

FOR IN VITRO DIAGNOSTIC USE

# LDL - Cholesterol

## Enzymatic Selective Protein method

- Direct method with no sample preparation
- Convenient, ready-to-use liquid type reagent
- No significant interference from serum components
- Suitable for automated analyzers



In recent years, in addition to total cholesterol, low density lipoprotein cholesterol (LDL-C) has become an important tool used to assess an individual risk of developing coronary heart disease (CHD) since a strong positive relationship between LDL-C concentration and the incidence of CHD exists. Thus, there has been substantial interest in LDL-C measurements, and most clinical laboratories routinely perform LDL-C analysis.

The currently accepted reference method is generally referred to as “beta quantification,” which involves ultracentrifugation. Because this method is labor intensive and technique dependent, it is not generally used for routine testing. The Friedewald formula is most commonly used for routine purposes. However, since the formula estimates the LDL-C level from measurements of total cholesterol, triglyceride and high density lipoprotein cholesterol (HDL-C), the LDL-C calculation depends on the accuracy and precision of the three measurements.

The FUJIFILM Wako L-Type LDL-C assay is a homogeneous assay, which eliminates the preparatory steps or calculation, and thus, can be applied on automated analyzers. The L-Type LDL-C is an in vitro assay for the quantitative determination of LDL cholesterol in serum or plasma.

Catalog No.	Product Name	Pkg Size	Storage
993-00404	L-Type LDL-C Reagent 1	2 x 60 mL	2-10°C
999-00504	L-Type LDL-C Reagent 2	2 x 20 mL	2-10°C
990-28011	HDL-C/LDL-C Calibrator	4 x for 3 mL	2-10°C

## PERFORMANCE CHARACTERISTICS

### Principle

The protecting reagent in Reagent 1 binds to LDL and protects LDL from enzyme reactions. Cholesterol esterase and cholesterol oxidase in Reagent 1 react with non-LDL lipoproteins (HDL, VLDL, and chylomicron). Hydrogen peroxide produced by the enzyme reactions with non-LDL cholesterol is reduced to H<sub>2</sub>O by catalase in Reagent 1. When Reagent 2 is added, the protecting reagent is removed from LDL and catalase is inhibited by sodium azide (NaN<sub>3</sub>.) Hydrogen peroxide produced by the enzyme reactions with LDL-C yields a blue color complex upon oxidase condensation with Trinder's reagent and 4-aminoantipyrine in the presence of peroxidase. By measuring the absorbance of the blue color complex, the LDL-C concentration in the sample can be calculated when compared with the absorbance of the HDL-C/LDL-C Calibrator.

### Accuracy

The accuracy of this method was demonstrated by a recovery study.

No.	Expected value (mg/dL)	Obtained value (mg/dL)	Recovery (%)
1	15.0	15.6	104
2	30.6	31.2	102
3	76.2	76.1	100

### Comparison

Comparison studies were done to compare the FUJIFILM Wako direct LDL assay with the reference method (beta-quantification) and a commercially available homogeneous direct LDL method.

	FUJIFILM Wako LDL vs. Reference Method	FUJIFILM Wako LDL vs. Homogeneous LDL	
		Serum	Plasma
n	60	60	60
Mean (mg/dL)	x=136.6 y=137.1	x=117.0 y=119.3	x=109.1 y=110.8
Regression	y=0.97x+5.12	y=1.018x+0.135	y=0.98x+4.18
Correlation coefficient	r=0.983	r=0.986	r=0.998

### Precision

#### Within-run precision

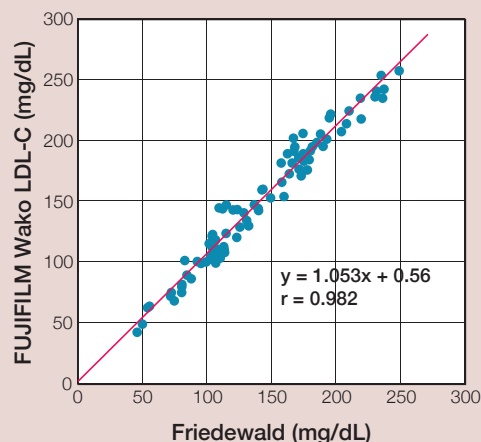
Sample #	Replicates	Mean (mg/dL)	SD	CV (%)
1	10	101.2	0.62	0.61
2	10	164.5	0.72	0.43

#### Total precision

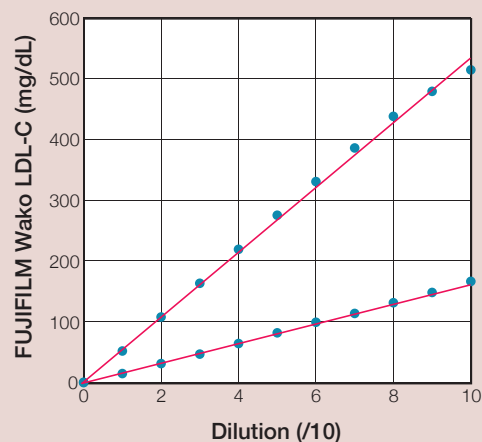
Number of assay days	Replicates	Mean (mg/dL)	SD	CV (%)
24	2	126.2	0.761	0.60
24	2	225.8	1.229	0.54

### Correlation

Assigned values for the calibration are based upon US CDC reference methods.



### Linearity 1 - 400 mg/dL



### Interference Studies

	No interference up to
Ascorbic Acid	50 mg/dL
Bilirubin, free	50 mg/dL
Bilirubin, conj.	40 mg/dL
Hemoglobin	500 mg/dL

### Instruments

Various automated analyzer applications are available.

# FUJIFILM

FUJIFILM Healthcare Americas Corporation  
81 Hartwell Avenue, Suite 300, Lexington MA 02421  
ivd.fujimed.com

For additional information, please contact us at:  
email: fmsuivdsalesinquiry@fujifilm.com

© 2021 FUJIFILM Healthcare Americas Corporation

DOC-0048266-B