

FOR IN VITRO DIAGNOSTIC USE

HDL - Cholesterol

Immunoinhibition method

- Excellent correlation with CDC reference method
- Direct method with no sample preparation
- Convenient, ready-to-use liquid type reagent
- No significant interference from serum components
- No metal ion precipitation step



High density lipoprotein cholesterol (HDL-C), in addition to total blood cholesterol levels, are important tests used to assess an individual risk of developing coronary heart disease (CHD), since a strong negative relationship between HDL-C concentration and the incidence of CHD exists. Thus, there has been substantial interest in HDL-C measurements, and most clinical laboratories routinely perform HDL-C analysis. HDL-C can be measured by methods such as ultracentrifugation, precipitation, high performance liquid chromatography (HPLC), and more recently by direct methods.

The FUJIFILM Wako L-Type HDL-C assay is a direct method consisting of convenient liquid type reagents and employs a specific antibody which allows this assay to be directly measured on automated analyzers. The L-Type HDL-C test is an in vitro assay for the quantitative determination of high density lipoprotein cholesterol in serum.

Catalog No.	Product Name	Pkg Size	Storage
997-72591	L-Type HDL-C Reagent 1	4 x 270 mL	2-10°C
993-72691	L-Type HDL-C Reagent 2	4 x 90 mL	2-10°C
991-00101*	L-Type HDL-C Reagent 1	4 x 600 mL	2-10°C
997-00201*	L-Type HDL-C Reagent 2	4 x 600 mL	2-10°C
990-28011	HDL-C/LDL-C Calibrator	4 x for 3 mL	2-10°C

* Product size is available as a special purchase only.

PERFORMANCE CHARACTERISTICS

Principle

Anti-human B-Lipoprotein antibody in Reagent 1 binds to lipoproteins (LDL, VLDL, and chylomicrons) other than HDL. The antigen-antibody complexes formed block enzyme reactions when Reagent 2 is added. Cholesterol esterase and cholesterol oxidase in Reagent 2 react only with HDL-C. Hydrogen peroxide produced by the enzyme reactions with HDL-C yields a blue color complex upon oxidase condensation with FDAOS* and 4-aminoantipyrine in the presence of peroxidase. By measuring the absorbance of the blue color complex, the HDL-C concentration in the sample can be calculated when compared with the absorbance of the HDL-C/LDL-C Calibrator.

*N-ethyl-N-(2-hydroxy-3-sulfo-propyl)-3, 5-dimethoxy-4-fluoroaniline, sodium salt

Accuracy

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

No.	Expected value (mg/dL)	Obtained value (mg/dL)	Recovery (%)
1	31.3	30.2	96.5
2	14.8	15.3	103.4
3	7.5	7.6	101.3

Precision

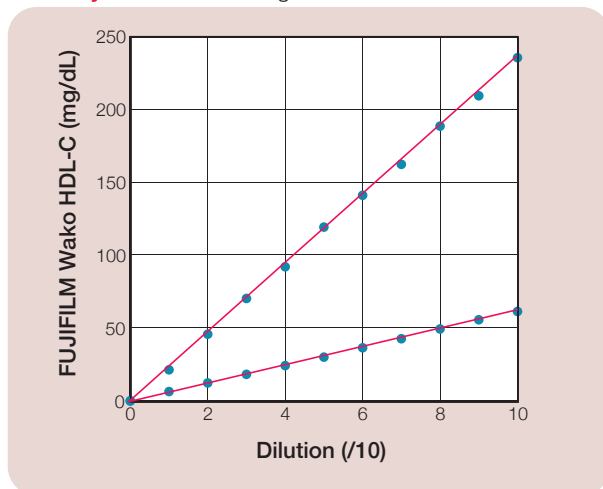
Within-run precision

Sample #	Replicates	Mean (mg/dL)	SD	CV (%)
1	20	31.4	0.36	1.15
2	20	53.6	0.32	0.60
3	20	73.1	0.70	0.96

Total precision

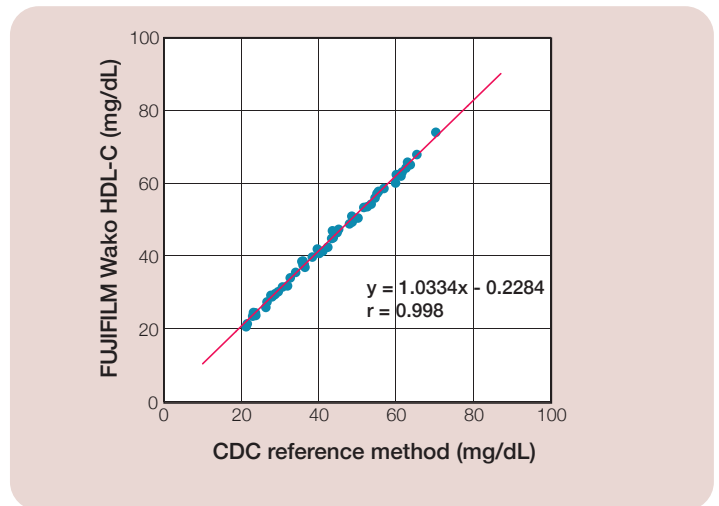
Number of assay days	Replicates	Mean (mg/dL)	SD	CV (%)
22	2	68.9	1.67	2.42
22	2	23.2	0.56	2.41
22	2	112.2	2.38	2.12

Linearity 1 - 180 mg/dL



Correlation

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



Interference Studies

Interfering Substance	No interference up to
Ascorbic Acid	50 mg/dL
Bilirubin, free	40 mg/dL
Bilirubin, conj.	40 mg/dL
Hemoglobin	500 mg/dL
Triglyceride	1600 mg/dL
Turbidity	5%

Instruments

Various automated analyzer applications are available.

FUJIFILM

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