

Plasma/Serum test for total cholesterol

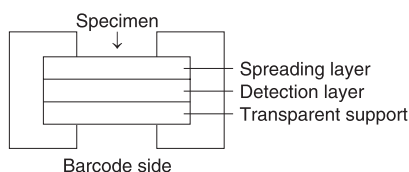
FUJI DRI-CHEM SLIDE TCHO-PIII

[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 0.38 U
- Cholesterol oxidase 0.67 U
- Peroxidase 7.1 U
- Diarylimidazole leuco dye 0.075 mg (0.15 μmol)

3. Other Ingredients

- Surfactant
- Potassium ferrocyanide

[Intended use]

Quantitative measurement of total cholesterol concentration in plasma or serum.
For *in vitro* diagnostic use only.

[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE TCHO-PIII. After depositing, the specimen spreads uniformly on the spreading layer and lipoproteins are dissociated to lipid (cholesterol) and protein by the action of surfactant. Following this, cholesterol ester is hydrolyzed to produce free form of the cholesterol by cholesterol esterase (CHE). This free cholesterol and endogenous cholesterol generate hydrogen peroxide by the reaction with cholesterol oxidase (COD). Hydrogen peroxide and peroxidase (POD) oxidize leuco-dye to form the blue color dye. 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 505 nm. The change in optical reflection density is then converted into the total cholesterol concentration using a calibration curve preinstalled in the analyzer.

Lipoprotein $\xrightarrow{\text{Surfactant}}$ Cholesterol + Cholesterol ester + Protein

Cholesterol ester + H₂O $\xrightarrow{\text{CHE}}$ Cholesterol (free) + Fatty acid

Cholesterol + O₂ $\xrightarrow{\text{COD}}$ H₂O₂ + Cholestenon

Diarylimidazole leuco dye + H₂O₂ $\xrightarrow{\text{POD}}$ Blue color dye + 2H₂O

[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]

- After collecting the blood specimen, immediate measurement is recommended.
- For plasma, heparin or EDTA salt can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. When using EDTA salt, less than 5 mg should be used per 1 mL of whole blood. Do not use sodium fluoride, citric acid, oxalic acid and moniodoacetic acid.
- Avoid using plasma or serum with precipitate such as fibrin.
- High concentration of triglycerides may cause minus bias to the measurement value.
- 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.

[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]

3.88–5.66 mmol/L (150–219 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** 1.29–11.64 mmol/L (50–450 mg/dL)

2. **Accuracy**

Concentration range	Accuracy
1.29–11.64 mmol/L	Within ±15 %

3. **Precision**

Concentration range	Precision
1.29–11.64 mmol/L	CV ≤ 5 %

4. **Correlation**

Correlation was evaluated between CHE-COD Method and FUJI DRI-CHEM system. CHE-COD Method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

	n	Slope	Intercept	Correlation coefficient
Serum	78	0.992	0.05	0.997

5. **Known interfering substances**

- Dobutamine hydrochloride (cardiotonic reagent) gives minus bias.
- The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	0.57 mmol/L
Bilirubin	170 μmol/L
Hemoglobin	3000 mg/L
Total protein	45–85 g/L
Uric acid	119–536 μmol/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 and/or QP-H.

- Select control level in accordance with your purpose.
- Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
- When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause.
For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Total cholesterol...NIST (SRM1951)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

NIST: National Institute of Standards & Technology

[Storage and shelf life]

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

[Contents]

: Slide 24
: QC card 1



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

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