BIOLABO
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L.D.H. (LDH-P) DGKC Method

Reagent for quantitative determination of Lactate Dehydrogenase activity [EC 1.1.1.27] in human serum.

I REF K1011	**R1** 2 x 16 mL	**R2** 1 x 8 mL
I REF K2011	**R1** 2 x 32 mL	**R2** 2 x 8 mL
I REF K4011	**R1** 2 x 40 mL	**R2** 1 x 20 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biololabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (automated method). It allows the quantification of global activity of LDH enzyme in human serum.

GENERALITES (1) (4) (5)

Lactate dehydrogenase (LDH) activity is present in all cells of the body. Enzymes levels are particularly high, compared with those in serum, in liver, heart, kidney, skeletal muscles and erythrocytes. In addition to their higher enzyme activity, many of these tissues show different isoenzyme composition (separable by electrophoresis).

PRINCIPLE (1)

UV Kinetic Method (DGKC):

$$\text{Pyruvate} + \text{NADH} + \text{H}^+ \xrightarrow{\text{L D H}} \text{L-Lactate} + \text{NAD}^+$$

The decrease in absorbance due to the conversion of NADH to NAD^+, directly proportional to LDH activity in the specimen, is measured at 340 nm.

REAGENTS COMPOSITION

R1	**LDH**	Substrate-Buffer	**Danger**
Imidazole Buffer	65	mmol/L	
Pyruvate	0,6	mmol/L	
Stabilizer			

R2	**LDH**	Coenzyme	**Danger**
Imidazole Buffer	65	mmol/L	
NADH	0,18	mmol/L	

Danger Repro. 1B: H360 - May damage fertility or the unborn child

P201: Obtain special instructions before use, P202: Do not handle until all safety precautions have been read and understood, P308+P313: IF exposed or concerned: Get medical advice/attention, P405: Store locked up, P501: Dispose of contents/container in accordance with dangerous waste regulations. Classification due to Imidazole < 1%. For more details refer to the safety data sheet (MSDS).

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- 2 separated reagents are stable at least 3 months.
- Discard any reagent if cloudy or if absorbance at 340 nm is < 1.000.

SPECIMEN COLLECTION AND HANDLING (1)

Unhemolysed serum promptly removed from clot.

LDH activity is stable in serum for 48 h from 4° C to 20° C.

Freezing will destroy liver isoenzymes and lead to a loss of activity of 10 to 20 % after 48 hours.

LIMITS (2) (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

REFERENCE INTERVALS (1)

DGKC Method (adult at 37° C): 230-460 IU/L

Note: Values for children are all the higher as children is young.

Each laboratory establishes its own normal ranges for the population it serves.

PERFORMANCES AT 37°C ON KENZA ONE

Refer to the application of analyzer used.

Linearity Range: between 37 and 1125 IU/L

Detection limit: approx. 14 U/L

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	132	409	1281
S.D. (IU/L)	5.0	5.3	11.0
C.V. %	3.8	1.3	0.9

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	136	392	1252
S.D. IU/L	5.4	18.4	55.2
C.V. %	4.0	4.7	4.4

Comparison studies with commercially available reagent:

Realized on serum specimens (n=50) between 20 and 400 IU/L

y = 0.8988 x + 2.583 r = 0.9916

Analytical Sensitivity: approx. 0.014abs/min for 100 IU/L

Interferences:

Turbidity	No interference up to 0.295 abs
Ascorbic acid	No interference up to 2500mg/dL
Total bilirubin	Negative interference from 437 µmol/L
Direct bilirubin	No interference up to 697 µmol/L
Hemoglobin	Negative interference from 19 µmol/L
Glucose	No interference up to 10440 mg/dL

Other substances may interfere (see § Limits)

On the board stability: 3 months

Calibration Stability: 30 days

Make a new calibration when changing reagent batch, if quality control results are found out of the range and after maintenance operations

Stability and performances data on Kenza 240TX/ISE and Kenza 450TX/ISE are available on request.

CALIBRATION

- REF 95015 Multicalibrator traceable to ERM-AD453

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result in IU/L.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

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