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

In Vitro Diagnostics
Marketing Notification No. 13A2X00197218098

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This package insert must be read carefully prior to use.

Lactate dehydrogenase assay kit
(Classification No.: 38504000)

QUALIGENT LD

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 Substrate Solution 1:
L-Lithium lactate
Diethanolamine buffer
LD Coenzyme Solution 2:
Nicotinamide adenine dinucleotide (oxidized form)

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 the heart, liver, and kidneys, as well as various solid malignancies, leukemia, and pernicious anemia, it plays an important role in the diagnosis and follow-up of these diseases.

Assay Principle **

1. Assay Principle

In samples, Lactate dehydrogenase (LD) catalyzes conversion of lactic acid to pyruvic acid in a diethanolamine buffer. The reaction also converts NAD to NADH, and its absorbance at 340 nm increases. LD activity is determined by measuring the velocity of NADH production.

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

2. Features

Final concentration of the principal ingredient matches with the final concentration stipulated in the JSCC Recommendation for Enzyme Activities.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Serum and plasma (heparin plasma and citrated 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[4].
Room temperature: for tests within 1 week
Please note that activity of samples may decrease when refrigerated or frozen.

2. Interfering substances

Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), formazin turbidity (up to 3000 FTU), or ascorbic acid (up to 50 mg/dL).Because LD is contained in blood cells, hemolyzed samples show artifactual elevation of the LD level.

3. Others

1) Always use Enzyme Calibrator Plus “Daiichi” for calibration.
2) Precautions for assay range
If the activity 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 Substrate Solution 1 is ready to use.
Reagent (2): LD Coenzyme Solution 2 is ready to use.

2. Assay Procedure

This product is compatible with Hitachi 9000 series and LABOSPECT series automated analyzers. An example of the assay procedure is indicated below.

Sample 4.0 μL + Reagent (1) 100 μL → (37°C, 5 min) → Reagent (2) 50 μL → (37°C, 41–162 sec) → Measurement (Absorbance ※) → Calculation of activity

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

Assessment of Assay Results **

1. Reference standard range [5)]
124–222 U/L

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 0.005/min
2) Sensitivity: The change in absorbance is 0.029–0.035/min per 200 U/L of LD activity.

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

3. Within-run Reproducibility:
Coefficient of variation ≤ 5%
(Test methods used for 1. –3. are in-house methods.)

4. Measurement Range[7)]: (On a Hitachi 9000 series automated analyzer)
5–750 U/L

5. Correlation [7)]
1) Serum N=70 r=0.999 $y=1.00_x+1.1$
Control method: using an already approved in vitro diagnostic product with method in line with the JSCC Recommendation for Enzyme Activities.
2) Plasma N=66 r=0.999 $y=1.00_x+4.6$
Control method: using an already approved in vitro diagnostic product with method in line with the JSCC Recommendation for Enzyme Activities.

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) Sodium azide is added as an antiseptic agent in the LD Coenzyme Solution 2. Therefore, if the reagent comes in accidentally contact with eyes, mouth or skin, rinse immediately with ample water as first aid, and consult the doctor if required.

2. Precautions for use
1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) 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.
5) Sodium azide has been added as an antisepticagent in the LD Coenzyme Solution 2. It can react with lead or copper pipes to produce the highly explosive metal azide. Therefore, the reagent should be flushed with large amounts of water during disposal.

4. Other precautions
1) Do not use the containers for other purposes.
2) Do not take apart the reagent cartridge before use.

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		
QUALIGENT LD	Set (Cassette for Hitachi 9000 series)	LD Substrate Solution 1 1×15.0 mL	×2
		LD Coenzyme Solution 2 1 × 7.5 mL	
	L set (Set for Hitachi LABOSPECT series)	LD Substrate Solution 1 1 × 40 mL	×2
		LD Coenzyme Solution 2 1 × 20 mL	

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

References **

1) Japan Society of Clinical Chemistry: Jpn J Clin Chem, 19, 228, 1990.
2) Japan Society of Clinical Chemistry: Jpn J Clin Chem, 19, 232, 1990.
3) Osawa S.: Med Tech, 20, 1022, 1992.
4) Sasaki M. et al.: Sampling of constituents of the human body, 217, Kodansha, 1972.
5) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 581, Kanehara Shuppan, 2015.

6) Japan Society of Clinical Chemistry: Jpn J Clin Chem, 25, 135, 1996.
7) In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer **

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