

PLAC[®] Test Reagent Kit

Olympus AU-400, AU-640, and AU-2700
Clinical Chemistry Analyzers 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. 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 analyzer operating instructions.
2. Load the reagent bottles as described in the analyzer operating instructions.
3. 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:

SPECIFIC TEST PARAMETERS			
Test Name	[]		Type [Serum] Operation [Yes]
Sample vol.	[6.0] μ L	Diluents vol. [0] μ L	Pre-Dilution Rate [1]
R1 vol.	[185] μ L	Diluents vol. [0] μ L	Min OD Max OD
R2 vol.	[60] μ L	Diluents vol. [0] μ L	L [-2.0000] H [2.5000]
			Reagent OD Limit
			FST.L [-2.0000] FST.H [2.5000]
Wave length	Pri. [600] Sec [None]		LST.L [-2.0000] LST.H [2.5000]
Method	[FIXED]		Dynamic Range
Reaction slope	[+]		L [-99999.9] H [99999.9]
Measuring point-1	FST [12] LST [27]		Correlation Factor
Measuring point-2	FST [] LST []		A [1.000000] B [0.000000]
Linearity	[] %		Onboard Stability Period []
NO-LAG-TIME	[]		

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CALIBRATION TEST PARAMETER

Test Name	[]					Type	[Serum]
Calibration type	[5AB]	Formula [Spline]				Counts	[2] Process [CONC]
	Cal No.	OD	Conc.	Factor/OD-L	Factor/OD-H		
Point 1	[1]	[]	[0.0]	[-2.0000]	[2.5000]		
Point 2	[2]	[]	[50.0]	[-2.0000]	[2.5000]		
Point 3	[3]	[]	[100.0]	[-2.0000]	[2.5000]		
Point 4	[4]	[]	[250.0]	[-2.0000]	[2.5000]		
Point 5	[5]	[]	[500.0]	[-2.0000]	[2.5000]		
Point 6	[]	[]	[]	[]	[]		
Point 7	[]	[]	[]	[]	[]		

RE-RUN PARAMETER

Test Name	[]					Type	[Serum]
Diluted		Normal					
	Sample vol.	[2.0]	μL		Sample vol.	[6.0]	μL
	Diluents vol.	[0]	μL		Diluents vol.	[0]	μL
	Pre-Dilution Rate	[1]			Pre-Dilution Rate	[1]	
Condense							
	Sample vol.	[6.0]	μL				
	Diluents vol.	[0]	μL				
	Pre-Dilution Rate	[1]					
Repeat Decision Level	L	[-99999.9]					
	H	[500.0]					

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PERFORMANCE CHARACTERISTICS

Performance characteristics were established using the Olympus AU-400.

On-Board Analyzer Reagent Storage

Open bottles of reagents stored in the refrigerated compartment on the Olympus 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 8 ng/mL as determined by the limit of quantitation (the lowest concentration with acceptable precision).

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	117	2.5	171	7.5
High Serum	450	1.2	408	6.5

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 97%, demonstrating linearity of the diluted samples over a range of 81 to 502 ng/mL Lp-PLA₂.

Method Comparison

Correlation studies were performed comparing the PLAC Test turbidimetric immunoassay to the values established on the Hitachi 917. Human serum samples with Lp-PLA₂ concentrations ranging from 93 to 377 ng/mL were tested. Results from linear regression analysis are shown below.

Linear Regression

Slope = 0.90

y-intercept = 12.1

Correlation coefficient $r = 0.98$

Number of samples = 55