This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Notification No.13A2X00197218068

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This package insert must be read carefully prior to use.

Lactate dehydrogenase assay kit
(Classification No.: 38504000)

Pureauto S LD-P

General Precautions

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
4. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
5. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
6. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients

LD-P Coenzyme Solution 1:
Nicotinamide adenine dinucleotide (reduced form)
2-Amino-2-hydroxymethyl-1,3-propanediol buffer

LD-P Substrate Solution 2:
Sodium pyruvate
2-Amino-2-hydroxymethyl-1,3-propanediol buffer

Intended Use

Measurement of lactate dehydrogenase in serum or plasma

Lactate dehydrogenase catalyzes hydrogen transfer reactions between lactic acid and pyruvic acid. It is widely distributed in all tissues of the body.
Since the blood level of lactate dehydrogenase is increased in various diseases of heart, liver, and kidneys, as well as various solid tumors, leukemia, and pernicious anemia, it plays an important role in the diagnosis and follow-up of these diseases.

Assay Principle

1. Assay Principle

Lactate dehydrogenase (LD) converts pyruvic acid to lactic acid. The reaction also converts NADH to NAD, and its absorbance at 340 nm decreases. LD activity is determined by measuring the percent change in absorbance.

$$\text{Pyruvic acid} + \text{NADH} \xrightarrow{\text{LD}} \text{Lactic acid} + \text{NAD}$$

2. Features

1) This reagent is based on the method recommended by the French Society of Clinical Biology (SFBC) and has been modified so that it is compatible with automated analyzers.
2) Wide assay range.
3) Liquid reagents, ready-to-use.
4) Applicable to various automated analyzers.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Serum and plasma may be used.
2) Storage of samples
If the isolated serum or plasma sample cannot be tested on the same day, specimens should be stored as follows.
Room temperature: for tests within 1 week
Please note that activity of samples may decrease when refrigerated or frozen.

2. Interfering substances

1) Assay results are not affected by free bilirubin (up to 20 mg/dL) or conjugated bilirubin (up to 20 mg/dL).
2) Because LD is contained in blood cells, hemolyzed samples show artifactual elevation of the LD level.

3. Others

1) Compatible with the JSCC Standards
Use Enzyme Calibrator Plus "Daiichi" (manufactured by SEKISUI MEDICAL CO., LTD.) as the calibration material.
2) Compatible with the SFBC Standards
For calibration, use the factor specified for each model by SEKISUI MEDICAL CO., LTD.
3) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

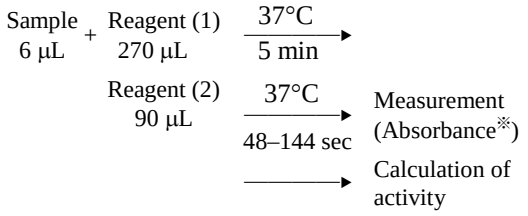
Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent (1): LD-P Coenzyme Solution 1 is ready to use.
Reagent (2): LD-P Substrate Solution 2 is ready to use.

2. Assay Procedure

This product is compatible with various types of automated analyzer. An example of the assay procedure is indicated below.



※ Absorbance: The difference in absorbance between 405 nm and 340 nm
Calibration material: Enzyme Calibrator Plus "Daiichi" (Manufacture's assigned value) or the factor
Reagent blank: Purified water or saline

Assessment of Assay Results **

1. Reference standard range
(Compatible with the JSCC Standards) 124–222 U/L[4)]
(Compatible with the SFBC Standards) 233–497 U/L[5)]

2. There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance *

1. Sensitivity
1) Reagent blank: change in absorbance being equal to or lower than 0.010/min
2) Sensitivity: The change of absorbance is 0.017–0.025/min per 200 U/L of LD activity.

2. Accuracy:90–110% of the expected assay value.

3. Within-run reproducibility:
Coefficient of variation ≤ 3%
(Test methods used for 1. –3. are in-house methods.)

4. Measurement Range[5)]: (On Hitachi 7070 automated analyzer)
8–2500 U/L

5. Correlation [5)]
1) Serum N=122 r=0.999 y=1.07x–5.6
Control method: Approved in vitro diagnostic (enzyme activity measuring assay)
2) Plasma N=70 r=0.999 y=1.09x–5.5
Control method: Approved in vitro diagnostic (enzyme activity measuring assay)

6. Standard Material
Enzyme Calibrator Plus, the calibration material used for this product, is in line with the Japanese Standard for Certified Enzyme Reference Materials.

Precautions for Use or Handling **

1. Precautions for Handling (to Ensure Safety)
1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
2) Proclin 300, which possesses skin-irritative potential, is added as an antiseptic agent in the LD-P Coenzyme Solution 1 and LD-P Substrate Solution 2. Therefore, if the reagent comes in contact with skin or clothes, rinse immediately with ample water, and consult the doctor if skin irritation develops.

2. Precautions for use
1) This product should be stored as directed, avoid freezing. Freezing can cause deterioration of the reagents, leading to inaccurate results. Therefore, do not use the product if it has been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not replenish the reagents.
4) Do not perform the assay under direct sunlight.

3. Precautions for Disposal
1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.

4. Other precautions
Do not use the containers for other purposes.

Storage and Shelf Life **

1. Storage temperature: 2–10°C
2. Shelf life: 1 year from the date of manufacture
(The expiration date is printed on the outer package.)

Packaging

Name			Package
Pureauto S LD-P	(1)	LD-P Coenzyme Solution 1	4 × 100 mL
	(2)	LD-P Substrate Solution 2	2 × 100 mL

Constituent reagents are available in other configurations. For further details please contact SEKISUI MEDICAL CO., LTD.

References **

1) Kanai M. (editor): Kanai's manual of clinical laboratory medicin e. 32nd ed. 615, Kanehara Shuppan, 2005.
2) Y. ARTUR et al.: Ann Biol Clin, 40, 160, 1982.
3) Sasaki M. et al.: Sampling of constituents of the human body, 217, Kodansha, 1972.
4) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 581, Kanehara Shuppan, 2015.
5) In house data, SEKISUI MEDICAL CO., LTD.

Contact

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