Bioway Chemistry Reagent Series

The Serum LDH Reagent Kit

Detection of Lactate Dehydrogenase in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R041K11 ***The Serum LDH Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

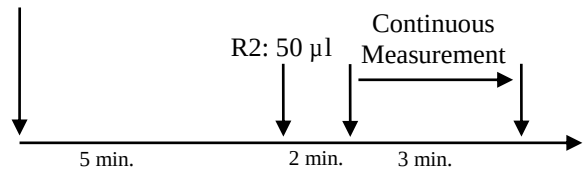

Table 1: Instrument Parameters*

F factor	8199	Slope of reaction	Increase
Testing wavelength	Dλ : 340 nm Sλ : 405 nm	Sample volume	6 µl
Test method	Rate Method	R1 volume	250 µl
Reaction temperature	37℃	R2 volume	50 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **LDH Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Lactate Dehydrogenase in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Lactate Dehydrogenase is a cytoplasmic enzyme distributed widely in human bodies, especially concentrated in heart, liver, kidney, and skeleton muscle. Damage to these tissues results in increased serum concentration of LDH. Elevated LDH level may indicate destructive renal disease, progressive muscular dystrophy, megaloblastic anaemia, liver cirrhosis, hepatitis, hepatic metastasis, hepatoma and pulmonary embolism.

TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the LDH activity (U/L) in human serum or plasma.

$$\text{L-Lactate} + NAD^+ \xrightarrow[pH\ 8.9]{LDH} \text{Pyruvate} + NADH + H^+$$

Lactate dehydrogenase catalyzed the transforming of L-Lactate to pyruvate and the reaction reduces NAD to NADH. The activity of LDH can be measured proportional as an increased in absorbance at 340 nm.

MATERIALS PROVIDED

Reagents:

R1	Tris buffer, pH8.9 L-Lactate Potassium chloride	100 mmol/L 100 mmol/L 190 mmol/L
R2	Tris buffer, pH8.9 NAD	100 mmol/L 8.5 mmol/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. LDH control and calibrator set (commercially available)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. The reagent is stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum and use ultra-centrifuge to remove the platelets in the sample.
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at room temperature for 7 days.

TEST PROCEDURE (see Figure 1)

Reagent 1 and 2 are liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using commercially available calibrator set for optimal results.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 6 µl of sample and 250 µl of R1; mix well and incubate at 37℃ for 5 minutes.
2. Add 50µl of R2; mix well and incubate at 37℃ for 2 minutes.
3. Take continuous optical density measurement for 3 minutes.
4. Calculate average Δ A /min

RESULT

The LDH activity in U/L can be obtained by the following calculation:

$$\text{LDH (U/L)} = (\Delta A_{test}/\text{min} - \Delta A_{blank}/\text{min}) \times \text{factor (F)}$$

The calculation factor for UV spectrophotometer is 8199 when the optical path is 10 mm. It is recommended for each laboratory to establish its own F factor. Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

109-245U/L
It is recommended for each laboratory to establish its own expected values.

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QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Oxalic acid and fluorides should not be added in the sample for avoiding hemolysis because they can inhibit the activity of LDH.
4. Including but not limited to the following drugs may elevated the test result of LDH:

   allopurinol, amiodarone, androgens, anabolic hormones, aspirin, salicylic acid, captopril, Carbamazepine, chlorpromazine, cisplatin, clozapine, coumarin, dacarbazine, erythromycin, naproxen, papaverine, penicillamine, perhexiline, phenytoin, phenylbutazone, propylthiouracil, ranitidine, sulfasalazine, imatinib acid, valproic acid ,verapamil.
5. Samples with LDH exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 - 1000 U/L (R≥0.990)

Accuracy: Bias proportion 90%~110%

Precision: Within Run: CV≤5%;
Run-to-Run: CV≤6%

Reagent Blank Absorbance: At 340nm wavelength and 10mmoptical diameter, O.D. ≤0.60.

REFERENCES

1. Wachtel M. *et al.*, Lab Med, 26: 593-7 (1995)
2. Young DS. 5th Ed. Washington DC: AACC Press (2000)
3. Young DS. 3rd Ed. Washington DC: AACC Press; 2007

Not Intended for Sale in the United States.

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