LiquiCHEK™

AGAPPE

LDH-P (S.L)

2 x 10 mL, 2 x 30 mL
11407001, 11407004

Intended Use

This reagent is intended for *in vitro* quantitative determination of Lactate dehydrogenase in serum or plasma.

- Based on SCE recommended method
- Linear up to 2400 U/L

Clinical Significance

This enzyme is found in all organ cells, but especially plentiful in cardiac & skeletal muscle, liver, kidney & RBC. LDH is found in the form of iso-enzymes based on their electrophoretic mobility with each iso-enzymes being primarily from different organs.

Elevated levels are found in myocardial infarction, liver diseases, hemolytic anaemias, pernicious anaemia, Leukemia & Pulmonary diseases. Elevations in acute MI reaches a peak in 48-72 hrs. belonged elevations, (10-14 days) are useful in the late diagnosis of the condition.

Principle

Kinetic determination of lactate dehydrogenase according to the following reaction.

$$\text{Pyruvate} + \text{NADH} + H^+ \xrightarrow{\text{LDH}} \text{L-Lactate} + NAD^+$$

Kit Components

Reagent/ Component	Product Code: 11407001	Product Code: 11407004	Description
LDH-P (S.L) R1	2 x 8 mL	2 x 24 mL	Tris buffer (pH 7.4) - 80 mmol/L Pyruvate -1.6 mmol/L Sodium chloride - 200 mmol/L
LDH-P (S.L) R2	2 x 2 mL	2 x 6 mL	NADH-240 mmol/L

Risk & safety

Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation

Mix 4 volumes of Reagent 1 (R1) with 1 volume of Reagent 2 (R2)

The working reagent is stable for 21 days at 2-8^{0}C.

NOTE: Discard the working reagent if the blank absorbance is less than 1.0 at 340 nm.

Reagent Storage and Stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8^{o}C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks if contamination is avoided.

On-board Calibration Stability

On-board Calibration stability is 20 days

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualichek Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using a fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.

Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management

Reagents must be disposed off in accordance with local regulations.

Sample

Serum / plasma (free of haemolysis).

Interferences

No interference for

Bilirubin up to	20 mg/dL
Turbidity up to	600 mg/dL

Note: Haemolysed sera should not be used since significant haemolysis may increase LDH concentration because of high levels of LDH in erythrocytes.

Materials Provided

LDH-P (S.L) Reagent R1& R2

Materials required but not provided

- Pipettes& Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameter

Mode of Reaction	Kinetic
Slope of reaction	Decreasing
Wavelength	340 nm
Temperature	37^{0}C
Factor	16030
Blank	DI Water
Linearity	2400 U/L
Delay	60 sec.
No of reading	3
Interval	60 sec
Sample volume	10 µL
Reagent volume	1000 µL
Cuvette	1 cm light path

Application parameters for various instrument are available. Please contact customer support department for specific information.

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
U/L	µKat/L	x 0.017

Calibration

Agappe multi calibrator is recommended for calibration of this assay on fully auto analyzer.

Use provided factor (16030) for estimation of LDH-P on semi auto analyzers

Procedure notes

Laboratory procedure for Semi Auto Analyzer	
Working reagent	1000 µL
Sample	10 µL
Mix and incubate at 37^{0}C for 1 minute. Measure the change in absorbance per minute (△ OD/min) during 3 minutes.	

Calculation

LDH-P activity (U/L) = (△ OD/min) x 16030

Quality control

It is recommended to use Agappe Qualicheck Norm & Path (11601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

AGAPPE DIAGNOSTICS LTD.
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Rev.02.020720

CE ISO 9001 : 2015
EN ISO 13485: 2016

Reference Range

It is recommended that each laboratory establish its own reference values.

The following values may be used as guide line.

Serum /Plasma :	1- 3 years	:490-730 U/L
	4 - 9 years	:320-520 U/L
	10 - 13 years	:250-500 U/L
	Adults	:225-450 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1. **Linearity**
   This reagent is linear up to 2400 U/L.
   If the concentration is greater than linearity (2400 U/L) dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.
2. **Comparison**
   A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.988 and a regression equation of y = 0.9963 .

3. Precision

Intra Run		
	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	351.3	850.6
SD	9.7	17.2
CV(%)	2.8	2.0

Inter Run		
	Control Level 1	Control Level 2
n	20	20
Mean (U/L)	347.73	835.01
SD	7.35	24.34
CV(%)	2.11	2.92

Accuracy (U/L)		
Control	Expected Value	Measured Value
Control Level 1	365 ± 90	380
Control Level 2	855 ± 180	910
Qualichek Norm	335 ± 75	335.4
Qualichek Path	600 ± 75	621.8

Sensitivity

Lower detection Limit is 0.2 U/L.

Bibliography

1. Z.Klin. chem. Klin Biochem.8,658 (1970), 1, 1820(1972)
2. Wei Bhaar, D., *et al.*; Med.Welt 26,387 (1975)
3. Burtis, Ashwood, Bruns & Saunders : Tietz Text Book of Clinical Chemistry 4th Edition -2006

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