

Read this package insert carefully before use

In Vitro Diagnostics

July 2017(2<sup>nd</sup> Version)

Generic Name: HDL Cholesterol Kit  
Notified Number: 12A2X10005HDL0021

Reagent for measuring HDL Cholesterol in serum or plasma

## Measure HDL

### 【General Precautions】

- 1) For **in vitro diagnostics** use only.
- 2) Diagnosis should be made in a comprehensive manner and in accordance with other related test results and clinical symptoms by the doctor in attendance.
- 3) For guaranteed results, usage of this product must comply with the instruction in this manual.
- 4) If you use an automatic analyzer, follow their instructions carefully.

### 【Structure and Composition of the Kit】

Reagent Name	Component
Reagent R-1	HDAOS: N-(2hydroxy-3-sulfopropyl)-3,5-dimethoxy aniline sodium salt Ascorbate Oxidase Phosphoric Acid
Reagent R-2	Cholesterol Oxidase(CHOD) Cholesterol Esterase(CHER) Peroxidase(POD)

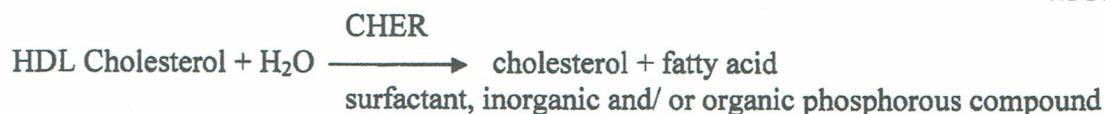
### 【Purpose of Use】

Determination of HDL Cholesterol in serum or plasma.

### 【Measurement Principle】

This method enables determination of HDL Cholesterol only in a selective manner by combination of surfactant, inorganic and organic phosphorus compounds which inhibits reaction against LDL, VLDL and chylomicron.

In the 1<sup>st</sup> reaction, LDL, VDL and chylomicron except for HDL-Cholesterol are bound to surfactant, inorganic and organic phosphorous compounds. In the 2<sup>nd</sup> reaction, only HDL-Cholesterol can be determined by addition of CHER and CHOD without doing fractionation.



\*1) 4-AA: 4-aminoantipyrine

\*2) HDOS: N-(2hydroxy-3-sulfopropyl)-3,5-dimethoxy aniline sodium salt

### 【Operating Precautions】

#### (1) Types of specimen and Blood collection.

- 1) Collect blood from patients fasting for at least 12-14 hours prior to the specimen draw.
- 2) Store the specimen at 2~8°C and use it for determination within 4 days.
- 3) We recommend heparin lithium as anticoagulant.

#### (2) Interfering substances

- 1) Influence of 50mg/dl of ascorbic acid was within 3% when it was added for 42mg/dL of HDL-Cholesterol.
- 2) Influence of 20mg of unconjugated bilirubin was within 3% when it was added for 42mg/dL of HDL-Cholesterol.
- 3) Influence of 500mg/dl of hemoglobin was 1% when it was added for 42mg/dL of HDL-Cholesterol.
- 4) Influence of 1600 unit of formazin turbidity was within 1% when it was added for 42mg/dL of HDL-Cholesterol.

### 【Direction for use】

- 1, Preparation method for liquid reagent Reagent ( R-1 and R-2) Use as it is.
- 2, Store dark and cool place (2~8°C) keep light shield container
- 3, Please contact us for our lipid standard materials of human origin.

## Measurement Procedures (Standard Operation Procedures)

	Specimen (S)	Standard solution(std)	Test blank (B)
Serum or plasma(mL)	0.02	—	—
Standard Solution((mL)	—	0.02	—
Saline(mL)	—	—	0.02
Reagent R-1(mL)	1.5	1.5	1.5
Mix well and warm for 5 minutes at 37°C			
Reagent R-2(mL)	0.5	0.5	0.5
Mix well and warm for 5 minutes at 37 °C . Measure absorbance(Es) of specimen(S) and absorbance (Estd) of Standard Solution(std) setting Blank (B) as reference. Wavelength of Spectrophotometer: 583 nm			

\*Please contact us for parameters to be used with automatic analytical instruments.

**【Reference Value】**

**Reference range:** 40 ~70 mg/dL

Each laboratory should verify the validity of these values for the population it serves.

Doctor in attendance should judge clinical diagnosis based on measurement results in a comprehensive manner together with clinical symptoms and other measurement results.

**【Performance】****1. Performance**

**Sensitivity** Absorbance when using purified water is 0.001  
 ~0.050 and standard solution (cholesterol 50 mg/dL) is 0.050  
 ~0.150

**Specificity test** when measuring a known control serum, the accuracy is within  $\pm 10.0\%$ .

**Reproducibility** within-run CV is below 3.0% (n=10)

**Measuring range** 5 ~120 mg/dL

**2. Correlation**

correlation between our Measure HDL and HDL Cholesterol of a company and the results are as follows; (Y : Measure HDL X: A Company HDL Cholesterol)

Serum: regression equation  $Y=1.002X-0.900$  (n=90),  
 Correlation coefficient  $r=0.999$

**Reference Material for Calibration JCCRM 224****【Precaution for Use and Handling】**

1. Precaution for handling of specimen.  
 Specimen can be potentially positive for infectious agents including hepatitis B virus and HIV. Observe universal protection carefully. (E.g. wear gloves etc.)
2. Precaution for use.

Store reagents under specified condition. Do not use them after expiration date. Reagent R-1 left on skin can cause inflammation. Wash it away with plenty of water and see a doctor if necessary.

If specimen exceeds the dynamic range, dilute it with twice as much as of saline or purified water before measurement.

Do not use the container and auxiliaries included in this kit for other purposes.

### **【Precautions at Disposal】**

- 1) All specimens, as well as all instruments (e.g. test tubes) that come in contact with the specimens, must be treated by the following methods, or they must be treated according to the manual for infectious medical waste provided in each facility.
  - Sterilize with an autoclave, subjecting them to high pressure saturated steam at 121 °C for more than 20 minutes. Do not process waste containing sodium hypochlorite solution with an autoclave.
  - Immerse at least one hour in sodium hypochlorite solution (active chloride concentration of over 1000 ppm).
- 2) This reagent contains sodium azide. it can react with lead pipe and/or steel pipe and can generate explosive metal azide. Make sure to use plenty of water at disposal. Concentration of sodium azide in R-2 is 0.05%.

### **【Storage and Shelf Life】**

Store dark and cool place : at 2 ~ 8 °C. keep in the Light shielding container. Shelf Life: 24 months from production before open the bottle.

### **【Package Unit】**

Reagent R-1: 90mL, 150mL, 300mL, etc.

Reagent R-2: 30mL, 50mL, 100mL, etc.

Standard solution: 5mL

R-1, R-2 can be packaged separately.

Please contact us for other packages.