GLDH (Glutamate dehydrogenase) Lyophilised Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Catalogue No.	*Quantity*	*Reagent*	*Storage*
GLC24048	2 x 19 mL	GLDH Reagent 1	2 – 8 °C
	2 x 19 mL	GLDH Reagent 1A	
	2 x 5 mL	GLDH Reagent 2	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of glutamate dehydrogenase (GLDH) in human serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION:

GLDH is a largely liver-specific enzyme found exclusively in the mitochondria and located predominantly within the liver cell acinus. GLDH activity in other organs such as the kidneys, pancreas. Heart, brain and intestines is negligible. Determination of GLDH activity is performed to diagnose liver disorders, and in particular to assess the severity of damage to individual cells. Necrotizing liver damage such as acute hepatic dystrophy, necrotizing hepatitis, multiple liver metastases and obstructive jaundice are accompanied by elevated GLDH activities in serum.In 1972, the German Society for Clinical Chemistry (DGKC) recommended the optimized standard method for determination of GLDH with optimized substrate concentration, NADH excess, and activation of GLDH by addition of ADP. The method described here is derived from the formulation recommended by the German Society for Clinical Chemistry (DGKC) and optimized for performance and stability.

PRINCIPLE OF THE TEST:

UV test according to a standardised method.

- Sample and addition of R1
- Addition of R2 and start of reaction

$$\alpha\text{-ketoglutarate} + NADH + NH_4^+ \xrightarrow{GLDH} \text{glutamate} + NAD^+ + H_20$$

GLDH catalyzes this NADH-dependent reaction; the equilibrium is on the side of glutamate and NAD. The decrease in NADH is directly proportional to the GLDH activity.

WARNINGS AND PRECAUTIONS:

In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination , do not use the reagent pack and contact your distributor.

Safety precautions:
For in vitro diagnostic use. Exercise the normal precautions required tor handling all laboratory reagents. Material Safety Data Sheet is available upon request.

Handling precautions:

- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration*
Reagent 1 & 1a	Triethanolamine Buffer, pH 8.0	60 mmol/L
	EDTA	< 5 mmol/L
	Ammonium acetate	124 mmol/L
	ADP	≥ 1.36 mmol/L
	NADH (yeast)	0.27 mmol/L
	LDH (rabbit muscle)	≤ 45 µkat/L
Reagent 2	Triethanolamine Buffer, pH 7.9	8.6 mmol/L
	α-ketoglutarate	< 50 mmol/L

REAGENT PREPARATION AND STABILITY:

Reagent 1 – Connect one bottle 1 to one bottle 1a using the enclosed adapter and dissolve the lyophilizate completely in the buffer.
Reagent 2 – ready for use.

If stored at 2-8°C and handled properly, unopened components are stable until expiry date stated on the label.
Reagent 1 – 7 days opened and refrigerated on the analyser.
Reagent 2 – 56 days opened and refrigerated on the analyser.

TYPE OF SPECIMEN:

For specimen collection and preparation only use suitable tubes or collection containers.
Only the specimens listed below were tested and found acceptable.
Serum
Plasma: Li-, Na- or NH_4^+-heparin plasma: K_3-EDTA plasma.

Centrifuge samples containing precipitates before performing the assay.

Stability: 7 days at 15-25°C
7 days at 2-8°C
4 weeks at (-15)-(-25)°C

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalogue No.*	*Description*	*Catalogue No.*
General Chemistry Calibrator	GL983	Photometer	N/A
General Chemistry Controls	GL922 / GL932	General Laboratory Equipment	N/A

Assay procedure:
Refer to relevant user's manual for instructions on instrument start-up, loading components and samples, calibration, sample testing procedures, calculating and reporting results.

Calibration:
Using the recommended calibrator, calibrate the assay:

- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part.
- When Quality Control results are out of range.

A 2-point calibration is recommended.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program:
Controls should be assayed:

- Prior reporting patient results.
- Following any maintenance procedure.
- At intervals established by the Q.C. laboratory programme.

CALCULATION:

The analyser automatically calculates the analyte activity of each sample.

Concentration factor: U/L x 0.0167 = µkat/L

EXPECTED VALUES:

	U/L	µkat/L
Men	Up to 6.4	Up to 0.11
Women	Up to 4.8	Up to 0.08
Consensus values for adults*		
Men	Up to 7.0	Up to 0.12
Women	Up to 5.0	Up to 0.08

Each laboratory should establish its own reference range. Results should always be reviewed with the patient's medical examination and history.

LIMITATIONS:

Limitations - interference
Criterion Recovery within ± 10 % of initial values.
Icterus[5]:No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).
Haemoylsis[5]: No significant interference up to an H index of 10 (approximate haemoglobin concentration: 6 µmol/L or 10 mg/dL).
Lipemia (Intralipid) [5]: No significant interference up to an L index of 180. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.
Pyruvate: No significant interference up to a pyruvate concentration of 300 µmol/L (26 mg/dL).
Ammonia, which is produced in the cuvette when determining GLDH, interferes with the determination of urea/BUN. The GLDH reagent must therefore not be placed on the analyser together with reagents for ammonia or the determination of urea/BUN.
Drugs: No interference was found at therapeutic concentrations using common drug panels.[6,7]
Physiological plasma concentrations of Sulfasalazine or Sulfapyridine may lead to false results. Temozolomide at therapeutic concentrations may lead to erroneous results.
In very rare cases, gammopathy (in particular, type IgM) (Waldenström's macroglobulinemia), may cause unreliable results.[8]

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

PERFORMANCE CHARACTERISTICS

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values

Measuring Range:
1 – 80 U/L (0.02 – 1.33 µkat/L).

Lower Detection Limit:
1 U/L (0.02 µkat/L).

Precision:

	Repeatability (N=21)			**Intermediate precision** (3 aliquots/run, 1 run/day, 21 days)		
Sample	Mean		CV	Mean		CV
	U/L	µkat/L	%	U/L	µkat/L	%
Human Serum	21	0.350	0.9	22	0.367	1.6
Precinorm U	13	0.217	1.4	13	0.217	2.7
Precipath U	22	0.367	0.8	22	0.367	2.2

Method Comparison:
Using 145 samples (sample activities were between 1.29 and 79.6 U/L), a comparison study gave the following results:

Passing/Bablok	y = 0.967x + 0.423	r = 0.941
Linear Regression	y = 0.960x + 0.491	r = 0.999

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SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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Glenbio
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Application Guide
Prestige/Biolis 24i

Application: GLUTAMATE DEHYDROGENASE (GLDH)

GLDH

Item No. :	*

Data Information	
Units	U/L
Decimals	1

Aspiration Volume	
Type	Double
R1 Volume (µL)	250
R2 Volume (µL)	50
Sample Volume (µL)	20

Analysis	
Method	RATE method
Main Wavelength	340 nm
Second Wavelength	405 nm

Data Processing		
Read	Start	End
Main	35	51
Sub		

Blank Value	Water

Absorbance Limit	-3	3

Calibration	
Type	Linear 1
Factor Value	N/A

Correction Value	
End Point Limit	3
Linearity Check %	0

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