

PLAC[®] Test Reagent Kit

BioLis 24i (Prestige 24i) 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 BioLis 24i User Instructions.
2. Transfer PLAC Test reagents into the appropriate BioLis 24i reagent cartridge.
3. Load the cartridge 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:

Item Name	PLAC
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DATA INFORMATION	
UNITS	ng/dL
DECIMALS	0

ANALYSIS	
TYPE	END
MainW.Length1	570
SubW.Length2	
METHOD	

CORR.	
Y=	X=
SLOPE	INTER
1.000	0

CALIBRATION			
TYPE	Polynomial		
STANDARD			
#1	0.001	#4	250
#2	50	#5	500
#3	100	#6	

	MALE		FEMALE	
	LOW	HIGH	LOW	HIGH
Serum				
Urine				
Plasma				
CSF				
Dialysis				
Other				

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Item Name

ASPIRATION

KIND Single Double

	VOLUME	
SAMPLE	6	μL
REAGENT 1	185	
REAGENT 2	60	

DATA PROCESS

READ

	START	END
MAIN	52	54
SUB	35	36

ABSORBANCE LIMIT

LOW	0.000
HIGH	3.000

FACTOR

Blank correction	1.0000
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ENDPOINT LIMIT	2
LINEAR CHECK (%)	90

Third Mix OFF ON
R1 Blank Water-B R1-B

Dilution Diluent 99:Di1 100:Di2

MONITOR

0 LEVEL POINT	1
SPAN	3.000

PROZONE CHECK

	START	END	LIMIT (%)
FIRST			
SECOND			
THIRD			

Low High
 Low High

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Item Name

Auto Rerun SW

ON OFF

Auto Rerun Condition (Absorbance)

Absorbance Range

Lower ON OFF

Higher ON OFF

Prozone Range ON OFF

Auto Rerun Range (Result)

ON OFF ON OFF

	Lower	Higher
Serum		
Urine		
Plasma		
CSF		
Dialysis		
Other		

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PERFORMANCE CHARACTERISTICS

Performance characteristics were established using the BioLis 24i chemistry analyzer.

On-Board Analyzer Reagent Storage

Open bottles of reagents stored in the refrigerated compartment on the BioLis 24i 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 5.6 ng/mL as determined by the limit of quantitation (the lowest concentration with acceptable precision).

The analytical sensitivity of the assay is 1.6 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 Sample	144	1.4	146	2.0
High Sample	321	1.2	332	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 99.3%, demonstrating linearity of the diluted samples over a range of 55 to 494 ng/mL Lp-PLA₂.

Interfering Substances

Endogenous substances found in blood were evaluated for interference in the assay. Four individual serum samples with Lp-PLA₂ values ranging from 299 to 460 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
Hemoglobin	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 102 to 442 ng/mL were tested. Results from linear regression analysis are shown below.

Linear Regression

Slope = 1.08

y-intercept = 12.4

Correlation coefficient r = 0.99

Number of samples = 30