



SUMMARY AND PRINCIPLE

1. Low HDL Cholesterol levels are associated with coronary heart disease. HDL particles regulate the cholesterol levels by up taking and transport From peripheral tissue to liver.
2. The reagent is for use on automated clinical chemistry analyzer such as Hitachi 704 / 902 / 912 / Synchron CX.

Cholesterol esters → Cholesterol + Fatty Acids

Cholesterol + O₂ → H₂O₂ + Cholestenone

H₂O₂ + Chromogen → Blue Dye + H₂O

REAGENT COMPONENTS

The following components are present in :

Reagent 1 : Goods Buffer 20 mmol/l, pH 7.0, HDAOS 1 mmol/l

Reagent 2 : Goods buffer 20 mmol/l, pH 7.0. COD 1.0 U/ml,
CE 5.0 U/ml. POD 15 U/ml. 4-AAP 3.0 mmol/l.

Stabilizers. inactive ingredients and surface active agents.

REAGENT

- Ready to use
- ✓ Stable up to expiry at 2^o - 8^oC
- ✓ Stable for 30 days when opened and refrigerated on the analyzer.

APPLICATION PROGRAMME

Refer to operators manual of instrument for setting up the following Programme. Employ a suitable calibrator for assay. Calibrator value of Direct homogeneous method is preferred.

Calibrator Preparation :

Calibrator should be reconstituted with 0.5 ml 0.1 Diluted water Reconstitution stability or calibrator at 2-8°C up to 7 days,

ASSAY PARAMETERS

Test Parameters :

- Reaction Type ... End point.
- Reagent Vol 1000 µl
- Wave length ... 620nm
- Calibrator con : As on vial
- Zero Setting : Reagent blank
- Linearity 250 mg/dl
- Incubation : 5mins. at 37°C
- Units : mg/dl
- Sample Vol 10 µl

MANUAL ASSAY PROCEDURE :

Prewarm at 37°C take the required amount of reagent before use.

	Blank	Calibrator	Test
HDL Cholesterol	1000 µl	1000 µl	1000 µl
HDL Calibrator	-	10 µl	-
Sample	-	-	10 µl

Mix well and keep at 37°C for 5 mts. Read Abs of Test (T) and calibrator (C) against reagent blank at 620 nm

CALCULATIONS

HDL-c (mg/dl) = Abs x conc. Of calibrator.

EXPECTED VALUES

Desirable HDL Cholesterol	35-80 mg/dl
---------------------------	-------------

NOTE: The reference value should be used as guide only.

MEASURING RANGE

This procedure is linear up to 250 mg/dl

INTERFERENCE

There is no significant Interference In samples containing up to 40 mg/dl of free bilirubin, 40mg/dl. of conjugated bilirubin, 500 mg/dL of haemoglobin and 100 mg/di. absorbic acid.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures Optimum quality control.

Consistent use of same type and methodology of control serum provides between run precision and accuracy data.

We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument. Apparatus and operator.

NOTE :

HDL Reagents include ingredients which may affect magnesium assays, therefore it is recommended to wash the cuvettes thoroughly after using the reagents. Recalibrate the instrument (with freshly reconstituted calibrator) if control sera values shows inaccurate results.

BIBLIOGRAPHY

1. Gordon T, Castelli WP Hjortland MC,et al.Am J Med 1977;62:707.714.
2. Dominiczak M,Mc Namara J.The system of cardiovascular prevention.1 03- 125:Nauk M,Wiebe D,Warnick G.Measurement of High density lipoprotein Cholesterol 221 -244.
3. Handbook of lipoprotein Testing (eds.Rifai,Wanick and Dominiczak), 2nd edition, uji Y, Okabe H, irie T et al.Direct measurement of High density lipoprotein cholesterol in serum with polyethylene Glycol modified enzymes and sulfated alfa Cyclodextrin Clin Chem 1995;41:717-723.
4. Ham's N Galpchian V, Rifai N. Three routine methods for measuring high density lipoprotein cholesterol compared with reference method. clin chem 1996;42:738~743. Pa : WB Saunders Company. 1995 : 130 131.
5. Hatch FT, Lees RS Practical methods for plasma lipoprotein analysls Adv Lipid Res 1968, 6: 1-68.
6. Matsuzaki Y, Kawaguchi E. Morita Y et al Evaluation of two kinds of Reagents for direct determination of HDLCholesterol J Anal Bio sc 1996: 19:4 19-42 7.