LDH-P – SCE Pyruvate → Lactate
Instructions for use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
OPEN KONELAB INDIKO	REF B75182517	n° 10 vials x 9 mL (R.A) n° 1 vials x 10 mL (R.B)
	REF B75182518	n° 15 vials x 4,5 mL (R.A) n° 1 vials x 8 mL (R.B)

INTENDED USE

Product for use in the quantitative determination in vitro of the LDH activity in human serum. The results of the test must always be interpreted in conjunction with the clinical context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE

LDH is an enzyme which catalyzes the reduction of pyruvic acid to lactic acid. The wide-spread diffusion of LDH in the organism explains why this enzyme increases in the serum in numerous pathological conditions involving various different tissues, such as the liver (viral hepatitis), cardiac muscle (myocardial infarction), skeletal muscle and kidneys. The kidney is the organ containing the highest concentration of the enzyme, followed by the myocardium, skeletal muscle, spleen, liver and lungs. LDH activity in the serum is determined by a group of five isoenzymes deriving from different tissues. LDH activity can be determined by measuring the conversion of lactate to pyruvate or pyruvate to lactate.

PRINCIPLE OF THE METHOD

Method SCE Pyruvate → Lactate. LDH catalyzes the following reaction:

$$\text{pyruvate} + \text{NADH} + \text{H}^+ \xrightarrow{\text{LDH}} \text{lactate} + \text{NAD}^+$$

The rate of NADH oxidation is proportional to the LDH activity.

Storage and stability

= storage temperature 2-8°C

stored at 2-8 ° C avoiding direct light, the reagents are stable until the expiration date printed on the label.

Concentrations

Reagent A: Substrate buffer		
	Conc.	**U.M.**
TRIS buffer pH 7.4 ± 0.2	50.1	mmol/L
Sodium pyruvate	1.20	mmol/L
EDTA	5.00	mmol/L
Sodium azide	13.8	mmol/L
Reagent B: NADH		
	Conc.	**U.M.**
TRIS buffer pH 10.2 ± 0.2	50.0	mmol/L
NADH (from yeast)	1.80	mmol/L
Sodium azide	13.8	mmol/L

* Warning**: -** The product is not classified, according to CLP regulation

Reagents included in the kit

The reagent is described above.

Materials required but not supplied in the kit

Controls, calibrators and pipettes with adequate volume

PRECAUTIONS and WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles)
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

Quality control

Control sera with a known titer of LDH are commercially available for quality control, with values and confidence limits included. Sclavo Diagnostics Normal and pathological control sera are available: Clinicontrol N 5x5mL cod. B35181700 and Clinicontrol A 5x5 mL code B35181701. The values obtained must be within the acceptability range.

Calibration

For calibration use the "Calibrator serum Sclavo" code B35181702.

Traceability

The Lactate Dehydrogenase concentration is reported in the package insert supplied with the "Calibrator Serum".

SAMPLE

Type of sample and storage

Use fresh non-haemolysed serum samples. LDH is stable in serum 1 week at 4-20°C and one month at -20°C.

REAGENT PREPARATION

Add 1 volume of Reagent B to 9 volume of Reagent A and mix gently.
After reconstitution the reagent is stable for 15 days if closed and stored at 2-8°C. A slight variation in colour among batches, does not affect test results.

Automation

The kit can be used with all automatic analyzers that can meet the operating conditions of the reagent while maintaining the volumetric ratios R1 / R2 / C. Validated applications are available for Sclavo Konelab® - Indiko® instruments. Applications not approved by Sclavo Diagnostics do not guarantee the performance of the reagent and must therefore be approved under the responsibility of the user.

MANUAL METHOD

The kit, in Open format, can be used manually through the use of spectrophotometer or photometer with the following parameters:

Reaction conditions

Wavelength (primary):	340 nm
Temperature:	37°C
Reaction	Kinetic (decreasing reaction)

Technique – Monoreactive

Bring the reagents to reaction temperature and operate away from direct light.

	U.M.	Calibrator Serum	Sample
Reagent (A+B)	µL	1000	1000
Calib. Serum	µL	20	-
Sample	µL	-	20

Mix gently and incubate at reaction temperature for 30 sec.
After the incubation, read the absorbance at 340 nm. Repeat readings at 30 seconds or 1-minute intervals. Recording a minimum of 3 absorbance changes is recommended. Determine the mean Δ O.D./min.
The reaction volumes can be varied proportionally without altering the result.

Results:

Manual Method

Calculation of Lactic Dehydrogenase concentration:

$$\frac{\Delta \text{ O.D. sample}}{\Delta \text{ O.D. Calib. serum}} \times \text{Calib. serum conc. (U/L)} = \text{U/L LDH}$$

Automation

The results are automatically calculated by the analyzer based on the calibration line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration line is calculated automatically by the different instruments.

Calculation of the results obtained using a multiplication factor

Δ O.D./min x K-factor* = U/L of LDH
Explanation of the calculation:

$$\frac{\text{Vt} \times 1000}{\text{M.E.C.} \times \text{O.P.} \times \text{Vc}} = \text{K – factor} * \times \Delta \text{ O.D./min.} = \text{U/L LDH}$$

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*K-factor = 8199
where:
U/L = activity in serum in international units
Δ O.D./min. = variation in absorbance per minute
Vt = total reaction volume (µL)
1000 = conversion to the concentration per liter
M.E.C. = micromolar extinction coefficient of NADH 6.22 cm ^{2}/ µmol at 340 nm
O.P. = optic path (1cm)
Vc = sample volume in the mixture (µl)

REFERENCE RANGE
Serum: 208-378 U/L
Each laboratory must establish its own normal values on the basis of its local population.

ANALYTICAL CHARACTERISTICS / PERFORMANCE
Linearity
The method is linear up to 2100 U/L at 340 nm.

Accuracy / Recovery
Commercial control sera were analyzed with the kit in question following the guidelines of the CLSI protocol. The data obtained are shown in the table below.

Range	Replicates	Mean	ES medio	CV%	Recovery
Basso	5	247	1.77	1.61	101 %
Alto	5	894	2.31	0.58	100.5 %

Interferences

Interference	Limits
Triglycerides	**2000 mg/dL**
Ascorbic acid	**30 mg/dL**

Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	U/L	232	6.14	2.65	30
High	U/L	620	10.82	1.75	30
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	U/L	236	8.80	3.73	20
High	U/L	583	26.07	4.47	20

Limit of Sensitivity
The Sensitivity limit has been measured using serial dilutions of high concentrated sera. The smallest detectable concentration is about 8.2 U/L of Lactic Dehydrogenase.

Comparison between methods
The method was compared with a similar commercial method analysing 20 human sera. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	6.08
Slope	0.901
Correlation Coeff. (R)	0.999

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

REFERENCES

1. The Committee on Enzymes of the Scandinavian Society for Clinical Investigation and Clinical Physiology. Scand J Clin Lab Invest 1974; 32: 291
2. **Amador E, Wacker WE** (1965) Enzymatic methods used for diagnosis. Methods Biochem Anal.;13:265-356.
3. **Clinical Laboratory Standards Institute (CLSI). User Verification of Performance for Precision and Trueness**; Approved Guideline – Second Edition. EP15-A2.
4. **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Precision Performance of Quantitative Measurements Methods; Approved Guideline – Second Edition. EP05-A2.
5. **Clinical Laboratory Standards Institute (CLSI).** Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition. EP09-A3.
6. **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition – EP17.
7. **Clinical Laboratory Standards Institute (CLSI).** Interference Testing in Clinical Chemistry, – Third Edition. - EP07.
8. **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Linearity of Quantitative Measurement Procedures, 2nd Edition - EP06.

REVISION	DATE	CHANGE
Rev.B	05/2025	Out of production of chemilab line

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