

N-geneous[®] LDL Reagent

FOR THE QUANTITATIVE MEASUREMENT OF LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C)

METHOD: ENZYMATIC (DIRECT HOMOGENEOUS); ENDPOINT

LDL-C measurements are a useful tool in identifying patients at increased risk of coronary artery disease.

The Sekisui N-geneous[®] LDL assay is a homogeneous method for directly measuring LDL-C levels in serum or plasma, without the need for any off-line pre-treatment or centrifugation steps. The assay directly measures LDL-C levels in serum and plasma samples.

Features:

- Correlates to the Reference Method (Ultracentrifugation) and immunoseparation method
- Meets 1998 NCEP total error goals for both normal and high triglyceride samples
- Liquid stable, ready to use reagents
- Non-fasting serum or plasma samples are acceptable

Benefits:

- Confidence in results and correct classification of patients
- Easy to use, no additional preparation required
- Convenient and ensures accuracy regardless of patient fasting status

Performance Characteristics

Precision

- Within-Run: $\leq 0.73\%$
- Total Precision: $\leq 2.27\%$

Accuracy^(a)

- Slope: 0.95
- Intercept: 3.02 mg/dL (0.08 mmol/L)
- Correlation Coefficient: 0.96

Linearity

- 6.6-992 mg/dL (0.17-25.65 mmol/L)

No Significant Interferences Up to Levels Indicated

- Triglyceride: 1293 mg/dL (14.6 mmol/L)
- Ascorbic Acid: 50 mg/dL (2840 $\mu\text{mol/L}$)
- Bilirubin: 20 mg/dL (342 $\mu\text{mol/L}$)
- Hemoglobin: 500 mg/dL (78 $\mu\text{mol/L}$)
- Gamma Globulins: 5000 mg/dL (50 g/L)

Reference Range⁽¹⁾

LDL CHOLESTEROL	CLASSIFICATION
<130 mg/dL (3.36 mmol/L)	Desirable
130-159 mg/dL (3.36-4.11 mmol/L)	Borderline High Risk
>160 mg/dL (4.14 mmol/L)	High Risk

It is recommended that each laboratory establish the normal range for its patient population.

(a) The performance of this method (y) on a Roche/Hitachi[®] 911 analyzer was compared with the performance of the ultracentrifugation reference method (x).

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Ordering information		
	Configuration	Catalog Number
N-geneous[®] LDL Cholesterol Reagent	R1 1 x 250 mL	80-4598-00
N-geneous[®] LDL Cholesterol Reagent	R2 1 x 80 mL	80-4601-00
LDL Direct Liquid Select Cholesterol Reagent	R1 1 x 30 mL R2 1 x 10 mL	7120
N-geneous[®] LDL Cholesterol Calibrator	3 x 1 mL	80-4601-02

(1) Bachorik P.S. et al. National Cholesterol Education Program Recommendations for Measurement of Low-Density Lipoprotein Cholesterol: Executive Summary. Clin Chem 1995; 41(10):1414.

SEKISUI DIAGNOSTICS



Experience + Technology + Portfolio + Support = **CLINICAL CHEMABILITY[™]**

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