

Plasma/Serum test for lactate dehydrogenase

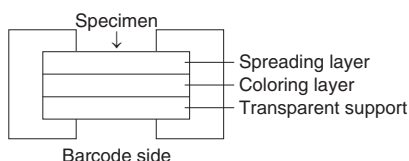
FUJI DRI-CHEM SLIDE LDH-PIII

[Warnings and precautions]

- Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
- Do not touch either the center part of the surface or the back of the slide.
- A new slide must be used for each measurement. Do not reuse.
- Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
- Used slides are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, melting, sterilization or disinfection.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

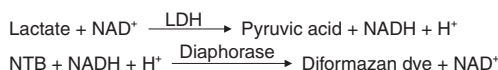
• L-Lithium lactate	0.16 mg (1.7 μmol)
• NAD ⁺	0.037 mg (0.055 μmol)
• Nitroterazolium blue	0.12 mg (0.15 μmol)
• Diaphorase	0.12 U

[Intended use]

Quantitative measurement of lactate dehydrogenase activity in plasma or serum. For *in vitro* diagnostic use only.

[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE LDH-PIII. After depositing, the specimen spreads uniformly on the spreading layer and diffuses into the underlying coloring layer. As the process proceeds, large molecular components such as proteins or dye components are filtrated, and only small molecular components are able to permeate and diffuse into the coloring layer. The LDH catalyses the reaction of lactic acid salt with nicotinamide adenine dinucleotide (NAD⁺) while spreading uniformly in the spreading layer. The formed reduction type coenzyme (NADH) reduces nitroterazolium blue (NTB) by the catalytic reaction of diaphorase to form a diformazan dye (purple). The increase of absorbance by the generated dye is measured from 1 min to 2 min at 540 nm by reflective spectrophotometry and the LDH activity is calculated according to the installed formula.



[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER
 Other implements: FUJI DRI-CHEM QC CARD (attached)
 : FUJI CLEAN TIPS or FUJI AUTO TIPS
 : FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

[Specimen requirements]

- After collecting the blood sample, immediate measurement is recommended.
- For plasma, heparin can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
- Avoid using plasma or serum with precipitate such as fibrin.
- Do not use hemolytic plasma or serum.
- When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Procedure]

- Read in the new QC-card when you switch to a new box of slides.
- Set slides on FUJI DRI-CHEM ANALYZER.
- Set a sample tube in the specified sample rack.
- Input a sequence No. and a sample ID if appropriate.
- Press the "START" key to initiate testing.
 For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

106–211 U/L (JSCC* standard method, 37 °C) (1.77–3.52 μkat/L)

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals. The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

*JSCC: Japan Society of Clinical Chemistry

[Performance characteristics]

1. **Dynamic range** 50–900 U/L (0.84–15.03 μkat/L)

2. Accuracy

Concentration range	Accuracy
50–100 U/L	Within ± 20 U/L
100–900 U/L	Within ± 20 %

3. Precision

Concentration range	Precision
50–100 U/L	SD ≤ 5 U/L
100–900 U/L	CV ≤ 5 %

4. Correlation

Correlation was evaluated between JSCC standard method, 37 °C and FUJI DRI-CHEM system. JSCC standard method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

	n	Slope	Intercept	Correlation coefficient
Serum	62	1.029	-5.41	0.995

5. Known interfering substances

- (1) Dobutamine hydrochloride (cardiotonic reagent) and dopamine hydrochloride (cardiotonic reagent) give plus bias.
- (2) Lower protein concentration gives plus bias.
- (3) The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	0.57 mmol/L
Bilirubin	170 μmol/L

These results are representative;

- Test condition may have some influence on your results.
- Interferences from other substances are not predictable.

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause.
 For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

LDH...JCCLS (ERM)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

JCCLS: Japanese Committee for Clinical Laboratory Standards

[Storage and shelf life]

1. Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
2. Expiry date is printed on the carton.
3. Use immediately after opening the individual package.

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<http://www.fujifilm.com/products/medical/>

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