



LDH LR liquid reagent

REF C4000420 356 Test

CE C4000420A 356 Test

IVD For in vitro medical device

Use

Kit for measurement of lactate dehydrogenase in serum or plasma. Kinetic optimized method SCE.

Summary

LDH measurements are used in the diagnosis and treatment of liver disease such as acute viral hepatitis, cirrhosis and metastatic carcinoma, cardiac diseases such as myocardial infarction, and tumors of the lungs or kidneys.

Principle

Lactate dehydrogenase (LDH) catalyzes the reaction between pyruvic acid and NADH. The NADH oxidization into NAD⁺ allows to determine the LDH in the tested sample.

Reagents

R1	Goods buffer	pH 7.3	100.0 mmol/l
	EDTA Na2		5.0 mmol/l
	pyruvic acid		1.6 mmol/l
R2	Goods buffer	pH 7.3	100.0 mmol/l
	NADH		1.25 mmol/l

Reagents Preparation

Reagents are liquid and ready to use. About use as monoreagent ("sample-starter" procedure) add the entire content of one bottle of LDH R2 in the LDH R1 bottle and mix gently. For minor use add for every 4 ml of R1 reagent, 1 ml of R2 reagent. Keep out the reagents from refrigerator only for the use and recap them immediately.

Storage And Stability

- Store the kit at 2-8°C.
- After opening, the vials R1 and R2 are stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.
- Working solution stability (R1+ R2): 20 days at 2-8°C.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with care, according to good laboratory practice. Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum-heparinized plasma or EDTA plasma.
- Do not use samples with haemolysis.
- The serum must be separated, as soon as possible, from corpuscular part.
- The LDH activity decreases in 8% within 3 days at 2-8°C

Note

- The kit, according to this method, must be used in manual procedures. About automatic use follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the single vials.

Procedures

Wavelength λ : 340 (330 - 360) nm
 Working temperature 37°C
 Optical path 1 cm
 Reaction kinetic (decreasing)
 Bring the reagents at 15-25°C before use them.

Monoreagent Procedure "sample starter"

	BLANK	SAMPLE
Working Reagent	1000 μ l	1000 μ l
Distilled Water	20 μ l	--
Sample	--	20 μ l

Mix, then incubate for 1' a 37°C. Measure the absorbance of sample (EC) against distilled water. Make at least two readings at a distance of 60". Calculate the absorbance variation $\Delta E/min$ from performed readings.

Bireagent Procedure "substrate starter"

	BLANK	SAMPLE
Reagent R1	800 μ l	800 μ l
Distilled Water	20 μ l	--
Sample	--	20 μ l

Mix, then incubate for 1' a 37°C. Then add:
 Reagent R2 200 μ l 200 μ l
 Mix, then incubate for 1' a 37°C. Measure the absorbance of sample (EC) against distilled water. Make at least two readings at a distance of 60". Calculate the absorbance variation $\Delta E/min$ from readings executed.

Calculation

$$LDH [U/l] = \Delta E/min \times 8095$$

The factor and the reagent performances are related to 37 °C, 1 cm and 340 nm.

Reference Values at 37°C

Adults [U/l] < 480 U/l

The LDH level in children (up to 12 years old) is 10-15% higher than in the adults. Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

Reaction is linear up to a concentration of 800 U/l. Samples with values exceeding this range must be diluted with saline solution. Then multiply the result for diluting factor.

Analytical Sensitivity

The test sensitivity in terms of detection limit is 19.0 U/l.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal-High). Results:
 MEAN (U/l) N = 308.40 H = 522.20
 S.D. N = 2.29 H = 5.32
 C.V.% N = 0.74 H = 1.02

"Inter-Assay" precision (between-run)

Determined on 20 samples for each control (N-H). Results:
 MEAN (U/l) N = 308.13 H = 521.22
 S.D. N = 2.46 H = 5.83
 C.V.% N = 0.80 H = 1.12

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor $r = 0.92$
 $y = 0.9945 x - 24.655$

Interferences

No interferences was observed by the presence of:
 Bilirubin ≤ 25 mg/dl
 Triglycerides ≤ 800 mg/dl
 Ascorbate acid ≤ 20 mg/dl
 Haemolysed specimens should not be used for analysis. For a comprehensive review of interfering substances, refer to the publication by Young.

Quality controls

It's necessary, each time the kit is used, to perform quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

- Kreutzer, H. H. et al., Clin. Chim. Acta, 9, 64, (1964).
- Young, D.S. et al., Clin. Chem., 21 ID 432D, (1975).
- Fischbach, F., Zawta, B., Klin. Lab., 38:555-61, (1992).
- Kaplan, L.A., Pesce, A.J.: "Clinical Chemistry", Mosby Ed. (1996)
- Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed. 2000.

Symbols

- CE CE Mark (98/79 CE regulation)
- IVD in vitro medical device
- LOT Batch Code
- Hourglass Use by
- Thermometer Storage temperature limits
- Book Read instruction for use
- Gesan Production srl

LDH LR
Mod. 7.3.5 Rev. 0 of 2006-01

Gesan Production s.r.l