



ISO 13485:2016 ISO 9001:2015

Ver.240816

# **Lactate Dehydrogenase (LDH) Assay kit**

BC6603-01(50 Tests)

**FOR RESEARCH USE ONLY, DO NOT USE IT IN CLINICAL DIAGNOSIS**

## Intended Use

This reagent is intended for in vitro quantitative determination of Lactate dehydrogenase in serum or plasma

-Based on SCE recommended method

-Linear up to 2400 U/L

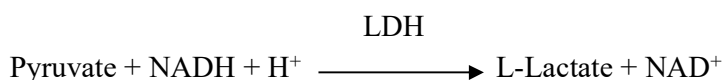
## Clinical Significance

This enzyme is found in all organ cells, but especially plentiful in cardiac & skeletal muscle, liver, kidney & RBC. LDH is found in the form of iso-enzymes based on their electrophoretic mobility with each iso-enzymes being primarily from different organs.

Elevated levels are found in myocardial infarction, liver diseases, hemolytic anaemias, pernicious anaemia, Leukemia & Pulmonary diseases. Elevations in acute MI reaches a peak in 48-72 hrs. belonged elevations, (10-14 days) are useful in the late diagnosis of the condition.

## Principle

Kinetic determination of lactate dehydrogenase according to the following reaction.



## Kit components

Reagent / Component	Volume
Extraction Reagent	1 × 60 mL
LDH (S.L) R1	2 × 24 mL
LDH (S.L) R2	2 × 6 mL

## Risk & Safety

Material Safety data sheets (MSDS) will be provided on request

## Reagent Preparation

Mix 4 volumes of Reagent 1 (R1) with 1 volume of Reagent 2 (R2)

The working reagent is stable for 21 days at 2-8°C.

NOTE: Discard the working reagent if the blank absorbance is less than 1.0 at 340 nm.

## Reagent Storage and Stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2-8°C and protected from light.

## Open Vial Stability

Once opened, the reagent is stable up to 4 weeks if contamination is avoided.

## Onboard Calibration Stability

On board calibration stability is 20 days.

## Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded.

## Precaution

- To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.
- Avoid direct exposure of reagent to light.
- Do not blow into the reagent bottles.
- This reagent is only for IVD use and follow the normal precaution required for handling all laboratory reagents.

## Waste Management

Reagents must be disposed off in accordance with local regulations.

## Sample

Serum / plasma ( free for haemolysis )

Tissue: 0.1 g of tissue could be mixed with 1 mL of Extraction reagent and fully homogenized on ice bath. Then centrifuge at 8000 x g for 10 minutes at 4 °C to remove insoluble materials and take the supernatant on ice before testing.

## Interferences

No interference for

Bilirubin up to 20 mg/dL ,

**Note:** Haemolysed sera should not be used since significant haemolysis may increase LDH concentration because of high levels of LDH in erythrocytes.

## Materials Required but Not Provided

Pipettes & Tips, Test Tubes & racks, Timer, Incubator, Analyzer

## Test Parameter

Mode of Reaction	Kinetic
Slope of Reaction	Decreasing
Wavelength	340 nm
Temperature	37°C
Factor	16030
Linearity	2400 U/L
Blank	DI Water
Delay	60 seconds
No of reading	3
Interval	60 seconds
Sample Volume	10 µL
Reagent Volume	1000 µL
Cuvette	1 cm light path

## Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
U/L	uKat/L	$\times 0.017$

## Calibration

Use provided factor (16030) for estimation of LDH on semi auto analyzers

## Procedure Notes

Laboratory procedures for semi Auto Analyzer	
Working Reagent	1000 µL
Sample	10 µL
Mix and Incubate at 37°C for 1 minute. Measure the change in absorbance per minute ( $\Delta$ OD/minutes) during 3 minutes.	

## Calculation

$$\text{LDH activity (U/L)} = (\Delta \text{OD/minutes}) \times 16030$$

## Reference Range

It is recommended that each laboratory should establish its own reference values.

The following value may be used as guide line.

Serum/Plasma	
1- 3 years	490-730 U/L
4- 9 years	320-520 U/L
10-13years	250-500 U/L
Adults	225-450 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for Interpretation and diagnosis.

## Performance

### 1. Linearity

This reagent is linear up to 2400 U/L

If the concentration is greater than linearity (2400 U/L) dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

### 2. Comparison

A comparison study has been performed between our reagent and another internationally available reagent yielded a correlation coefficient of  $r^2 = 0.988$  and a regression equation of  $y = 0.9963x$ .

### 3. Precision

Intra Run		
	Control Level 1	Control Level 2
n	20	20
Mean( U/L )	351.3	850.6
SD	9.7	17.2
CV(%)	2.8	2.0

Inter Run		
	Control Level 1	Control Level 2
<b>n</b>	20	20
<b>Mean( U/L )</b>	347.73	835.01
<b>SD</b>	7.35	24.34
<b>CV(%)</b>	2.11	2.92

Accuracy( U/L )		
Control	Expected Value	Measured Value
<b>Control Level 1</b>	365 ± 90	380
<b>Control Level 2</b>	855 ± 180	910

#### 4. Sensivity

Lower detection limit is 7 U/L.