HDL – Cholesterol Kit

CliniQuant - FSR

Phosphotungstic Acid Method, End Point

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Precipitating Reagent	R2 HDL-Cholesterol Standard
HDCFSR-01	4 x 25ml	4 x 25ml	1 x 5ml

INTENDED USE

This reagent is intended for quantitative determination of HDL Cholesterol concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

High Density Lipoprotein (HDL) Cholesterol consists of a number of heterogeneous particles varying in size and content of lipid and apolipoproteins. HDL plays important role in cholesterol efflux, reducing stored cholesterol and returning cholesterol from the periphery to the liver for removal as bile acid, also serves as scavenger of lipid and apolipoprotein during normal catabolism. HDL cholesterol values are 1/5th of the total cholesterol values. There is inverse relationship between HDL Cholesterol and coronary heart diseases.

PRINCIPLE OF THE METHOD

Chylomicrons, LDL and VLDL are precipitated from serum by phosphotungstate in the presence of magnesium ions. The unaffected HDL cholesterol in the supernatant is estimated using CliniQuant FSR Cholelsterol Reagent.

$$\text{Serum/Plasma} \xrightarrow{\text{Phosphotungstate}} \underset{\text{(supernatant)}}{\text{HDL}} + \underset{\text{(precipitate)}}{(\text{LDL}+\text{VLDL}+\text{Chylomicrons})}$$

KIT COMPONENTS

Composition:

R1 - Precipitating Reagent : Phosphotungstic acid 0.77 mmol/l, Magnesium Chloride 17.46 mmol/l

R2 - HDL-Cholesterol Standard : 25 mg/dl, Cholesterol powder 0.25 g/l, Surfactant

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, CliniQuant - FSR Cholesterol Reagent, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent is ready to use. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Stability since first opening of vials: preferable within 60 days at 2-8 °C.

REAGENT DETERIORATION

Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use unhaemolysed serum or EDTA plasma. Avoid use of citrate or heparin as anticoagulant. Serum / plasma is stable for 7 days at 2-8 °C or one month at -20°C when frozen once.

1. TEST PROCEDURE - PRECIPITATION

Precipitation of LDL, VLDL and Chylomicrons. Pipette in centrifuge tubes: precipitating reagent1 & specimen in ratio 2:1 (500 µl reagent + sample 250 µl). Mix well by inversion and allow to stand for 10 minutes at room temperature, centrifuge at 3000 r.p.m for 10 minutes.

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Meril Diagnostics Pvt. Ltd., Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. T+91-260-3052100, F +91-260-3052125, W www.merillife.com
EC REP Obelis s.a., Bd General Wahis 53, 1030, Brussels, Belgium. T +(32) 2 732-59-54, F +(32) 2 732-60-03, E mail@obelis.net

Separate the supernatant and use it as sample into following procedure

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc.	25 (mg/dl)
Filter – 1 (nm)	505
Filter – 2 (nm)	670
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	30
Reference High	80
Linearity Limit	125

2. TEST PROCEDURE – QUANTITATION

For Estimation with CliniQuant - FSR Cholesterol Reagent:

Dispense	Blank	Standard	Sample
Reagent 1	1ml	1ml	1ml
Distilled water	50 µl	-	-
Standard	-	50 µl	-
Supernatant	-	-	50 µl
Mix, incubate for 10min at 37°C. Read absorbance of standard (As) and samples (Ax) against reagent blank.			

RESULT CALCULATION

Serum/plasma:

HDL cholesterol mg/dl = Ax/As x Concentration of Standard x 3 (dilution factor)

SI conversion factor: 1 mg/dl x 0.0259 = 1 mmol/l

EXPECTED VALUES

Men: 30 - 80 mg/dl OR 0.8 – 2.1 mmol/l

Women: 30 - 65 mg/dl OR 0.7 – 1.7 mmol/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result.

Using the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 125 mg/dl or 3.23 mmol/l of HDL.

LIMITATIONS

1. Samples with values above 125 mg/dl should be diluted with 0.9% saline, re-run and results multiplied by dilution factor.

2. Repeat the precipitation test procedure if it fails to achieve assigned assay values of fresh control sera.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1028 – 1029.

2. Data on file: Meril Diagnostics.

IFU/HDCFSR01/00

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community