GLDH (DGKC)

DiaSystem Scandinavia AB

Diagnostic reagent for quantitative in vitro determination of glutamate dehydrogenase (GLDH) in serum or plasma on photometric systems

Order Information

Cat. No.	Kit size
01 00023 70 04 0125	R1 5 x 20mL + R2 1 x 25mL
CDT-GLDH	R1 3 x 30mL + R2 2 x 11,3mL

Summary [1,2]

Glutamate dehydrogenase (GLDH) is a mitochondrial enzyme which is present in many tissues. Significant elevations of the GLDH activity are measured in necrosis of hepatocytes, as in acute toxic liver necrosis and in hypoxic liver diseases. The measurement of GLDH is used to evaluate the extent of parenchymal liver damage and, in conjunction with the transaminases ALAT/GPT and ASAT/GOT, in the differential diagnosis of liver disorders. The calculation of the (ALAT+ASAT)/GLDH ratio enables to differentiate between inflammatory liver diseases and liver necrosis due to intoxication or ischemia.

Method

Optimized UV test, according to recommendations of the DGKC (German Society of Clinical Chemistry) [3]

Principle

$$\alpha\text{-Ketoglutarate} + NADH + NH_4^+ \xrightarrow{GLDH} L\text{-Glutamate} + NAD^+ + H_2O$$

Reagents

Components and Concentrations

R1:	Triethanolamine	pH 8.0	75 mmol/L
	α-Ketoglutarate		10 mmol/L
	Ammonium acetate		150 mmol/L
	EDTA 3.75 mmol/L		ADP 1.5 mmol/L
	LDH		≥ 2.3 kU/L
R2:	NADH		1.3 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents.

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 1 contains biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. Sulfasalazine and sulfapyridine medication may lead to false results in patient samples. Blood collection must be done before drug administration.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only! For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent and the standard are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin or EDTA plasma

Stability [4]:	7 days at	20 – 25°C
	7 days at	4 – 8°C
	4 weeks at	–20°C

Only freeze once!
Discard contaminated specimen

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	340 nm, Hg 334 nm
Optical path	1 cm
Temperature	37 °C
Measurement	Against air

Sample or standard	150 µL
Reagent 1	1000 µL
Mix, incubate for approx. 3 min., then add:	
Reagent 2	250 µL
Mix, read absorbance after 30 sec. and start stopwatch.	
Read absorbance again after 1, 2 and 3 min.	

Calculation

With factor

From absorbance readings calculate ΔA/min and multiply by the corresponding factor from the table below:

ΔΔ ΔA/min x factor = GLDH activity [U/L]

340 nm -1485
334 nm -1515

With calibrator

$$GLDH\ [U/L] = \frac{\Delta A/min\ Sample}{\Delta A/min\ Calibrator} \times Conc.\ Calibrator\ [U/L]$$

Conversion factor

GLDH [U/L] x 0.0167 = GLDH [µkat/L]

Calibrators and Controls

For calibration of automated photometric systems, DiaSystem UniCal CC is recommended. This method is traceable to the Molar Extinction Coefficient. DiaSystem UniLab N and P controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
UniCal CC	06 00122 70 04 0018	6 x 3 mL
UniLab N	07 00123 70 04 0030	6 x 5 mL
UniLab P	07 00124 70 04 0030	6 x 5mL

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Performance Characteristics

Measuring Range

The test has been developed to determine GLDH activities within a measuring range from 2 – 120 U/L. When values exceed this range samples should be diluted 1 + 5 with NaCl solution (9 g/L) and results multiplied by 6.

Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 60 mg/dL and hemoglobin up to 500 mg/dL. Lipemia interferes. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection

The lower limit of detection is 2 U/L

Precision

Intra-assay precision n = 20	Mean (mmol/L)	SD (mmol/L)	CV [%]
Sample 1	5.77	0.51	8.78
Sample 2	18.3	0.39	2.11
Sample 3	32.0	0.78	2.43

Inter-assay precision n = 20	Mean (mmol/L)	SD (mmol/L)	CV [%]
Sample 1	6.18	0.43	6.98
Sample 2	16.1	0.49	3.02
Sample 3	33.2	0.80	2.40

Method Comparison

A comparison of DiaSystem GLDH DGKC (y) with a commercially available reagent according to DGKC (x) using 76 samples gave following results:

y = 1.034 + 0.006 U/L; r = 0.999

Reference Range [1]

Women ≤ 5.0 U/L (0.083 µkat/L)
Men ≤ 7.0 U/L (0.117 µkat/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 86–88.
2. Moss DW, Henderson AR. Clinical enzymology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 617–721.
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4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

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