





# LEPU IVD<sup>®</sup> CE Cholesterol Analysis Solution

LP-M3-11 Cholesterol Analyzer &  
LP-S3-01 Total Cholesterol, Triglycerides, High Density  
Lipoprotein Cholesterol Test Card  
(Dry Chemical Method)

## Features

-  Micro blood sampling (35 $\mu$ L)
-  Long standby (Test more than 1000 times)
-  Light and convenient, easy to carry
-  Large screen display result clearly

## Intended Use:

In vitro quantitative determination of cholesterol (CHOL), high-density lipoprotein cholesterol (HDL) and triglyceride (TRIG) concentrations in human whole blood (capillary blood or venous blood) using the principle of light reflection.

- Please read IFU carefully or purchase and use under the guidance of medical staff
- Please refer to IFU for details of contraindications or precautions
- The product is only used as cholesterol monitoring tool, the results can't be used as a basis for clinical diagnosis



 Bluetooth Connection

## Clinical significance of

CHOL, HDL and TRIG are the basic clinical practical testing items in blood lipid testing items. These 3 tests are performed for individuals who need cardiovascular risk assessment and lipid-lowering drug treatment.

The main harm of hypercholesterolemia is to easily cause coronary heart disease and other atherosclerotic diseases; high-density lipoprotein has anti-atherosclerotic effect, and its value higher than 1.55mmol/L is considered to be protective against coronary heart disease. Factors; elevated triglycerides can directly or indirectly lead to atherosclerosis and increase the risk of coronary heart disease.

## LP-M3-11& LP-S3-01 Specifications

**Test Sample:** Whole blood (capillary blood or venous blood)

**Detection Range: CHOL:** 2.59-12.93mmol/L (100-500mg/dL)

**TRIG:** 0.51-7.34mmol/L (45-650mg/dL)

**Test Time:** ≤120 seconds

**Battery:** 4 AA/1.5V batteries

**Accessories:** Quality control test card, Disposable blood sampling needle (optional), Disposable micro blood collection device (optional)

**Test Temperature:** 10°C~30°C

**Dimensions:** 140mm x 82mm x 25mm (length x width x thickness)

**LP-S3-01 Adapted Equipment:** LP-M3-11 Cholesterol Analyzer

**LP-S3-01 Packaging Specifications:** 1/ 10/ 20/ 25/ 50 per box

**LP-S3-01 Store Condition:** 2°C~30°C, 12 months (Unopened)

(Note: Dear customer, LP-M3-11 Cholesterol Analyzer doesn't include LP-S3-01 Total Cholesterol, Triglycerides, High Density Lipoprotein Cholesterol Test Card. If LP-S3-01 is necessary, you need to purchase it separately)

**Blood Collection Method:** Blood collection needle

**HDL:** 0.39-2.59mmol/L (15-100mg/dL)

**Result Storage:** 200 latest results

**Battery Life:** 1000 times

**Test Humidity:** ≤80%

## Applicable People

It can be used by persons with medical expertise or non-professionals with hyperlipidemia (or their families) under the guidance of doctor to measure CHOL, HDL and TRIG concentrations.

## Detection Principle

After the sample to be tested is added to the sample adding area of the blood lipid test card, it penetrates into the reaction layer quickly and evenly. After the substance to be tested reacts with the enzymes and chemicals in the reaction layer, the intensity of the color is proportional to the concentration of the substance to be tested. The Cholesterol analyzer detects the color intensity of the reaction end point, and uses the reflectance ratio to calculate the concentration of Total Cholesterol (CHOL), High-density Lipoprotein Cholesterol (HDL) and Triglyceride (TRIG).

## Experimental data of Lepu LP-M3-11& LP-S3-01

Lepu IVD team conducted clinical tests of LP-M3-11& LP-S3-01 with peripheral blood samples, venous blood samples in relevant hospitals, the results are as follows:

The total cholesterol (CHOL), high-density lipoprotein cholesterol (HDL), triglyceride (TRIG) and low-density lipoprotein (LDL) obtained from venous and peripheral blood samples were detected in the clinical test, the differences of the calculated values of four detection indicators are evenly distributed on the upper and lower sides of the center line 0, indicating that the product data meets the requirements compared with the results of venous blood samples.



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