Glutamate Dehydrogenase Assay Kit (GLDH)

Method:α-oxoglutarate Substrate

Cat . No.	Size	Instrument
GS8051G	R1:1×60 ml R2:1×20 ml	For Hitachi 7170/7180& Olympus AU640/400/600
GB8050G	R1:1×60ml R2:1×20ml	For Hitachi 7060/7150& ShimadzuCL7200/8000
GX8051G	R1:1×60ml R2:1×20 ml	For Beckman

INTENDED USE

For the *in vitro* quantitative determination of glutamate dehydrogenase in serum or plasma.

CLINICAL SIGNIFICANCE

Glutamate dehydrogenase (GLDH) is a mitochondrial enzyme present in all tissues. The physiological function of GLDH is the oxidative deamination of glutamate. Measurable increases in serum levels are indicative of hepatocellular necrosis.

Elevated serum GLDH levels indicate liver damage and GLDH plays an important role in the differential diagnosis of liver disease, especially in combination with aminotransferases. GLDH is localised in mitochondria, therefore practically none is liberated in generalised inflammatory diseases of the liver such as viral hepatitides. Liver diseases in which necrosis of hepatocytes is the predominant event, such as toxic liver damage or hypoxic liver disease, are characterised by high serum GLDH levels. GLDH is important for distinguishing between acute viral hepatitis and acute toxic liver necrosis or acute hypoxic liver disease, particularly in the case of liver damage with very high aminotransferases.

ASSAY PRINCIPLE

α-oxoglutarate+ NADH + NH^{4+} $\xrightarrow{GLDH}$ glutamate + NAD+ +H_2O

As NADH is oxidised, the decrease in the absorbance per minute is measured at 340nm and is proportional to the GLDH activity.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris/HCl buffer	50mmol/L
EDTA	2.5mmol/L
α-oxoglutarate	7mmol/L
Reagent 2 (R2)	
Tris/HCl buffer	50mmol/L
ADP	1.0mmol/L
NADH	0.2mmol/L

SAMPLE COLLECTION AND PREPARATION

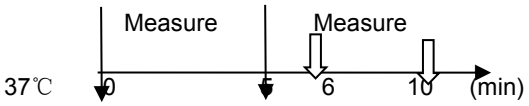
Fresh serum or plasma(EDTA or Heparin anticoaglulation). Sample can be stored at 4 ℃ for 7 days, at -20 ℃ for 4 weeks.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi 7180)
Assay Mode: Rate A 22-34
Wave length (sub/main): 405/340nm
Sample 16 µl
R1: 150µl R2: 50 µl



CALIBRATION

Recommend using Randox serum calibration-CAL2351/CAL2350.

CALCULATIONS OF RESULTS

Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of GLDH in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

For quality control, use Randox human serum HN1530/HE1532 as daily quality control and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Man < 7.0 U/L
Female < 5.0 U/L
It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

In the range of 2 ~ 120 U/L , the linear correlation

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CE version 2014

coefficient r ≥ 0.990. In the range of 2 ~ 20 U/L (containing 20 U/L), linearity deviation shall not exceed ± 2 U/L. Between 20 ~ 120 U/L, the linear deviation should not exceed ± 10%.

PRECISION

The CV of the test should be ≤ 10%.

Intar assay precision		
N=20	level 1	level 2
Mean(U/L)	15.6	30.4
SD	0.41	0.48
CV(%)	2.61	1.58

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(U/L)	15.6	15.7	15.5
$\bar{x}$	15.6		
(Xmax-Xmin)/$\bar{x}$	(15.7-15.5)/15.6*100=1.29%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Ascorbic acid: up to 50 mg/dl
Bilirubin: up to 50 mg/dl
Hemoglobin: up to 200 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

References

1. Bar-Or, D., et al., Characterization of the Co^{2+} and Ni^{2+} binding amino-acid residues of the N-terminus of human albumin. European Journal of Biochemistry, 2001. 268(1): p. 42-48.
2. Sinha, M.K., et al., Ischemia modified albumin is a sensitive marker of myocardial ischemia after percutaneous coronary intervention. Circulation, 2003. 107(19): p. 2403.
3. Bar–Or, D., E. Lau, and J.V. Winkler, A novel assay for cobalt-albumin binding and its potential as a marker for myocardial ischemia—a preliminary report. The Journal of emergency medicine, 2000. 19(4): p. 311-315.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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