



## 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

- 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<sup>(a)</sup>

- 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)

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

#### 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<sup>(1)</sup>

LDL Cholesterol	Classification
<130 mg/dL (3.36 mmol/L)	Desirable
130-159 mg/dL (3.36-4.11 mmol/L)	Borderline High Risk
$\geq 160$ mg/dL ( $\geq 4.14$ mmol/L)	High Risk

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

(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.

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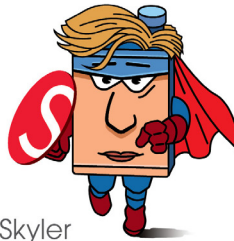
## Ordering Information

	Configuration	Catalog Number
N-GENEIOUS® LDL CHOLESTEROL REAGENT	R1 1 x 250 mL	80-4598-00
N-GENEIOUS® 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-GENEIOUS® LDL CHOLESTEROL CALIBRATOR	3 x 1 mL	80-4601-02

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Sam



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### THE AMERICAS

SEKISUI Diagnostics, LLC  
One Wall Street  
Burlington, MA 01803  
Phone: 800 332 1042

Email: [questions@sekisui-dx.com](mailto:questions@sekisui-dx.com)

### INTERNATIONAL

Sekisui Diagnostics (UK) Limited  
Liphook Way, Allington  
Maidstone, Kent, ME16 0LQ, UK  
Phone: +44 1622 607800

Email: [info@sekisui-dx.com](mailto:info@sekisui-dx.com)

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