA₂ concentrations distributed throughout the calibration range of the assay. The data are summarized below:

Sample	Intra-assay		Inter-assay	
	Mean Concentration Lp-PLA ₂ (ng/mL)	% CV (n=20)	Mean Concentration Lp-PLA ₂ (ng/mL)	% CV (n=20)
Low Serum	171	1.3	166	3.6
High Serum	456	0.6	412	4.9

Linearity

From three pairs of serum samples with known high or low Lp-PLA₂ levels, a dilution series was prepared for each pair combination to assess linearity. Percent recoveries of the combined samples were determined as the measured value divided by the expected value, multiplied by 100. The average recovery was 100%, demonstrating linearity of the diluted samples over a range of 80 to 468 ng/mL Lp-PLA₂.

Interfering Substances

Endogenous substances found in blood were evaluated for interference in the assay. Three individual serum samples with Lp-PLA₂ values ranging from 300 to 490 ng/mL were spiked with potential interferents. No appreciable interference was observed for the following substances at the spiked levels tested.

Endogenous	
Potential Interferent	Test Concentration
Bilirubin	20 mg/dL
Cholesterol	500 mg/dL
Triglycerides	3000 mg/dL
Total Albumin*	~9000 mg/dL
* 5 g/dL albumin added to plasma pool of presumptively 4 g/dL albumin	

Method Comparison

Correlation studies were performed comparing the PLAC Test turbidimetric immunoassay to the values established on the Hitachi 917 and Olympus AU-400. Human serum samples with Lp-PLA₂ concentrations ranging from 117 to 481 ng/mL were tested. Results from linear regression analysis are shown below.

Linear Regression

Slope = 1.03

y-intercept = 18.9

Correlation coefficient r = 0.99

Number of samples = 30