

Infinity™

HDL Cholesterol Automated Reagent

PRODUCT SUMMARY

Stability	:	Until Expiry at 2-8°C
Linear Range	:	3 - 150 mg/dL (0.08 - 3.88 mmol/L)
Specimen Type	:	Serum
Method	:	Endpoint
Reagent Preparation	:	Supplied ready to use.

IVD

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in vitro diagnostic use		Use by/Expiration Date
LOT	Batch code/Lot number		CAUTION. CONSULT INSTRUCTIONS FOR USE.
REF	Catalogue number		Manufactured by
	Consult instructions for use		
REAG 1	Reagent 1	REAG 2	Reagent 2

INTENDED USE

For the quantitative determination of HDL Cholesterol in human serum. For in vitro diagnostic use.

SUMMARY AND EXPLANATION

Lipoproteins serve to solubilize and transport cholesterol and other lipids in the bloodstream. Different lipoprotein classes have been shown to have various effects on the progression of coronary heart disease (CHD). High density lipoproteins are associated with decreased risk and seen as a protective factor. The measurement of HDL cholesterol (HDL-C) is a powerful predictor of CHD that provides the opportunity for early diagnosis and intervention to halt the progress of cardiovascular disease.^{1,2,3}

PRINCIPLE

Lipoproteins other than HDL (i.e., LDL, VLDL and Chylomicrons) are first removed via selective reaction with cholesterol esterase and cholesterol oxidase that is coupled to a non-colored endpoint via catalase reduction of the peroxide byproduct. In the second step, catalase is inhibited and the remaining HDL cholesterol is specifically reacted with cholesterol esterase and cholesterol oxidase. In the presence of peroxidase the peroxide byproduct now reacts with 4-aminoantipyrine and HDAOS (N-(2-hydroxy-3-sulfo-propyl)-3,5-dimethoxyaniline) to form a colored quinone dye, which is measured spectrophotometrically at 600 nm.⁴

REAGENT COMPOSITION

Active Ingredients

	Concentration
Reagent 1 (R1)	
buffer	
cholesterol esterase (yeast)	1200 U/L
cholesterol oxidase (bacteria)	500 U/L
catalase (bacteria)	225 000 U/L
ascorbate oxidase (bacteria)	10 000 U/L
HDAOS	0.56 mmol/L
stabilizers	
Reagent 2 (R2)	
buffer	
peroxidase (horseradish)	2000 U/L
4-aminoantipyrine	4 mmol/L
surfactants	
sodium azide	0.09%

WARNING: Do not ingest. Avoid contact with skin and eyes. If spilt, thoroughly wash affected areas with water. Reagent contains sodium azide which may react with copper or lead plumbing. Flush with plenty of water when disposing. For further information consult the Infinity HDL Cholesterol Automated Reagent Material Safety Data Sheet.

REAGENT PREPARATION

Reagent 1 and Reagent 2 are ready to use as supplied. Bring reagents to room temperature before use.

STORAGE AND STABILITY

- Reagents are stable until the expiration date stated on the labels when stored unopened at 2-8°C.
- The reagent has an on-board stability of 7 weeks when stored at 2-8°C.
- Do not use after expiration date printed on label.

SPECIMEN COLLECTION

- Fresh serum is the recommended sample. EDTA or heparinized plasma are also acceptable.
- Anticoagulants containing citrate should not be used.

INTERFERING SUBSTANCES

- Bilirubin: No interference was observed up to 25 mg/dL (427.4 µmol/L).
- Hemoglobin: No interference observed up to 500 mg/dL (77.5 µmol/L).
- Ascorbic Acid: No interference observed up to 50 mg/dL (2.84 mmol/L).
- Lipemia: No interference observed up to 1700 mg/dL (19.2 mmol/L) triglyceride concentration.
- Young has reviewed drug effects on serum HDL cholesterol levels.⁶

SAMPLE STORAGE

- The sample may be stored for up to one week at 2-8°C, or frozen at -20°C for up to one month. Samples may be stored up to 1 year at -70°C without deterioration of HDL cholesterol.
- Repeated freezing and thawing should be avoided.

MATERIALS PROVIDED

Infinity HDL Cholesterol Automated Reagent 1 (R1) and Reagent 2 (R2).

MATERIALS REQUIRED BUT NOT PROVIDED

- General laboratory equipment.
- Control material.
- Thermo HDL-C / LDL-C Calibrator, Catalogue Number: 1913-003.

AUTOMATED PROCEDURE

Wavelength (Secondary)	600 (700) nm
Temperature	37°C
Mode	Endpoint
Reaction Times	5 min. + 3 min.
Sample Volume	4 µL
Reagent 1 Volume	300 µL (R1)
Reagent 2 Volume	100 µL (R2)

QUALITY CONTROL

The reliability of test results should be monitored by including at least two levels of control sera, with known HDL-C concentrations, in each assay run. The National Cholesterol Education Program (NCEP) recommends controls that span the medical decision points and are traceable to the NRS/CHOL. The recovery of control results within the established acceptable range should be used only to monitor assay accuracy and precision.

Each laboratory should establish guidelines for corrective measures to be taken if values fall outside the range.

LINEARITY

The procedure is linear from 3 - 150 mg/dL (0.08 - 3.88 mmol/L) [defined by the lower detection limit]. Specify values below the lower detection limit as < 3 mg/dL (< 0.08 mmol/L). Specify values above the reportable range as > 150 mg/dL (> 3.88 mmol/L).

LIMITATIONS

A sample with more than 150 mg/dL (3.88 mmol/L) HDL-C should be diluted with 0.9% saline and reassayed, multiplying the result by the dilution factor. Specimens with more than 1700 mg/dL (19.2 mmol/L) triglycerides should be diluted with 0.9% saline before assaying, and the results multiplied by the dilution factor.

CALCULATION OF RESULTS

The instrument automatically calculates the HDL cholesterol concentration of each sample. Unit conversion: mg/dL x 0.026 = mmol/L.

EXPECTED VALUES⁵

HDL Cholesterol

MALES: 30 - 70 mg/dL (0.78 - 1.81 mmol/L)

FEMALES: 35 - 85 mg/dL (0.90 - 2.20 mmol/L)

National Cholesterol Education Program (NCEP) guidelines⁷

<35 mg/dL (<0.90 mmol/L): low HDL cholesterol (major risk factor for CHD)

>60 mg/dL (>1.55 mmol/L): high HDL cholesterol ("negative" risk factor for CHD)

These ranges should serve only as guidelines. It is recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories and local populations.

PERFORMANCE CHARACTERISTICS

PRECISION

Within-run and run-to-run precision studies were performed and are summarized in the following table:

WITHIN-RUN	MEAN	STD. DEV.	CV%
Normal (mg/dL / mmol/L)	25.4 / 0.66	0.6 / 0.02	2.3
Abnormal (mg/dL / mmol/L)	75.1 / 1.94	1.7 / 0.04	2.3
RUN-TO-RUN	MEAN	STD. DEV.	CV%
Normal (mg/dL / mmol/L)	26.2 / 0.68	1.0 / 0.03	4.0
Abnormal (mg/dL / mmol/L)	75.4 / 1.95	2.9 / 0.08	3.8


ACCURACY

A total of 167 sera with HDL cholesterol concentrations ranging from 18-118 mg/dL (0.45-3.05 mmol/L) were tested with this method (y) and compared with results of another homogenous HDL method (x) which uses PEG modified enzymes. The correlation coefficient was r = 0.966 and linear regression analysis yields y = 1.090x - 4.9 mg/dL (y = 1.090x - 0.13 mmol/L). In another study of 50 sera with HDLs ranging from 18-121 mg/dL (0.45-3.13 mmol/L), this method (y) was compared to a homogeneous method (x) which uses a "blocking" polymer. The data analysis yielded: r = 0.960 and linear regression analysis y = 1.05x + 1.5 mg/dL (y = 1.05x + 0.04 mmol/L). This procedure is pending participation in the NRS/CHOL Cholesterol Reference Method Laboratory Network program.

BIBLIOGRAPHY

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REF	Reorder Information		
	Catalogue No.	REAG 1	REAG 2
	TR39601	2 x 30 mL	2 x 10 mL
	TR39602	2 x 125 mL	2 x 42 mL
	TL39601 (ILab 600)	5 x 90 mL	3 x 50 mL
	TH39601 (Hitachi)	2 x 90 mL	2 x 30 mL