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Liquid Reagents – ready to use

GLDH

(Glutamate Dehydrogenase)
DGKC
2 Reagents

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

REF	Kit Size	Content
D03772B	**1 x 1 L**	1 x 0.8 L R1 + 1 x 0.2 L R2
D03774	**5 x 100 mL**	4 x 100 mL R1 + 1 x 100 mL R2
D03773	**5 x 50 mL**	4 x 50 mL R1 +1 x 50 mL R2
D03775	**5 x 25 mL**	4 x 25 mLR1 + 1 x 25 mL R2
D03776	**5 x 10 mL**	4 x 10 mL R1 + 1 x 10 mL R2
D03911	**5 x 50 mL**	4 x 50 mL R1 + 2 x 25 mL R2
D0424917	**5 x 50 mL**	4 x 50 mL R1 + 1 x 50 mL R2
DA0826	**5 x 20 mL**	4 x 20 mL R1 + 1 x 20 mL R2
DT1026	**5 x 20 mL**	4 x 20 mL R1 + 1 x 20 mL R2
DK0725	**5 x 50 mL**	4 x 50 mL R1 + 1 x 50 mL R2
DB0925	**2 x 100 mL**	2 x 80 mL R1 + 2 x 20 mL R2

Additionally offered:

D98485	5 x 3 ml	Calibrator	Diacal Auto
D98481	12 x 5 ml	Control normal	Diacon N
D98482	12 x 5 ml	Control abnormal	Diacon P

TEST PARAMETERS

Method:	UV, kinetic, decreasing reaction, DGKC
Wavelength:	340 nm, Hg 334 nm
Temperature:	37 °C
Sample:	Serum, EDTA-plasma, heparinized plasma
Linearity:	up to 120 U/L
Sensitivity:	The lower limit of detection is 2 U/L.

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 GPT (ALT) and GOT (AST), in the differential diagnosis of liver disorders. The calculation of the (GPT+GOT)/GLDH ratio enables to differentiate between inflammatory liver diseases and liver necrosis due to intoxication or ischemia.

TEST PRINCIPLE

α-Ketoglutarate + NH_4^+ + NADH <GLDH> L-Glutamate + NAD^+ + H_2O

Glutamate Dehydrogenase catalyzes the reduction of oxoglutarate and the simultaneous oxidation of NADH to NAD. The resulting rate of decrease in absorbance is directly proportional to the GLDH activity in the sample.

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION	
Reagent 1:		
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
Reagent 2:		
NADH	1.3	mmol/L

REAGENT PREPARATION

The reagents are ready to use.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light! Avoid contamination. Close immediately after use. Do not freeze the reagents!

Stability: at 2 – 8 °C up to the expiration date

SAMPLE STABILITY AND STORAGE

Stability [4]:

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

Discard contaminated specimens. Freeze only once!

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

MANUAL TEST PROCEDURE

Pipette into test tubes	37°C
Reagent 1	1000 µl
Sample	150 µl
Mix. Incubate for approximately 3 minutes at 37 °C. Then add:	
Reagent 2	250 µl
Mix. Read initial absorbance against air after 30 seconds and start a timer. Read absorbance again after exactly 1, 2 and 3 min. Determine ΔA during the linear part of the assay.	

CALCULATION

With factor (light path 1 cm)**:**

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

GLDH [U/L] = ΔA/min x factor

Factors (37 °C):

Factor at 340 nm	-1485
Factor at 334 nm	-1515

With calibrator:

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

UNIT CONVERSION

U/L x 0.01667 = µkatal/L

REFERENCE RANGE [1]*

Men	≤ 7 U/L (0.117 µkat/L)
Women	≤ 5 U/L (0.083 µkat/L)

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

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

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

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 2 U/L

PRECISION (at 37°C)

Intra-assay, n = 20	Mean [U/L]	SD [U/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, n = 20	Mean [U/L]	SD [U/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

SPECIFICITY/INTERFERENCES

no interference up to:

ascorbic acid	30 mg/dl
bilirubin	60 mg/dl
hemoglobin	500 mg/dl

Lipaemia interferes.
For further information on interfering substances refer to Young DS [5].

METHOD COMPARISON

A comparison between Dialab GLDH, DGKC (y) and a commercially available reagent according to DGKC (x) using 76 samples gave following results:
y = 1.034 x + 0.006 U/L; r = 0.999

CALIBRATION

The use of a GLDH Calibrator is optional.
We recommend the Dialab multi calibration serum **Diacal Auto**. This method is traceable to the molar extinction coefficient.

QUALITY CONTROL

All control sera with GLDH values determined by this method can be used.
We recommend the Dialab serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range).
Each laboratory should establish corrective action in case of deviations in control recovery.

AUTOMATION

Special adaptations for automated analysers can be made on request.

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.
6. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

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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.