

**TECO DIAGNOSTICS**  
 1268 N. Lakeview Ave.  
 Anaheim, CA 92807  
 1-800-222-9880

**LACTATE DEHYDROGENASE (LD-L)  
 KINETIC METHOD  
 TC MATRIX**

**INTENDED USE**

For the quantitative determination of lactate dehydrogenase activity in serum or plasma on TC Matrix analyzers.

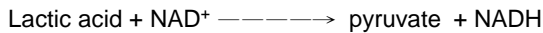
**SUMMARY AND EXPLANATION OF THE TEST**

LDH is widely distributed in mammalian tissues, being rich in myocardium, kidney, liver and muscle. Determination of serum LDH activity is one of the most frequently performed assays as an aid in the diagnosis of myocardial and pulmonary infarction. Other conditions, such as megaloblastic anemia, extensive carcinomatosis, severe shock and hypoxia, granulocytic or acute anemia, hemolytic anemia, infectious mononucleosis, progressive muscular dystrophy, hepatitis, cirrhosis, obstructive jaundice, and in delirium tremens are all caused increased activity of LDH.

LDH catalyzes the oxidation of lactate to pyruvate in the presence of NAD, which is subsequently reduced to NADH. The rate of NADH formation measured at 340 nm is directly proportional to serum LDH-L activity.

The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the activity of lactate dehydrogenase in the sample and is used by the TC Matrix System to calculate and express lactate dehydrogenase activity.

**LD-L**



**REAGENT CONTENTS:**

Each kit contains: Four Lactate Dehydrogenase Reagent 1 (4x40 ml)  
 Four Lactate Dehydrogenase Reagent 2 (4x8 ml)

Instruction Insert.

**REAGENT PREPARATION**

No preparation is required.

**REAGENT COMPOSITION**

Lactate: 50mM;

NAD<sup>+</sup>: 11 mM.

Also non-reactive chemicals for optimal system performance.

**REAGENT STORAGE AND STABILITY**

Lactate Dehydrogenase Reagent stored unopened at 2°C to 8°C is stable until the expiration date showed on the bottle label. Once opened, Lactate Dehydrogenase Reagent is stable for 21 days, unless the expiration date is exceeded.

**DO NOT FREEZE.**

**SPECIMEN COLLECTION AND HANDLING**

1. The test can be performed on serum, plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and allow clotting. The serum is then separated from the clot. A maximum limit of two hours from the time of collection is recommended.
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2°C to 8°C. Frozen samples are not recommended.

3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

**CALIBRATION**

Calibration is not required.

**MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT**

At least two levels of control material.

**LIMITATIONS**

1. The anticoagulants EDTA, Potassium Oxalate, Sodium Fluoride, Sodium Citrate and Lithium Heparin were found to be incompatible with this method.
2. The anticoagulants Ammonium Heparin and Sodium Heparin were found to be compatible with this method.

**INTERFERENCE**

1. Samples showing evidence of hemolysis should not be used.
2. Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.
3. On this method, refer to the work of Young for a review of drug and comprehensive list of substances effect on Lactate Dehydrogenase level.

**EXPECTED VALUE**

91 to 180 IU/L or 1.5 to 3.0 µkat/L

**PRECAUTIONS:**

1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

**PROCEDURES**

TEST NAME:	LDH	R1:	180
TEST NO.		R2:	36
FULL NAME: Lactate Dehydrogenase		SAMPLE VOLUME:	20
REFERENCE NO.:		R1 BLANK:	/
ANALY.TYPE:	Kinetic	MIX REAG. BLANK:	
PRI. WAVE :	340nm	CONCENTRATION:	/
SECON. WAVE:	405nm	LINEARITY LIMIT:	5 - 750
TREND:	Ascending	SUBSTRATE LIMIT:	/
REACT. TIME:	1 - 8	FACTOR:	1897
INCUBATE TIME:	3	PROZONE CHECK:	/
UNIT:	U/L	Q1: / Q2: / Q3: / Q4: /	
PRECISION:	Integer	PC: / ABS.: /	

## PERFORMANCE CHARACTERISTICS

**Analytical Range:** 5-750 IU/L

For Lactate Dehydrogenase analyte by Lactate Dehydrogenase Reagent on TC Matrix System, this method has been demonstrated to be linear from 5-750 IU/L

**Accuracy:** Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Lactate Dehydrogenase Reagent was used to compare with Lactate Dehydrogenase Reagent. The results of this study in yield a correlation coefficient of 0.99 with a regression equation of  $y=0.99X -2.3$ .

**Precision:** Within Run precision for Lactate Dehydrogenase Reagent Set was determined following a modification of NCCLS EP5-A. Two commercial human serum were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	171	371
Standard Deviation (mg/dl)	4.8	18
Coefficient of Variation (%)	2.7	5.3

Run-Day precision for Lactate Dehydrogenase Reagent was determined following a modification of NCCLS EP5-A. Two commercial human serum were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	171	371
Standard Deviation (mg/dl)	4.9	15
Coefficient of Variation (%)	2.9	5.1

## REFERENCES:

1. Wroblewski F., La Due J.S., 1955, Lactic dehydrogenase activity in blood. Proc. Soc. Exp. Biol. Med. 90:210.
2. Martinek R.G. 1972. A rapid ultraviolet spectrophotometric Lactic dehydrogenase assay. Clinical Chem. Acta 40:91
3. Tietz, N.W., " Speciman Collection and Processing; Sources of Biological Variation," Textbook of Clinical Chemistry, 2<sup>nd</sup> Edition, W.B. Saunders, Philadelphia, PA (1994)
4. National Committee for Clinical Laboratory Standards. Approved Guideline, NCCLS publication C28-A, Villanova, PA (1994).
5. Henry, J. B., ed., Clinical Diagnostics and Management by Laboratory Methods, 18<sup>th</sup> Edition, W.B. Saunders, Philadelphia.
6. Tietz, N.W., ed., Clinical Guide to Laboratory Tests, 2<sup>nd</sup> Edition, W.B. Saunders, Philadelphia, PA (1990)
7. National Committee for Clinical Laboratory Standards, Method Comparison and Bias Estimation Using Patient Samples; Tentative Guideline, NCCLS Publication EP9-T, Villanova, PA (1993)
8. National Committee for Clinical Laboratory Standards, Precision Performance of Clinical Chemistry Devices; Tentative Guideline, 2<sup>nd</sup> Edition, NCCLS publication EP5-T2, Villanova, PA (1992)
9. National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Evaluation Protocol Number 7, Vol. 4, No, June 1984.
10. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 3<sup>rd</sup>. Ed., AACC Press, Washington DC, 1990, 3-104 thru 3-106.

**L533-780TM: 11/2016**

Manufactured by:



TECO DIAGNOSTICS  
1268 N. LAKEVIEW AVE.  
ANAHEIM, CA 92807  
U.S.A.