TECO DIAGNOSTICS
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LACTATE DEHYDROGENASE (LDH)
KINETIC METHOD
TC MATRIX-160

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.

$$\text{Lactic acid} + NAD^+ \xrightarrow{\text{LD-L}} \text{pyruvate} + NADH$$

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Lactate: 50 mM;
NAD^+: 11 mM.
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Lactate Dehydrogenase Reagent stored unopened at 2ºC to 8ºC is stable until the expiration date shown on the bottle label. Once opened, Lactate Dehydrogenase Reagent is stable for 21 days, or until the expiration date on the label, whichever occurs first.
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 it is allowed to clot. The serum should be separated from the clot within two hours from the time of collection.
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 2ºC to 8ºC. 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
1. Calibrator required: TECO MULTI Calibrator.
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

Note: Refer to the TC Matrix manual for further instructions on calibrating the instrument

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 should perform the quality control testing to ensure the results are reliable before running the specimens.

PROCEDURES

Test Name:	LDH	R1:	160
Full Name:	Lactate Dehydrogenase	R2:	36
Pri. Wave:	340 nm	Sample volume:	2.0
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	Kinetic	K Value:	/
Start - End:	14 - 20	Point:	2
Decimal place:	1	Blank Type:	Water
Unit:	U/L	Point 0 (Blank) Con.:	0.0
Linearity Range:	2.0000 - 3000.00	Point 1 (STD) Con.:	Calibrator/
Correlation Factor:	1.0000 - 0.0000		Standard

PERFORMANCE CHARACTERISTICS

Analytical Range: 2-3000 IU/L

For Lactate Dehydrogenase analyte by Lactate Dehydrogenase Reagent on TC Matrix System, this method has been demonstrated to be linear from 2-3000 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

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Manufactured by:

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