

Plasma/Serum test for high-density lipoprotein cholesterol

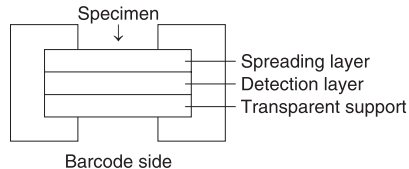
FUJI DRI-CHEM SLIDE HDL-C-PIIID

[Warnings and precautions]

- Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
- Do not touch either the center part of the surface or the back of the slide.
- A new slide must be used for each measurement. Do not reuse.
- Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
- Used slides are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, melting, sterilization or disinfection.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

| | |
|---|-------------------|
| • Cholesterol esterase | 0.57 U |
| • Cholesterol oxidase | 0.17 U |
| • Peroxidase | 9.4 U |
| • 4-Aminoantipyrine | 47 µg (0.23 µmol) |
| • N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline sodium salt (DAOS) | 70 µg (0.21 µmol) |

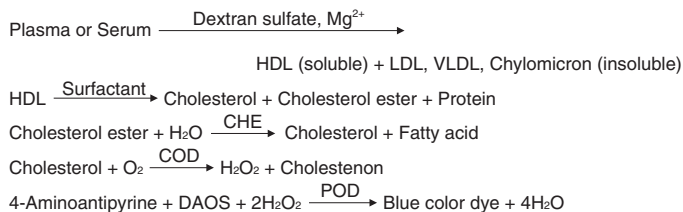
[Intended use]

Quantitative measurement of high-density lipoprotein cholesterol in plasma or serum.

For *in vitro* diagnostic use only.

[Principle of the measurement]

A drop (10 µL) of plasma or serum is deposited on the FUJI DRI-CHEM SLIDE HDL-C-PIIID. The specimen is uniformly distributed on the spreading layer. The chylomicron, very low density lipoprotein (VLDL) and low density lipoprotein (LDL) react with the dextran sulfate to form insoluble complexes. On the other hand, high density lipoprotein (HDL) dissociates into protein and lipid (cholesterol component) upon the reaction with the surfactant. The cholesterol esters in the lipids are converted into cholesterol by cholesterol esterase (CHE). The generated cholesterol and endogenous cholesterol are oxidized by cholesterol oxidase (COD) to form hydrogen peroxide. Peroxidase (POD) reacts with the hydrogen peroxide to initiate the coupling reaction between the 4-aminoantipyrine and DAOS forming a blue color dye. The reaction scheme is as shown below.



The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 600 nm. The optical reflection density is then converted into the HDL-C concentration using a calibration curve preinstalled in the analyzer.

[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER
 Other implements: FUJI DRI-CHEM QC CARD (attached)
 : FUJI DRI-CHEM CLEAN TIPS or FUJI DRI-CHEM AUTO TIPS
 : FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

[Specimen requirements]

- For plasma, heparin can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
- Avoid using plasma or serum with precipitate such as fibrin.
- When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.
- Specimen of high neutral fat (over 5.6 mmol/L) may be highly measured.

[Procedure]

- Read in the new QC-card when you switch to a new box of slides.
- Set slides on FUJI DRI-CHEM ANALYZER.
- Set a sample tube in the specified sample rack.
- Input a sequence No. and a sample ID if appropriate.
- Press the "START" key to initiate testing.
 For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

| | |
|--------|--------------------------------|
| Male | 0.96–1.73 mmol/L (37–67 mg/dL) |
| Female | 1.03–1.84 mmol/L (40–71 mg/dL) |

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals. The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

[Performance characteristics]

1. **Dynamic range** 0.26–2.84 mmol/L (10–110 mg/dL)

2. Accuracy

| Concentration range | Accuracy |
|---------------------|----------------------|
| 0.26–1.03 mmol/L | Within ± 0.21 mmol/L |
| 1.03–2.84 mmol/L | Within ± 20 % |

3. Precision

| Concentration range | Precision |
|---------------------|------------------|
| 0.26–1.03 mmol/L | SD ≤ 0.10 mmol/L |
| 1.03–2.84 mmol/L | CV ≤ 10 % |

4. Correlation

Correlation was evaluated between HDL homogenous method and FUJI DRI-CHEM system. HDL homogenous method was performed on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

| | n | Slope | Intercept | Correlation coefficient |
|--------|----|-------|-----------|-------------------------|
| Serum | 86 | 0.966 | 1.7 | 0.986 |
| Plasma | 63 | 0.973 | 1.3 | 0.993 |

5. Known interfering substances

- (1) Dobutamine hydrochloride (cardiotonic reagent) and dopamine hydrochloride (cardiotonic reagent) give minus bias.
- (2) No significant effect was observed to the following concentration for each substance.

| | |
|---------------|-------------|
| Ascorbic acid | 0.57 mmol/L |
| Bilirubin | 340 µmol/L |
| Hemoglobin | 2000 mg/L |
| Total protein | 40-95 g/L |
| Uric acid | 0.54 mmol/L |

These results are representative;

- Test condition may have some influence on your results.
- Interferences from other substances are not predictable.

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QP-L.

1. Measure FUJI DRI-CHEM CONTROL QP-L in the same way as patient specimens.
2. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L, investigate the cause.
 For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L.

[Traceability of calibrators and control materials]

HDL-cholesterol...ReCCS (CHT)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
 ReCCS: Reference Material Institute for Clinical Chemistry Standards

[Storage and shelf life]

1. Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
2. Expiry date is printed on the carton.
3. Use immediately after opening the individual package.

[Contents]

| | |
|-----------|----|
| : Slide | 24 |
| : QC card | 1 |

<http://www.fujifilm.com/products/medical/>

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