

## LDH FL (DGKC)

LD F120 CH	12 x 10 ml
LD F245 CH	12 x 20 ml

### SUMMARY OF TEST

Lactate dehydrogenase (LDH) is present in high levels in kidneys, heart, liver, and skeletal muscle, besides in other human tissues. An increase of circulating level of LDH is an index of myocardial infarction, renal failure, hepatitis, anemia, malignancies, and affections of skeletal muscles. At least 5 distinct isoenzymes are recognized, which could separate through electrophoretical techniques. Each of them are present in different tissues, and their differential determination is of high diagnostic value.

The formula of present reagent is based on DGKC recommendations.

### PRINCIPLE OF THE METHOD

Lactate dehydrogenase (EC 1.1.1.27.; L-lactate:NAD<sup>+</sup> oxidoreductase; LDH) catalyzes the conversion of pyruvate to L-lactate in presence of NADH, which is converted to NAD<sup>+</sup>. The rate of conversion of NADH/NAD<sup>+</sup>, monitored at 340 nm, is proportional to LDH activity.

### KIT COMPONENTS

#### For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

**Reagent A** F120: 12 x 8 ml (liquid) blue cap  
F245: 12 x 16 ml (liquid) blue cap

**Reagent B** F120: 2 x 12 ml (liquid) red cap  
F245: 3 x 16 ml (liquid) red cap

Composition in the test: phosphate buffer pH 7.50 50 mM, sodium pyruvate 0.60 mM, NADH 0.18 mM.

Store all components at 2-8°C.

### MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

### REAGENT PREPARATION

#### Serum as starter procedure:

Code F120: add 2 ml of reagent B to a vial of reagent A.

Code F245: add 4 ml of reagent B to a vial of reagent A.

Stability of working reagent: 30 days at 2-8°C, away from light sources.

#### Reagent as starter procedure:

use separate reagents ready to use.

Stability: up to expiration date on labels at 2-8°C;

Stability since first opening of vials: ≥ 60 days at 2-8°C.

### PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

### SPECIMEN

Serum, plasma heparinate or EDTA. Avoid hemolysis. LDH activity is stable 3 days in samples stored at 2-8°C.

### TEST PROCEDURE (sample as starter)

Wavelength:	340 nm
Lighthpath:	1 cm
Temperature:	37°C
dispense in cuvette working reagent:	1 ml
preincubate at 37°C for 5 minutes.	
add sample:	10 µl
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.	

### TEST PROCEDURE (reagent as starter)

Wavelength:	340 nm
Lighthpath:	1 cm
Temperature:	37°C
dispense in cuvette reagent A:	1 ml
add sample:	10 µl
incubate at 37°C for 5 minutes.	
dispense in cuvette reagent B:	250 µl
Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.	

### RESULTS CALCULATION

Perform calculation in units per litre, multiplying the ΔA/min by the factor as it is indicated.

Calculation in U/l: ΔA/min x 16030 (sample starter)

Calculation in U/l: ΔA/min x 20080 (reagent starter)

Activity in µkat/l: U/l x 0.0167 = µkat/l

### EXPECTED VALUES

225 - 450 U/l (3.75 - 7.51 µkat/l)

Each laboratory should establish appropriate reference intervals related to its population.

### QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

**QN 0050 CH** QUANTINORM CHEMA 10 x 5 ml  
with normal or close to normal control values

**QP 0050 CH** QUANTIPATH CHEMA 10 x 5 ml  
with pathological control values.

If required, a multiparametric, human based calibrator is available:

**AT 0030 CH** AUTOCAL H 10 x 3 ml

Please contact Customer Care for further information.

### TEST PERFORMANCE

#### Linearity

the method is linear up to 4000 U/l.

If a ΔA/min of 0.100 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

#### Sensitivity/limit of detection (LOD)

the limit of detection is 2 U/l.

#### Interferences

no interference was observed by the presence of:

hemoglobin	≤ 500 mg/dl
bilirubin	≤ 40 mg/dl
lipids	≤ 1000 mg/dl

#### Precision

intra-assay (n=10)	mean (U/l)	SD (U/l)	CV%
sample 1	329.90	6.33	1.90
sample 2	531.90	7.75	1.50

inter-assay (n=20)	mean (U/l)	SD (U/l)	CV%
sample 1	331.51	7.39	2.20
sample 2	546.04	11.76	2.20

#### Methods comparison

a comparison between Chema and a commercially available product gave the following results:

$$\begin{aligned} \text{LDH Chema} &= x \\ \text{LDH competitor} &= y \\ n &= 99 \end{aligned}$$

$$y = 0.99x + 2.41 \text{ U/l} \quad r = 0.99$$

### WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. Refer to special instructions/safety data sheets.

### REFERENCES

HU Bergmeyer - Methods of enzymatic analysis, Vol. III (1987).

DGKC - Eur.J.Clin.Chem.Clin.Biochem., 31 (1993)








Kreutzer H.H. et al. - Clin. Chim. Acta 9,64 (1964)

Young D.S., et al. - Clin. Chem. 21 ID, 432D (1975)

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### SYMBOLS

	for in vitro diagnostic use only
	lot of manufacturing
	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	read the directions