Lipase(LIP)
(Enzymatic/Colorimetric Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **LI0011**	R.1: 1x 40 ml R.2 1x10ml total 50 ml	2-8°C
Cat. No.: **LI0017**	R.1: 1 x 40 ml R.2 1x 10ml total 50 ml	2-8°C

- **Intended Use:**

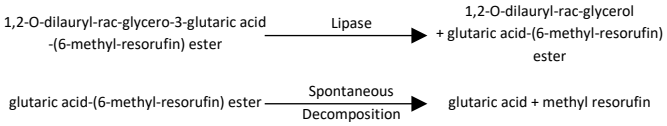
In Vitro Diagnostic reagent pack for the quantitative determination of Lipase, in human serum on automated and semi-automated photometric systems.

- **Summary and Explanation:**

The lipase enzyme is hydrolyzed lipids to the glycerol and fatty acids. The major of this enzyme is in pancreas. However, there is small amount of lipase in salivary glands, bowl mucus and lung. The acute injury in pancreas lead to entrance the lipase to the blood stream. So, the concentration of this enzyme during 4 to 8 hours elevated and finally after 24 hours the concentration will in highest amount that should be. The lipase test is critical even the increase of it is more later compare to amylase. Therefore, this increasing indicates that some disease such as cholecytitis, chronic pancreatitis, pancreas carcinoma, pancreas clogged ducts and bowl torsion.

Principle of the Method:

The principle of this assay is measurement the level of Lipase. The exclusive substrate in the present of lipase is broken and make color complex. The intensity of color is related to amount of lipase in the sample which can measure at 578 Nano.



- **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. R1 is transparent and colorless but R2 is turbidity and orange.

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- haemolysied and plasma heparinized. (Avoid to using oxalate, citrate, fiuoride and ADTA due to suppress the Lipase activity) The stability of Lipase in serum/plasma samples at 2-8°C for 2 days and at-20°C for 2 months. Avoid contamination samples.
The serum should be collected from the blood less than 2 hours.

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 150 U/L
LOD: 5 U/L
For samples with a higher concentration (150 U/L), dilute 1:4 with 0.9 % NaCl and re-assay. Multiply result by 5.
Precision:
Intra Assay-Within run Lipase

Sample	n	Mean (mg/dl)	SD (mg/L)	CV (%)
1	20	119	4.13	3.34
2	20	215	5.97	2.78

Inter Assay-Between run Lipase

Sample	n	Mean (mg/L)	SD (mg/L)	CV (%)
1	20	119	5.43	4.54
2	20	215	10.7	5.02

- **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 = 0.50054 (X) + 3.9443 mg/L
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**

Bilirubin (mixed isomer)	No interference up to 20 mg/dl Bilirubin
Triglycerides	Less than 10% interference up to 300 m g/dl triglycerides
Haemolysis	Less than 10% interference up to 150mg/dl Hemoglobin.

- **Reference Values:**

Adults	**< 60 U/L**

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

- **Assay Procedure:**

Allow reagents to reach working temperature before using.
A proportional variation of the reaction volumes indicated does not change the result
Assay conditions:

578nm	**Wavelengths**
37°C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

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Control/Sample/Calibrator	Blank	
1000 µl	1000 µl	**R1**
25 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate 37°C **for 3 minutes**. then added R2.		

250 µl	250 µl	**R2**
Gently mix and incubate for 2 minute at 37°C. Measure the sample and calibrator. Turn on the counter exactly 1 and 2 min after start reaction measure the absorbance. **ΔAbs/min.**		

ISO 13485:2016
ISO 9001:2015

IVD

- **Calculations:**

The calculation of change of absorbance ΔA is should applied by after 1 minutes and 2 minutes added together. then divided by 2. The average change absorbance for samples, calibrators and blank should calculated.

$$\text{Lipase (U/L)} = \frac{\Delta A \text{ sample} - \Delta A \text{ Blank}}{\Delta A \text{ Calibrator}} \times \text{Cal.Conc. (U/L)}$$

Conversion units:

Lipase (µKat/l) = (U/L) x 0.017

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

- **References:**

1- Greiling H, Gressner AM, eds. Lehrbuch der Klinischen Chemie und Pathobiochemie, 3rd ed. Stuttgart/New York: Schattauer Verlag, 1995.

2- Keller H, ed. Klinisch-Chemisch Laboradiaqnostik fur die Praxis, 2nd ed. Stuttgart/New York: Georg Thieme Verlag, 1991:354- 361.

3-Kazmierczak S, Catrou P, Van Lente F. diagnostic accuracy of pancreatic enz. evaluated by use of multivariate data analysis. Clin. Chem. 1993; 39:1960-1965.

4-Steinberg WM, Goldstein SS, Davies ND et al. Diagnostic assays in acute pancreatitis [Review]. Ann Intern Med 1985; 102:576-580.

5-Panteghini M et al. Diagnostic value of four assays for lipase determination in serum: A comparative reevaluation. Clin Biochem 1991; 24:497-503.

6-Tietz NW et al. Lipase in serum – the elusive enzyme: An overview. Clin Chem 1993; 39:746-756.

7-Tietz NW. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, Pa: WB Saunders, 1995:865.

8-Neumann U et al. new substrates for the optical determination of lipase. EP 207252 (1987).

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

Rev 01: Issued on 20 February 2023

Revised:20231129