GLDH FS* (DGKC)

Order Information

Cat. No.	Kit size		
G 82100	R1 2 x 40 mL	+	R2 2 x 10 mL

Intended Use

Diagnostic reagent for quantitative in vitro determination of glutamate dehydrogenase (GLDH) activity in human serum or heparin plasma on automated DxC 500 AU.

Summary

Glutamate dehydrogenase (GLDH) is a mitochondrial enzyme, which is localized in all tissues but predominantly expressed in the liver. The main function of GLDH is to catalyze the nitrogen clearance from the organism. Significant elevations of the GLDH activity are detected in necrosis of hepatocytes, in acute toxic liver necrosis and in hypoxic liver diseases. Moreover, measurement of GLDH activity is a pivotal tool for the evaluation of the damage severity of parenchymal cells and for the indication of alcohol addiction [1]. In conjunction with the transaminases ALAT/GPT and ASAT/GOT, GLDH assessment is mainly utilized for differential diagnosis of liver disorders. The calculation of the (ALAT+ASAT)/GLDH ratio enables to differentiate between inflammatory liver diseases and liver diseases in which necrosis is the predominant event [1,2].

Method

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

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

One unit of GLDH is the amount of enzyme that will oxidize 1.0 µmol of NADH per minute at the enzyme specific conditions.

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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The in-use stability of the reagent is 18 months.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [4].
4. Sulfasalazine and sulfapyridine medication may cause false results in patient samples. Blood collection must be performed prior to drug administration.
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
7. Please refer to the safety data sheets (SDS) 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.
8. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [5]:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
4 weeks	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the molar extinction coefficient. Use DiaSys TruLab N and P for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size		
TruCal U	5 9100 99 10 063	20	x	3 mL
	5 9100 99 10 064	6	x	3 mL
TruLab N	5 9000 99 10 062	20	x	5 mL
	5 9000 99 10 061	6	x	5 mL
TruLab P	5 9050 99 10 062	20	x	5 mL
	5 9050 99 10 061	6	x	5 mL

Performance Characteristics

Data evaluated on DxC 500 AU

Measuring range up to 120 U/L. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	3 U/L
Onboard stability	4 weeks
Calibration stability	2 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	75 mg/dL	6.76
	75 mg/dL	23.1
Bilirubin (conjugated)	30 mg/dL	7.81
	30 mg/dL	23.0
Bilirubin (unconjugated)	56 mg/dL	6.96
	56 mg/dL	22.8
Hemoglobin	360 mg/dL	7.70
	360 mg/dL	23.8
Lipemia	180 mg/dL	6.93
	290 mg/dL	23.0
For further information on interfering substances, refer to the literature [6-8].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	6.78	14.6	40.9
CV [%]	2.12	1.84	0.817
Total Precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [U/L]	7.15	15.0	42.7
CV [%]	3.77	2.47	1.96

Method comparison (n=126)	
Test x	Competitor GLDH (cobas c 501)
Test y	DiaSys GLDH FS DGKC (DxC 500 AU)
Slope	0.974
Intercept	–0.689 U/L
Coefficient of correlation	0.995

** according to CLSI document EP17-A2, Vol. 32, No. 8

Conversion Factor
GLDH [U/L] x 0.0167 = GLDH [µkat/L]

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 [Internet]. Prof. Lothar Thomas; 2020 [cited 2022 January]. Available from: https://www.clinical-laboratory-diagnostics-2020.com/
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4. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med. 2007; 45:1240-1243.
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8. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001;38:376-85.

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