

### • Kit Specifications:

	Reagent/Quantity	Storage
Cat. No.: <b>LD0211</b>	R1.1 x 45 ml R2.1 x 15 ml total 60ml	2-8°C
Cat. No.: <b>LD0011</b>	R1.3 x 40 ml R2. 2 x 20 ml total 160 ml	2-8°C
Cat. No.: <b>LD0111</b>	R1.6 x 40 ml R2. 2 x 40 ml total 320 ml	2-8°C
Cat. No.: <b>LD0217</b>	R1.1 x 45 ml R2.1 x 15 ml total 60 ml	2-8°C
Cat. No.: <b>LD0017</b>	R1.2 x 60 ml R2. 2 x 20 ml total 160 ml	2-8°C
Cat. No.: <b>LD0117</b>	R1.4 x 60 ml R2. 2 x 40 ml total 320 ml	2-8°C

### • Intended Use:

In Vitro Diagnostic reagent pack for the quantitative determination of low density lipoprotein, LDL- Cholesterol in serum, plasma on automated and semi-automated photometric systems.

### • Summary and Explanation:

Cholesterol, synthesized by body cells and absorbed with food, is a component of cell membranes, a precursor for steroid hormones and bile acids. Cholesterol is transported in plasma via lipoproteins, complexes between lipids and Apo lipoproteins. Four lipoprotein classes exist: High density lipoproteins (HDL), low density lipoproteins (LDL), very low density lipoproteins (VLDL) and chylomicrons. These classes show distinct relationship to coronary atherosclerosis. LDL is involved in the cholesterol transport to the peripheral cells, contributing to atherosclerotic plaque formation within the arterial intima and is strongly associated with coronary heart disease (CHD) and related mortality. The elevated LDL-C levels usually correlate with increased cardiovascular high risk of atherosclerotic heart disease, even at or below recommended. LDL-C goals, preferred screening tests for dyslipidemia or lipid disorders are total cholesterol (TC) and HDL-C but the majority of screening guidelines nowadays recommend a full lipid profile including TC, LDL-C, HDL-C and triglycerides. However, these techniques require physical separation via centrifugation, which is not suited to large scale laboratory use. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

### • Principle of the Method:

The direct LDL Cholesterol assay is a homogeneous method for directly measuring serum LDL-C levels without the need for any pre-treatment and centrifugation steps. First step, the substances with high affinity to block HDL, VLDL and chylomicrons to involving in this enzyme reaction. Second step is the one exclusive surfactant release LDL in the enzymatic reaction and the color complex appear. The base on measurement at (578-620) 600 Nano meter. The intensity of the color is related to the amount of LDL on the sample.

LDL/VLDL/Chylomicrons  $\xrightarrow{\text{CHE+CO}}$  elimination LDL/VLDL/Chylomicrons

HDL + Cholesterol + O<sub>2</sub>  $\xrightarrow{\text{POD}}$  Cholestenone + H<sub>2</sub>O<sub>2</sub>

H<sub>2</sub>O<sub>2</sub> + 4-Aminoantipyrine + HSDA  $\xrightarrow{\text{POD}}$  Colored Compound

### • 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 reagent over the expiration date.

Do not freeze and protect from light.

R1: transparent and light yellow.

R2: 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.

Carefully read instructions for use.

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 and non-haemolysed serum or heparinized plasma, as specimen.

Do not use EDTA plasma.

Specimen must be completely cleared before assay.

It is recommended to follow CLSI procedures (or similar standardized conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. The stability of the samples on 6 days at 2-8°C and -20°C for 7 days. The serum/plasma should be collected immediately after blood collection. Avoid any contamination, freezing and DE freezing the samples.

### • Materials Required but not Supplied:

Direct HDL/LDL Cholesterol Calibrator from TKS or other valid calibrators.

Lipid 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** 700 mg/dl.

For samples with a higher concentration (700 mg/dl), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.

**LOD:** The lowest detectable level was estimated at 2 mg/dl.

### Precision:

#### Intra assay-Within run LDL-C

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	100.3	0.46	0.45
2	20	159.6	0.39	0.24

#### Inter assay-Between run LDL-C

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	103.1	0.77	0.74
2	20	141	1.5	1

### • Accuracy:

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).

**Correlation coefficient (r):** 0.9978

**Regression equation:** Y = 1.0166 (X)

The results of the performance characteristics depend on the analyzer used.



### Interfering Substances:

No interferences were observed to:

Ascorbic acid	Less than 5% interference up to 50 mg/dl
Haemolysis	Less than 5% interference up to 500 mg/dl
Bilirubin (free)	Less than 5% interference up to 20 mg/dl
Intralipid	Less than 5% interference up to 500 mg/dl

### Reference Values:

NCEP Classification of LDL cholesterol	Adults mg/dl	Adults mmol/L	Children & Adolescents mg/dl	Children & Adolescents mmol/L
Desirable	<130	<3.36	<110	<2.85
Borderline	130 to 160	3.36-4.15	110-120	2.85-3.11
High	≥ 160	>4.15	≥130	>3.37

Each laboratory should establish its own expected values. The LDL-C 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:

Wave length	600 nm
Temperature	37°C
Cuvette	1 cm

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	Blank	
900 µl	900 µl	R1
12 µl	-	Control/Sample/Calibrator
Gently mix and incubate at 37°C for 5 minutes. Measure the first absorbance A1 and A calibrator against the blank.		

300 µl	300 µl	R2
Gently mix and incubate 37°C for 5 minutes. Measure the second sample A2 and calibrator against the blank. $\Delta A = A2 - A1$		

### Calculations:

$$\text{LDL-C (mg/dl)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Calibrator}} \times \text{Conc. Cal (mg/dl)}$$

### Conversion Factor:

$$\text{LDL-C (mg/dl)} \times 0.02586 = \text{LDL-C (mmol/L)}$$















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

### References:

- 1-Izawa, S., et.al. A new Direct Method for measuring HDL-Cholesterol, J. Med. and Pharm. Sci., 37,1997,1385-88.
- 2-Schaefer EJ, McNamara J. Overview of the diagnosis and treatment of Lipid disorders. In: Raffia N, Warnick GR, Dominiczak MH, eds. 3-Handbook of Lipoprotein testing. Washington: AACC Press;1997. p.25-48.
- 4-Tietz N., Fundamentals of clinical chemistry Philadelphia W.B. Saunders 335-337, 1976.
- 5-Young D.S., Effect of Drugs on Clinical Laboratory Tests, AACC 5th ed.2000
- 6-Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 6th edition (2018).
- 7-Rifai N, Warnick GR. ed. Laboratory Measurement of Lipids, Lipoproteins and Apolipoproteins. AACC Press, Washington, DC, USA, 1997.
- 8-Recommendation of the second Joint Task Force of European and other Societies on Coronary Prevention. Prevention of coronary heart disease in clinical practice; Eur. Heart J. 1998; 19:1434-1503.
- 9-Third report of the National Cholesterol Education Programmed (NCEP) Expert Panel on detection, Evaluation and treatment of High blood cholesterol in adults (Adult treatment Panel III). JAMA Publication, Vol 285, No.19, P2486-2497; 2001.
- 10-Shih WJ, Bachorik PS, Haga JA, Myers GL, Stein EA; Clinical Chemistry, 2000; 46:3:351-364.

### Symbols:

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

 IVD	In Vitro Diagnostics		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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