

Direct HDL Cholesterol

D-HDL-C

Reagent for direct measurement of HDL Cholesterol concentration in human serum and plasma.

Liquid. Dual reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

| Ref No | Pack | Ref No | Pack | Ref No | Pack | Ref No | Pack |
|--------|------------|--------|------------|--------|------------|--------|------------|
| HD2211 | 4 x 100 mL | SHD20 | 2077 Tests | NHD20 | 577 Tests | MHD21 | 1273 Tests |
| HD2212 | 4 x 50 mL | SHD21 | 1292 Tests | NHD21 | 393 Tests | RHD20 | 600 Tests |
| HD2213 | 4 x 25 mL | SHD22 | 738 Tests | KHD20 | 2909 Tests | RHD21 | 2700 Tests |
| HD2214 | 4 x 10 mL | THD20 | 3130 Tests | KHD21 | 1636 Tests | LHD20 | 2700 Tests |
| BYH220 | 5950 Tests | THD21 | 1532 Tests | MHD20 | 2162 Tests | LHD21 | 1273 Tests |
| BYH221 | 4463 Tests | DMHD20 | 1020 Tests | | | | |

*THD20 (02R06-31) /THD21 (02R06-21) Ref Number Products are Produced Specifically for Abbott Architect Biochemistry Analyzer Series

INTENDED USE

The test is used for quantitative determination of HDL cholesterol concentration in human serum and plasma.

High-density lipoproteins (HDL) are one of the major classes of plasma lipoproteins. They are composed of a number of heterogeneous particles, including cholesterol and vary with respect to size and content of lipid and apolipoprotein. HDL serve to remove cholesterol from the peripheral cells to the liver, where the cholesterol is converted to bile acids and excreted into the intestine.

An inverse relationship between HDL-cholesterol (HDL-C) levels in serum and the incidence/prevalence of coronary heart disease (CHD) has been demonstrated in a number of epidemiological studies. The importance of HDL-C as a risk factor for CHD is now recognized (1).

Accurate measurement of HDL-C is of vital importance when assessing patient risk from CHD. In this diagnostic test kit a method for direct measurement of HDL-C, without sample pretreatment, is presented. Direct measurement gives improved accuracy and reproducibility when compared to precipitation methods.

TEST PRINCIPLE

After adding of magnesium ions, dextran sulfate selectively forms water-soluble complexes with LDL, VLDL and chylomicrons which are resistant to PEG-modified enzymes.

The cholesterol amount of HDL-Cholesterol can be tested enzymatically by cholesterol esterase and cholesterol oxidase coupled with PEG to the amino

groups. This is around %40.

Cholesterol esters are broken down quantitatively into free cholesterol and fatty acids by cholesterol esterase.

HDL-C in human serum is resolved with special detergent, and makes color reactions with Cholesterol esterase (CEH), Cholesterol oxidase (CHOD), Peroxidase (POD). Because Non-HDL-Lipoproteins such as chylomicron (CM), low density lipoprotein (LDL), very low density lipoprotein (VLDL) are inhibited by detergents on their surface, the cholesterol in them do not react with the enzyme. Remain HDL Cholesterol is determined by color intensity over trinder reaction.

TEST PARAMETERS

Method : Colorimetric, End Point Reaction
Wavelength : Main: 578 - 600 –
Sub: 700 - 750 nm
Temperature : 37°C
Sample : Serum
Linearity : 12 mg/dL - 120 mg/dL

REAGENT COMPOSITION

| Reagent 1: Components | Concentration |
|----------------------------------|---------------|
| Dextran Sulfate | ≤ 10 gr/dL |
| Magnesium Chloride Hegezahydrate | ≤ 5 gr/dL |
| Preservative | |
| Brij 35 | ≤ 10 gr/dL |

Reagent 2:

| Components | Concentration |
|----------------------------|---------------|
| Detergent | ≤ 2 % |
| PEG - Cholesterol Esterase | ≤ 5 KU/L |
| PEG - Cholesterol Oxidase | ≤ 5 KU/L |
| 4 AAP | ≤ 1 gr/dL |
| Peroxidase | ≤ 8000 U/L |

REAGENT PREPARATION

Reagents are ready to use, liquid.

REAGENT STABILITY AND STORAGE

Stability: up to expiration date on labels at 2-8°C. Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. There is a strong relation between on board stability and auto analysers cooling specification and carry-over values.

SAMPLE

Samples:

Fresh Serum, or EDTA and heparinized plasma on an empty stomach are the recommended specimens. Samples are collected by standard procedures.

Note: Separate the serum or plasma as soon as possible after collection (within 3 hours). Store serum no more than 12 hours at room temperature, no more 7 days at 2-8 °C. HDL in sample is stable for 30 days at – 70 °C.

TEST PROCEDURE

Sample Start

In case of request, ready application procedures dedicated to different kind of photometers and ready manual working procedures can be supplied.

In case of request, ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied.

Substrate Start

In case of request, ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied.

CALCULATION

$$\frac{A_{\text{calibrator}}}{A_{\text{sample}}} \times \text{Conc. of Std./Cal (mg/dL)}$$

= Cholesterol (mg/dL)

LDL = Cholesterol-(HDL + Triglycerid/5)

Unit Conversion

mmol/L *38.67= mg/dL
 mg/dL*0.02586=mmol/L

REFERENCE INTERVALS (NORMAL VALUES)

Adult Males :<35 mg/dL (0.90 mmol/L) High Risk
 >55 mg/dL (1.45mmol/L) No Risk
 Adult Females :<45 mg/dL (1.15 mmol/L) High Risk
 >65 mg/dL (1.68mmol/L) No Risk
 For general limits (Male and Female): 35-70 mg/dl.

National Cholesterol Education Program (NCEP) guidelines:

<40 mg/dL:Low HDL (major risk factor for CHD)
 ≥60 mg/dL:High HDL("negative" risk factor for CHD)
 HDL-cholesterol is affected by a number of factors, e.g. smoking, exercise, hormones, sex and age.
 *It is recommended that each laboratory establishes its own normal range.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of a HDL/LDL Standard (Calibrator). Any commercially available Standard or Calibrator suitable for this method may be used. We recommend:

ARCHEM Standard (Arcal Lipids HDL/LDL Calibrator)(recommended)

Cat. No. A39047 (01R95-01)

Or Arcal Auto calibrator
Cat. No. A39050

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 20 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low Linearty (LOQ): 12 mg/dL (0.31 mmol/L)

High Linearity: The test is linear up to 120 mg/dL (2.5 mmol/L). Considerable variation may be seen in linearity depending on the analyzer model and application method.

Precision Studies (Based on CLSI EP5 Doc.):

| Repeatability(within run)(intra-assay): | | | |
|--|-------|-------|----|
| Mean conc. | | CV | n |
| 106 | mg/dL | 1.70% | 20 |
| 22 | mg/dL | 2.80% | 20 |
| Reproducibility(run to run)(inter-assay): | | | |
| Mean conc. | | CV | n |
| 80 | mg/dL | 1.90% | 20 |
| 22 | mg/dL | 2.95% | 20 |

Sensitivity (LOD) (Based on CLSI EP17 document): Limit of detection of the test is 5 mg/dL.

Trueness: No systematic differences seen in results obtained with this reagent when compared with reference reagents. It's available to get details of comparison experiments in case of requirement.

Interferences:

- Bilirubin ≤ 40 mg/dL,
- Hemoglobin ≤ 1000 mg/dL,
- CM ≤ 250 Turbidity Unit,
- Vc ≤ 100mg/dL do not interfere. Other drugs and substances may interfere.

An analyzer has been used to obtain these performance characteristics. Usage of different analyzer or a manual procedure may cause the variance in results.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human&animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should capped and kept at 2-8°C. Caps of the reagents bottles can not be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general GLP guidelines.

- R36/38 : Irritating to eyes and skin.
 - S20/21 : When using, do not eat, drink or smoke.
 - S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 - S28 : After contact with skin wash immediately with plenty of water.
 - S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
 - S45 : In case of accident or if you feel unwell, seek medical advice immediately.
 - S56 : Dispose of this material and its container at hazardous or special waste collection point.
 - S57 : Use appropriate container to avoid environmental contamination.
 - S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
- Please consult local regulations for a correct waste disposal.

ABBREVIATIONS




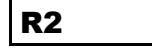








- CLSI : Clinical and Laboratory Standards Institute
- CV% : Coefficient of Variation Percentage
- EP : Evaluation Protocols
- GLP : Good Laboratory Practice
- IU : International Unit
- mA : miliabsorbance
- mL : milliliter
- NCCLS: National Committee for Clinical Laboratory Standards
- QC : Quality Control
- NCEP :National Cholesterol Education Programme

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SYMBOLS

| | |
|--|-----------------------------------|
|  | Only for invitro diagnostic use |
|  | Lot of manufacturing |
|  | Reagent 1 |
|  | Reagent 2 |
|  | Concentration |
|  | Reagent Ingredients |
|  | Reference Number (Catalog Number) |
|  | Serial Number |
|  | Expiration date |
|  | Storage temperature interval |
|  | Read the directions |
|  | Biological risk |

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