Hipro Biotechnology Co.,Ltd

EN
ENGLISH

LDL-C

Low Density Lipoprotein Cholesterol Test Kit
(Enzymic Method)

Instructions for Use

Version: A/3

REF HP-LDL-C-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.
No. 3 Building, Block C, Fangyi Science Park, No. 365 Huai'an East Road, Hi-tech Zone, Shijiazhuang, 050000 Hebei P.R. China

After sale service: 400-0191-606

www.hipro.us

EC REP Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Tel: +31644168999

Product Name

General Name: Low Density Lipoprotein Cholesterol Test Kit (Enzymic Method)

Specification

Package Specification

25 Tests/ Kit.

Intended Use

The Low Density Lipoprotein Cholesterol (LDL-C) test kit is intended for in vitro quantitative determination of Low Density Lipoprotein Cholesterol (LDL-C) concentration in human serum using the Hipro immunoassay analyzer. It is mainly used in clinical diagnosis of hypercholesterolemia, coronary heart disease and atherosclerosis.

Test Principle

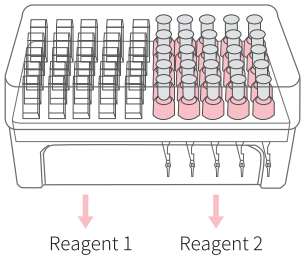
R1 eliminates high-density lipoprotein cholesterol and very low-density lipoprotein cholesterol in the sample.

After adding R2, the esterified low-density lipoprotein cholesterol is hydrolyzed by cholesterol lipase to produce cholesterol, and the cholesterol is oxidized by cholesterol oxidase. The resulting H2O2 reacts with 4-amino-antipyrine and N,N-dimethyl-m-toluidine to produce quinone dye, and the change of light intensity resulting from the reaction is proportional to the content of LDL cholesterol in the sample. Determination of light intensity through the standard curve to calculate the content of the sample to be measured.

Component

The Hipro LDL-C test kit consists of two reagents R1 and R2, as shown on figure 1.

Figure 1



Name	Content	Quantity
Reagent 1 (R1)	Buffer solution (PH 7.0)	100mmol/L
	4-aminoantipyrine	1mmol/L
	Cholesterol esterase	800U/L
	Cholesterol oxidase	507U/L
	catalase	800U/L
Reagent 2 (R2)	Buffer solution (PH 7.0)	100mmol/L
	N, N-dimethylm-toluidine	1.2%
	peroxidase	4KU/L

Do not mix different batches of reagents.

Storage&stability

Store reagent 1 and reagent 2 at: 2°C-8°C until the expiration date indicated on the label.

Avoid exposure to direct sunlight. The two reagents are stable for one year when unopened.

Do not freeze the reagents.

Do not mix use different lot of R1 and R2.

Special Instrument Requirements

HP-AFS/1 Automatic Immunoassay System,

HP-AFS/3 Automatic Immunoassay System.

Specimen type

The specimen type of Hipro LDL-C test kit is human serum.

-Take blood samples in observance of the standard precautions for the withdrawal of biological fluids.

-In the serum samples, ensure adequate coagulation of the samples prior to centrifugation.

-Test tubes must be kept closed in a vertical position.

-Do not use samples that have remained at room temperature for more than 8 hours.

-Hermetically seal and refrigerate the samples (from 2°C-8°C) if dosage is not performed within 8 hours.

-Freeze the sample at -20°C or lower temperature if dosage is not performed within 72 hours.

-Due to possible evaporation effects, samples on the analyzer should be measured within 2 hours.

-Do not use samples and controls stabilized with azide.

Storage

Serum is stable if stored at 2°C-8°C for up to 72 hours. For longer storage, aliquot, cap tightly, and freeze at -20°C for up to 30 days. Avoid repeated freezing and thawing.

Required volume

There is a quantitative capillary on R2 for required sample volume. The capillary should be fully collected.

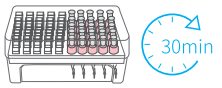
Procedures

HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

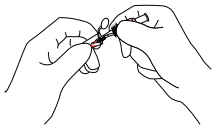
Note:

- Please read user manual of HP-AFS/1 and HP-AFS/3 before use;
- The analyzer will finish the self check after start-up;
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

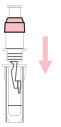
Step 1 Sample Preparation



1a Allow the test kit back to room temperature for 30 minutes before use.



1b Use the R2 with quantitative capillary to collect sample.

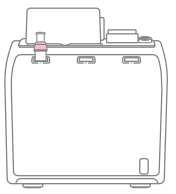


1c Insert the R2 into R1.

Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing



2a Insert the R1 into test channel of analyzer.

2b The analyzer will mix the sample from R2 capillary with R1 automatically.

2c The analyzer will mix the R2 and R1 automatically.

2d The analyzer will test and print the results automatically.

Calibration

Every Hipro LDL-C test kit contains specific information for calibration of the particular reagent lot, in the barcoded label on cuvette.

Renewed calibration is recommended as follows:

-after 1month(28days) when using the same reagent lot .

-before using new lot of reagent .

Quality Control

It is recommended that each laboratory routinely uses quality control materials and establish its own control ranges. The control intervals and limits should be adapted to each laboratory' s individual requirements. Multi-level controls should be tested in each LDL-C run. The LDL-C values obtained with the quality control material should not repeatedly fall outside the control ranges established in each laboratory. Suitable or published control material can be used.

Reference Value

The normal reference range should be < 4mmol/L.

The value is indicative only and may differ from other published values as a result of differences in methods and in the population being studied. It is recommended that each laboratory establish its own reference range.

Interpretation

Result≥4.00mmol/L indicates a risk of coronary atherosclerosis, and further examination and treatment are recommended.

Limitations

When bilirubin≤150μmol/L, hemoglobin≤5g/L, triglyceride≤0.3%, VC≤0.3g/L, it has no interference to this determination.

Interpretation

1.Linearity range:

0.25mmol/L ～ 25.8mmol/L, r≥0.995.

The linear deviation within the range of [0.25 - 3]mmol/L should not exceed ±0.2mmol/L;

The linear deviation within the range of (3 - 25.8]mmol/L should not exceed ± 10%.

2.Limit of Blank

Reagent blank absorbance< 0.05.

3.Precision

Within-lot precision (CV)≤ 3%

Between-lot precision(R)≤ 10%

4.Analytical sensitivity

When 1.00mmol/L sample was determined, the absorbance difference ΔA > 0.03

5.Accuracy

Relative deviation (B) shall not exceed ±10%

6.Precision

Test the control material by Low Density Lipoprotein Cholesterol Test Kit (Direct method - surfactant Clearance Method).2 times per day for 20 days (n=80) according to EP5-A2 of CLSI.

The data as below:

a.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean mmol/L	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	2.46	0.054	2.2	0.056	2.3
Control 3	5.68	0.098	1.7	0.151	2.7

b.

HP-AFS/1 Automatic Immunoassay System					
Sample	Mean mmol/L	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	2.53	0.048	1.9	0.21	1.7
Control 2	5.74	0.117	2.0	0.38	2.8

7. Methodology comparison

Compared to LDL-C LIA(x) by test the same serum sample, the relative data as below:

HP-AFS/3 Automatic Immunoassay System				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	Serum	50	Y= 1.01X+0.27	0.97

The concentration of sample is about 0.25mmol/L ～ 25.8mmol/L.

Precautions

⚠ Attention:

For in vitro diagnostic use

Only experienced laboratory personnel should use this test and handling all laboratory reagents should be based on normal precautions required.

Safety precautions

1.Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.

2.Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.

3.Disposal of all waste material should be in accordance with local guidelines.

Potential biohazard warning

Some reagents of Hipro test kits contain material of animal origin, even if they are certified as deriving from healthy animals, it is recommended to handle them with the same precaution used for potentially infectious samples.

Limitations-interference

Bilirubin ≤150μmol/L, hemoglobin ≤5g/L, triglyceride ≤0.3%, VC≤0.3g/L have no influence on the determination. For diagnostic purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.

Risk Phrases

R 36/38 Irritating to eyes and skin

Safety Phases

S 26 In case of contact with eyes, rinse immediately with plenty of water and seek for medical advice.

S 37 Wear suitable gloves

S 60 This material and /or its container must be disposed of as hazardous waste.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	
	Use-By date		Do not freeze
LOT	Batch code		Biological risks
	Manufacturer		Do Not Reuse
2℃ 8℃	Temperature Limit		
Σ	Contains sufficient for <n> tests		
	Do not use if package is damaged		
	Consult Instructions for use		
	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

Shang Hong, Wang Yusan, Shen Ziyu et al. National Clinical Laboratory Operating Procedures (4th edition) [M]. Beijing: People's Medical Publishing House, 2015:323-326.

Approval Date&Revision Date

Approval Date: Sept 9,2015

Revision Date: Jul 15, 2021

Revision Date: Jan 1, 2023

Revision Date: Dec 22,2023

CE IVD

尺寸:24*25cm展开尺寸,横向三折页再垂直方向两次对折