CE IVD

Lp-PLA2 Reagent Kit (14-NPC Substrate Method)

Instructions for Use REF CC1093

PRODUCT NAME

Lp-PLA2 Reagent Kit (14-NPC Substrate Method)

PACKAGE SPECIFICATION

R1：1×20mL R2a：1×4.75mL R2b：1×0.25mL
R1：1×40mL R2a：1×9.5mL R2b：1×0.5mL
R1：1×60mL R2a：1×14.25mL R2b：1×0.75mL
R1：2×60mL R2a：2×14.25mL R2b：2×0.75mL
R1：4×60mL R2a：4×14.25mL R2b：4×0.75mL
Calibrator (optional)：1×1mL
Control (optional)：2×1mL

INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of lipoprotein-associated phospholipase 2 (Lp-PLA2) activity in human serum.
Clinically, it is mainly used for the auxiliary diagnosis of cardiovascular and cerebrovascular diseases.
For professional and laboratory use only.

TEST PRINCIPLE

Lipoprotein-associated phospholipase A2 (Lp-PLA2) in human serum or plasma is a calcium-independent phospholipase that hydrolyzes the sn-2 ester bond of the enzyme substrate 1-myristoyl-2-(4-nitrophenylsuccinyl) phosphatidylcholine, generating the colored product 4-nitrophenol. The absorbance (A value) is measured using a biochemical analyzer, where the rate of 4-nitrophenol formation is directly proportional to the enzymatic activity of Lp-PLA2 in the sample. By continuously monitoring the increase in absorbance over time, a calibration curve is established using the A values and Lp-PLA2 calibrators. The enzymatic activity of Lp-PLA2 in the sample is then calculated and expressed in units per liter (U/L).

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	4-(2-Hydroxyethyl)-1-piperazineethanesulfonic acid	100 mmol/L
Reagent 2a	Citric acid buffer	20 mmol/L
Reagent 2b	1-myristoyl-2-(4-nitrophenylsuccinyl) phosphatidylcholine	50 mmol/L
Calibrator(optional)	Lp-PLA2	400-600 U/L
Control(optional)	Lp-PLA2	150-800 U/L

Note: Mix R2a and R2b in a proportion of 19:1 before use. The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. After mixing R2a and R2b, opened reagents are stable for 10 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration date.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Fresh serum is required for analysis;
2. Fasting blood samples should be collected, and serum must be separated promptly separate serum promptly;
3. Avoid hemolysis and lipemia;
4. Serum remains stable at room temperature for 8 hours, at 2-8°C for 7 days, and at -20°C for 60 days, with repeated freeze-thaw cycles to be avoided.

TEST PROCEDURE

1. Test conditions: Different analyzer may require different board parameters.

Primary Wavelength	405 nm	**Sample(s)**	2 μL
Secondary Wavelength	505 nm	**Reagent 1**	200 μL
Calibration Type	Linearity	**Reagent 2ab**	50 μL
Method	Rate method	**Reaction temperature**	37˚C
Calibration Method	Two-point calibration	**Cuvette path**	1 cm
Direction	Upward		

Operational Procedure:
2.Calibration procedure:

	Blank tube（B）	Standard tube(S)	Test tube（T）
Reagent1	240 μL	240 μL	240 μL
Distilled water	2 μL		
Calibrator		2 μL	
Sample			2 μL
Mix well, incubate at 37˚C for 1-5min			
Reagent 2ab	50 μL	50 μL	50 μL
Mix well, incubate at 37˚C for 1min, continuously monitor the change of the absorbance for 2min at the measured wavelength, and calculate △A/min			

3. A calibrator from Getein is recommended.
4. Quality control procedure:
   A control from Getein is recommended. Its measured value should be within the range of its label claim.
   If the results appear to be out of range, the following steps can be taken to determine the cause:
   4.1 Check that the parameter settings and light source are correct.
   4.2 Check that the colorimetric beaker and the pipette needle are clean.
   4.3 Check that the water is not contaminated; bacterial growth can cause erroneous results.
   4.4 Check the reaction temperature.

4.5 Check the expiration date of the kit.

5. Result calculation

Lp-PLA2 activity（U/L）= Lp-PLA2 Calibrator concentration × $\triangle A_{test} / \triangle A_{Calibrator}$

REFERENCE RANGE

Lp-PLA2 was detected in 196 healthy people, and the normal reference value was <670 U/L (95th percentile) It is recommended that each laboratory establish its own reference range based on the region and population.

RESULT INTERPRETATION

The test results only reflect the state at the time of sampling, and clinicians need to make relevant judgments based on other clinical test indicators. If the authenticity of the test results cannot be determined, the sample should be remeasured directly or diluted and retested, and if necessary, it can be retested by other methods.

LIMITATIONS

There is no interference with the measurement when hemoglobin ≤ 1000 mg/dL, chyle ≤ 0.3% .

PERFORMANCE CHARACTERISTICS

1. Appearance
   In the kit, Reagent 1 is a colorless or yellowish clear liquid, Reagent 2a is a colorless or yellowish clear liquid, Reagent 2b is a yellowish clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blank absorbance
   Reagent blank absorbance A_{405nm} ≤ 1.000.
3. Accuracy
   Use the comparison method to calculate the correlation coefficient (r), r is not less than 0.975. The relative deviation of each concentration point should not be greater than ± 15%.
4. Linear range
   4.1 Linear correlation coefficient
   Linear correlation coefficient (r) should be ≥ 0.990 in the range of [50, 1500] U/L.
   4.2 Linear deviation
   Within the range of [50, 200] U/L, the linear absolute deviation should not exceed ± 25 U/L;
   Within the range of (200, 1500] U/L, the linear relative deviation should not exceed ± 10%.
5. Analytical sensitivity
   When testing sample,concentration of (100 ± 10) U/L , the absorbance difference should between 0.0200-0.4000.
6. Precision
   6.1 Repeatability
   The coefficient of variation (CV) should not exceed 5.0%.
   6.2 Between-run precision
   Between-run precision should not be greater than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnostic use only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
2. Precautions for operation
   2.1 Treat the samples as dangerous materials that may cause infection with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Hemolysis should be avoided during the operation procedure.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Avoid using the reagent if it displays any signs of turbidity.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the calibration result.
   5.5 Please do not mix reagents in different batches.

REFERENCE

1.Orem C , Kahraman N , Orem A ,et al.Increased plasma lipoprotein-associated phospholipase A2 (Lp-PLA2) levels are related to good collateral development in patients with isolated left coronary artery disease[J].International Journal of Cardiology, 2011, 148(1):117-119.DOI:10.1016/j.ijcard.2011.01.051.

2.None.Lipoprotein-Associated Phospholipase A2 as an Independent Predictor of Coronary Heart Disease. Packard CJ, O'Reilly DSJ, Caslake MJ, et al. N Engl J Med 2000;343:1148–55[J]. 2001, 10(2):20-21.DOI:10.1016/s1062-1458(01)00
160-x.

3.Tsimikas, et al. "Lipoprotein-associated phospholipase A2 activity, ferritin levels, metabolic syndrome, and 10-year cardiovascular and non-cardiovascular mortality: results from the Bruneck study." European heart journal 30.1(2009):107-15.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Lp-PLA2 Reagent Kit (14-NPC Substrate Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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