Lactate Dehydrogenase (LDH)
(SCE/DGKC Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **LH0011**	R.1: 2x 50 ml R.2 1x20ml total 120 ml	2-8°C
Cat. No.: **LH0111**	R.1: 4x 50 ml R.2 1x40ml total 240 ml	2-8°C
Cat. No.: **LH0017**	R.1: 2 x 50 ml R.2 1x 20ml total 120 ml	2-8°C
Cat. No.: **LH0117**	R.1: 4x 50 ml R.2 1x40ml total 240 ml	2-8°C

- **Intended Use:**

In Vitro Diagnostic reagent pack for the quantitative determination of LDH, in human serum/plasma on automated and semi-automated photometric systems.

- **Summary and Explanation:**

Lactate dehydrogenase (LDH) contain 4 poly peptide chains with 5 iso enzymes. This enzyme has two kinds: M for muscles and H for heart. The action of this enzyme is catalyzed reaction to convert pyruvate to lactate. The LDH enzyme can be find on cytoplasm of entire human body tissue and not belong to the specific tissue. The high concentration of LDH where find in other tissues such as liver, skeleton muscles and heart. However, the low concentration of LDH where find in other tissues like pancreas, kidney, stomach and red blood cells. The increase of LDH has a pathological sign in some conditions such as viral hepatitis, liver metastasis carcinoma, heart diseases (heart infarction), lung, kidney tumors and hemolytic diseases. Therefore, this measuring should be beside of measuring liver enzymes such as ALP, ALAT and ASAT to evaluate, analysis and diagnostic the condition.

Principle of the Method:

The principle of this assay is measurement of lactate dehydrogenase (LDH). Lactate dehydrogenase enzyme convert pyruvate to lactate. Also, in this reaction NADH oxidase to NAD+. The reduce speed of NADH will be measurement on 340 Nano meter which is related to amount of LDH on the sample.

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

- **Reagent Preparation and Stability:**

Reagent is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date. Do not freeze and protect from light.
If using single reference depending usage, 1 vol of R2 with 5 vol R1 should mixed(Ratio1:5.)
The stability of ready to use reference is 5 days.
R1 is transparent and colorless.
R2 is transparent and colorless.

Waste Management:

Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**

For In Vitro Diagnostics Use Only.
For Professional Use Only.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
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.

- **Type of Specimen:**

Use fresh serum, non-hemolysis, plasma heparinized with EDTA.(Extremely avoid to use oxalate) The stability of LDH in serum/plasma samples at 2-8°C for 3 days and at -20°C for 1 months.
The serum should be collected from the blood less than 2 hours.
Decreased LDH activity at 2-8°C after 3 days is less than 8% but in 15-25 °C may less than 2%.

Required but not Supplied:

General chemistry calibrator from TKS or other valid calibrators.
General chemistry control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**

Carefully read instructions for use.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.
Disposable and glassware material used must be free of metals, ions and detergents.

Performance Characteristics:

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

Maximum determination in this assay is 1256 U/L
LOD: 10 U/L
For samples with a higher concentration (1256 U/L), dilute 1:4 with 0.9 % NaCl and re-assay. Multiply result by 5.

Precision:

Intra Assay-Within run LDH

Sample	n	Mean (U/L)	SD (U/L)	CV (%)
1	20	391	9.51	2.43
2	20	601	12.43	2.07

Inter Assay-Between run LDH

Sample	n	Mean (U/L)	SD (U/L)	CV (%)
1	20	400	16.78	4.2
2	20	757	44.69	5.9

- **Accuracy:**

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.997
Regression equation: Y = 0.987 (X) + 0.640 U/L
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**

The less concentration of below items are not interfering in this assay. The hemolysis has interference in this assay.

Bilirubin (mixed isomer)	Less than 10% interference up to 600 µmol/l Bilirubin
Lipemia	Less than 10% interference up to 2.5 g/L Intralipid

- **Reference Values:**

Temperature	At 25 °C	At 30 °C	At 37 °C
Adult	**105-210 U/L**	**140-280 U/L**	**200-400 U/L**

Premature infants	**<1103 U/L**
One day infants	**<1327 U/L**
2-5 days infants	**<1732 U/L**
6 days – 6 months infants	**<975 U/L**
7-12 months infants	**<1100 U/L**
Child 1-3 years	**<850 U/L**
Child 4-6 years	**<615 U/L**
Girls 7-12 years	**<580 U/L**
Boys 7-12 years	**<746 U/L**
Girls 13-17 years	**<436 U/L**
Boys 13-17 years	**<683 U/L**

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Each laboratory should establish its own expected values. The LDH results should always be reviewed with the patient's medical examination and history.

- **Assay Procedure:**

Allow reagents to reach working temperature before using.

Assay conditions:

340nm	**Wavelengths**
30°C (25°C or 37°C)	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
1000 µl	1000 µl	**R1**
20 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate 37°C **for 5 minutes**. then added R2.		

200 µl	200 µl	**R2**
Gently mix and incubate 37°C for 2 minutes. Measure the A sample and calibrator. Then turn on the counter after 1,2 and 3 minutes after the start of reaction, measure the absorbance. **ΔOD/min**		

Calibrator/sample/Control	**Blank**	**Single reference**
1000 µl	**1000 µl**	**Reference ready to use**
20 µl	-	**Calibrator/sample/Control**
Gently mix and incubate 30°C (25 or 37) for 2 minutes. Measure the A sample and calibrator. Then turn on the counter after 1,2 and 3 minutes after the start of reaction, measure the absorbance. **ΔOD/min**		

- **ΔA/min=ΔA/sample or calibrator – ΔA/min Blank**

- **Calculations:**

LDH (U/L) = $\frac{\text{ΔOD sample/min}}{\text{ΔOD Cal/ min}}$ x Cal.Conc. (U/L)

Calculation with two references

LDH(U/L) = ΔA/min x 9682

Calculation with single reference

LDH(U/L) = ΔA/min x 8095

Conversion units:

LDH (µkat/l) = LDH (U/L) x 0.0167

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 362-366 and 993.

2-Ann. Biol. Clin. 40 (1982) 123.

3-Guder WG, Narayanan S, Wisser H, Zawta B. List of Analytes Preanalytical Variables. Brochure in: Samples: From the patient to the Laboratory. Darmstadt: GIT Verlag, 1996.

4-Amador E, et al (1963) Clin Chem 9:331.

5-Fischbach F, Zawta B. Age-dependent reference limits of several e enzymes in plasma at different measuring temperatures. Klin Lab 1 1992; 38:555-61.

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Symbols:

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics	Σ	Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight

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ISO 13485:2016
ISO 9001:2015

IVD