

Read this package insert carefully before use

In Vitro Diagnostics

June 2016 (2nd Version)

Notified Number: 12A2X10005LDL001

Generic Name: LDL Cholesterol Kit

Reagent for measuring LDL Cholesterol in serum or plasma

Measure LDL

【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.
- 5) This product contains sodium azide as preservative. If eye, mouth or skin comes in contact with this product, take emergency procedures (for example, wash away with plenty of water), and consult with a doctor if necessary.

【Structure and Composition of the Kit】

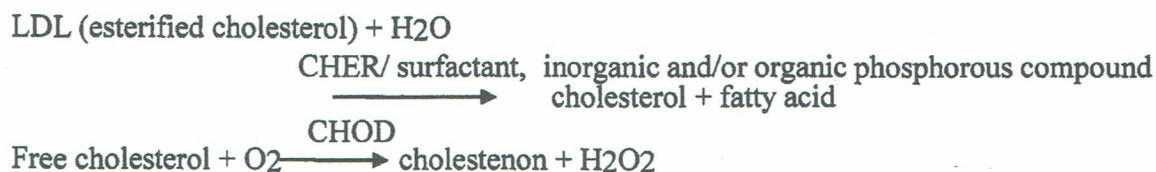
Reagent Name	Component
Reagent R-1	HDAOS: N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxy aniline sodium salt Ascorbate Oxidase Peroxidase
Reagent R-2	Cholesterol Oxidase(CHOD) Cholesterol Esterase(CHER) Peroxidase(POD) 4-aminoantipyrine(4-AA) Sodium Azide

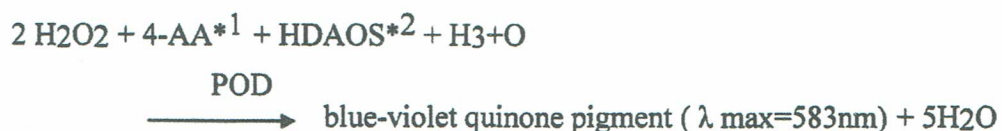
【Purpose of Use】

Determination of LDL Cholesterol in Serum or Plasma

【Measurement Principle】

Within a measurement system where cholesterol esterase and/or cholesterol oxidase are used, this method separates LDL from other lipoprotein (HDL, VLDL and chylomicron) by inhibiting their reaction through the selective inhibitory function of inorganic and organic phosphorous compound as well as surface acting agent. This enables an exclusive and direct determination of the LDL cholesterol level.





*1) 4-AA: 4-aminoantipyrine

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

【Operating Precautions】

- (1) Types of specimen, method of harvest
 - 1) Specimen for the measurement can be both, blood serum and blood plasma.
 - 2) Use immediately after separation. Specimen can be stored cold at 2-8 °C for up to three days after separation.
- (2) Interfering substances
 - 1) ascorbic acid concentration of more than 50 mg/dL can influence the measured values.
 - 2) conjugated bilirubin concentration of over 20 mg/dL can influence the measured values.
 - 3) Hemoglobin concentration of more than 500 mg/dL can influence the measured values.
 - 4) over 1200 FTU (formazin turbidity unit) can influence the measured values.
 - 5) triglyceride concentration of over 600 mg/dL must be diluted more than twice of the original volume with saline before measurement.

【Direction for use】

1. Preparation method for liquid reagent Reagent R-1 and Reagent R-2: Use as it is. , Store dark and cool place (2~8°C), keep light shield container
Aside from them, please contact us for our lipid standard materials of human origin.
2. Measurement Procedures(Standard Operation Procedures)

	Specimen (S)	Standard	Reagent Test Blank
Serum or plasma(mL)	0.015	—	—
Standard	—	0.015	—
Saline(mL)	—	—	0.015
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 Reagent Blank Test(B) as reference. Wavelength of Spectrophotometer: 600 nm.			

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

【Judgment Method of measurement results】

1. Reference range should be set at each facility.
2. Doctor in attendance should judge clinical diagnosis based on measurement results in a comprehensive manner together with clinical symptoms and other measurement results.
3. Reference range: below 120 mg/d L

【Performance】

1. Performance

- 1) Sensitivity Abs of purified water is \triangleleft 0.001 ~ 0.050,
Abs of standard solution (cholesterol 100mg/dL) is \triangleleft 0.090 ~ 0.330.
- 2) Specificity a known concentration of control serum, the accuracy is within \pm 10.0%
- 3) Reproducibility identical specimens within-run cv is below 5.0% (n=10)

4) Measuring range 5 ~ 700 mg/dL

2. Correlation

Measure LDL and LDL Cholesterol of a Company and the results are as follows;

(Y; Measure LDL, X; A Company LDL Cholesterol)

Serum: $Y = 1.0025X + 0.4028$ (n=63) $r = 0.9938$

3. Reference Material for Calibration (standard material) 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.
 - 1) Store reagents under specified condition. Do not use them after expiration date.
 - 2) Reagent R-1 left on skin can cause inflammation. Wash it away with plenty of water and see a doctor if necessary.
 - 3) Reagent R-2 can become opaque at around 15 °C, But the efficiency will stay unchanged, and it can be used as it is.
 - 4) If specimen exceeds the dynamic range, dilute it with twice as much as of saline or purified water before measurement.
 - 5) Do not use the container and auxiliaries included in this kit for other purposes.

【Precautions at Disposal】

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 1000ppm).
- 1) This reagent contains sodium azide. Sodium azide 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%.
 - 2) Do not use the container and auxiliaries included in this kit for other purposes.

【Storage and Shelf Life】

Store dark and cool place :at 2 ~ 8°C. keep in the Light shielding container. Shelf Life: 18 months from production before open the bottle.

【Package Unit】

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

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

R-1, R-2 can be packaged separately. Please contact us for other packages.