

# Ultra N-geneous<sup>®</sup> HDL Reagent

FOR THE QUANTITATIVE MEASUREMENT OF HIGH-DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C)

**METHOD: ENZYMATIC (ACCELERATOR SELECTIVE DETERGENT); ENDPOINT**

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

The Sekisui Ultra N-geneous<sup>®</sup> HDL is based on accelerating the reaction of cholesterol oxidase with non-esterified cholesterol and dissolving HDL selectively using a specific detergent. The assay directly measures HDL-C levels in serum and plasma samples.

## Features:

- Meets 1998 NCEP total error goals of <13%
- Liquid stable, ready to use reagent
- Wide linear range\*

## Benefits:

- Confidence in results and correct classification of patients
- Easy to use, no additional preparation required
- Reduced need for repeat testing and sample dilutions

## Performance Characteristics

### Precision

- Within-Run:  $\leq 0.8\%$
- Total Precision:  $\leq 1.5\%$

### Accuracy<sup>(a)</sup>

- Slope: 0.99
- Intercept: 2.8 mg/dL (0.07 mmol/L)
- Correlation Coefficient: 0.996

### Linearity

- 2.5-200.0 mg/dL (0.06-5.17 mmol/L)

### No Significant Interferences Up to Levels Indicated

- Conjugated Bilirubin: 60 mg/dL (712  $\mu\text{mol/L}$ )
- Total Bilirubin: 60 mg/dL (1026  $\mu\text{mol/L}$ )
- Hemoglobin: 1000 mg/dL (155  $\mu\text{mol/L}$ )
- Ascorbic Acid: 100 mg/dL (5680  $\mu\text{mol/L}$ )
- Lipemia (Intralipid<sup>®</sup>): 1800 mg/dL (20.34 mmol/L)
- Gamma-globulins: 5000 mg/dL (50 g/L)

### Reference Range

- Males: 30-70 mg/dL (0.78-1.81 mmol/L)
- Females: 30-85 mg/dL (0.78-2.20 mmol/L)<sup>(1)</sup>

(a) The performance of this method (y) on a Roche/Hitachi<sup>®</sup> 911 analyzer was compared with the performance of the designated comparison method (x).

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

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Ordering information		
	Configuration	Catalog Number
<b>Ultra N-geneous<sup>®</sup> HDL Reagent</b>	R1 1 x 750 mL	80-6283-00
<b>Ultra N-geneous<sup>®</sup> HDL Reagent</b>	R2 1 x 250 mL	80-6277-00
<b>Ultra N-geneous<sup>®</sup> HDL Calibrator</b>	6 x 1 mL	80-6449-00
<b>HDL Ultra</b>	R1 1 x 60 mL R2 1 x 20 mL	6121
<b>HDL Ultra</b>	R1 1 x 250 mL R2 1 x 80 mL	6122
<b>HDL Ultra Cholesterol Calibrator</b>	3 x 1 mL	6272-3

(1) Tietz, N. W., Clinical Guide to Laboratory Tests, W. B. Saunders Co., Philadelphia, p. 256 (1986).

\* Compared to the reference range



Experience + Technology + Portfolio + Support = **CLINICAL CHEMABILITY<sup>™</sup>**

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*Because every result matters<sup>™</sup>*

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