

PRODUCT CODE CS020

INTENDED USE

For the quantitative determination of HDL Cholesterol in serum.

CLINICAL SIGNIFICANCE

The fraction of the cholesterol bound to high density lipoprotein is an indicator of the risk of coronary heart disease. High levels of HDL-cholesterol appear to act as protective factor, while low values are one of the major risk factors.

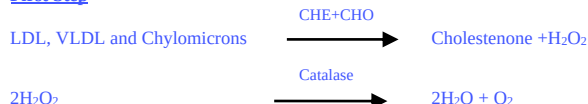
Determination of HDL-cholesterol along with the comprehensive study of the lipid profile of the patient, allows assessing the risk of coronary heart disease.

Low level of HDL-cholesterol are found in cases of unbalanced diet, sedentary lifestyle, alcoholism or smoking.

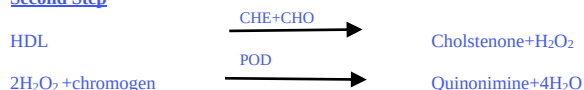
PRINCIPLE

The assay combines two specific steps: in the first step chylomicrons, VLDL and LDL cholesterol are specifically eliminated and destroyed by enzymatic reactions. In the second step remaining cholesterol from the HDL fraction is determined by well-established specific enzymatic reactions in the presence of specific surfactants for HDL.

First Step



Second Step



REAGENT COMPOSITION

Reagent 1

N,N-bis(2-hydroxyethyl)-2-aminoethanesulphonic acid pH 6,6	100 mmol/L
N-(2-hydroxy-3sulfopropyl)-3,5-dimethoxyaniline (HDAOS)	0.7 mmol/L
Cholesterol esterase	≥800 U/L
Cholesterol oxidase	≥500 U/L
Catalase	≥300 U/L
Ascorbic oxidase	≥300 0U/L

Reagent 2

N,N-bis(2hydroxyethyl)-2- aminoethanesulphonic acid pH 7,0	1.1 mmol/L
4-Aminoantipyrine	100 mmol/L
Peroxidase	≥3500 U/L

HDL CAL

Calibrator, lyophilized human serum

REAGENT PREPARATION

Reagent 1 and Reagent 2 are ready to use.

HDL CAL: Reconstitute with 1 mL of distilled water, cap the vial and mix gently to dissolve the content. The concentration of calibrator stated on the label

REAGENT STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not freeze the reagents.

HDL CAL: Once reconstitute 2 weeks at 2-8°C or 3 months at -20°C.

Do not use reagents over the expiration date

Signs of reagent deterioration: Presence of particles and turbidity.

SPECIMEN

Serum, heparinized plasma or EDTA plasma. If any samples show precipitates, centrifuge before using.

Stability of the sample: 6 days at 2-8°C and 1 year when stored at -70°C.

PRUCEDURE

APPLICATION ON AUTO BIOCHEMISTRY ANALYZERS

BR-160 AUTO BIOCHEMISTRY ANALYZER					
TEST NAME	HDL		SAMPLE VOLUME	2	
FULL NAME	HDL DIRECT				
	PRL	SEC.	REAGENT VOLUME	R1	R2
WAVE LENGTH	578	NONE		195	65
ASSAY /POINT	2 POINT END	START	END		
		11	25		
DECIMAL PLACE	2				
UNIT	mg/dl				
LINEARITY RANGE	LOW	HIGH			
	0	150			

BR-120 AUTO BIOCHEMISTRY ANALYZER					
TEST NAME	HDL		SAMPLE VOLUME	2	
FULL NAME	HDL DIRECT				
	PRL	SEC.	REAGENT VOLUME	R1	R2
WAVE LENGTH	578	NONE		195	65
ASSAY /POINT	2 POINT END	START	END		
		17	39		
DECIMAL PLACE	2				
UNIT	mg/dl				
LINEARITY RANGE	LOW	HIGH			
	0	150			

PRECAUTION

To avoid contamination, use clean laboratory wares.

HDL CAL, Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.

LINEARITY

Up to 150 mg/dL HDL.

If the result obtains greater than the linearity limit, dilute sample 1+1 with normal saline and repeat the test, multiply the result by 2

INTERFERENCE

No interferences were observed to bilirubin up to 30 mg/dL, haemoglobin up to 500 mg/dL, rheumatoid factors up to 1000 IU/mL or lipemia up to 1200 mg/dL.

Lipemic samples with a triglyceride concentration >1200 mg/dL should be diluted 1/10 with NaCl 9 g/L and multiply the result by 10.

NORMAL RANGE

	Men	Women
Low risk	>50 mg/dL	>60 mg/dL
Normal risk	35-50 mg/dL	45-60 mg/dL
High risk	<35 mg/dL	<45 mg/dL

These values are for orientation purpose, each laboratory should establish its own reference range.

QUALITY CONTROL

All human serum-based control sera with HDL values determined by this method can be employed.

NOTES

- The reagent 2 presents yellowish coloration due to the peroxidase, but it does not affect its functionality.
- Keep reagents and samples out of direct sunlight.

SYMBOL ON LABELS

IVD in vitro diagnostics	 manufacturing date
LOT lot number	 expiry date
REF catalogue number	 manufacturer
 temperature limit	 instruction for use

BIBLIOGRAPHY

- National Institutes of Health Consensus Development Conference Statement: Triglyceride, High Density Lipoprotein and Coronary Heart Disease. Washington D.C. Feb 26-28, 1992.
- Izawa S., Okada M., Matsui H., and Horita Y. J. Medicine and Pharmaceutical Sci., 1385 - 1388, 37 (1997).
- Shih WJ, Bachorik PS, Haga JA, Myers GL, Stein EA; Clinical Chemistry, 2000; 46:3:351 – 364.
- Jacobs, D. et al. In Laboratory and Test Handbook; Jacobs, D.S; Kasten, B.L., De Mott, W.R., Wolfson, W.L., Eds; Lexi - Comp Inc: Hudson (Cleveland), 1990; P. 219.

