[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 sample 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 converted to the total cholesterol concentration using a calibration curve preinstalled in the analyzer.

Lipoprotein → Cholesterol + Cholesterol ester + Protein
Cholesterol ester + H₂O → Cholesterol (free) + Fatty acid
Cholesterol + O₂ → H₂O₂ + Cholestenon
Diarylimidazole leuco dye + H₂O₂ → POD + Blue color dye + H₂O

[Composition of the slide]
1. Multi-layered structure
   - Sample
   - Spreading layer
   - Detection layer
   - Transparent support
   - Barcode side

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

[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

[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.

[Warnings and precautions]
1. Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not touch the membrane in the center of the slide.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle all patient samples, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
5. Used slides are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribes the proper method of disposal, such as incineration, melting, sterilization or disinfection.
6. Because it is highly sensitive to light, as soon as the slide is taken out of its package, it should be set in the cartridge with the slide weight placed on the top of it.
7. Keep QC card away from magnetic material.
8. Do not use the slide if the individual package is damaged.

[Sample requirements]
1. After collecting blood sample immediate measurement is recommended.
2. 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 monomidoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. High concentration of triglycerides may cause minus bias to the measurement value.
5. 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]
1. Read in the new QC-card when you switch to a new box of slides.
2. Set slides on FUJI DRI-CHEM ANALYZER.
3. Set a sample tube in the specified sample rack.
4. Input a sequence No. and a sample ID if appropriate.
5. Press the “START” key to initiate testing.

CAUTION: Use immediately after opening the individual package. For further details of operation procedure, consult “INSTRUCTION MANUAL” for FUJI DRI-CHEM ANALYZER.

[Internal quality control]
The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QP-L and/or QP-H.
1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient samples.
3. 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.

[Reference intervals]
150–219 mg/dL (3.88–5.66 mmol/L)
As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals.

[Limitation of the examination procedure]
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.

Known interfering substances
(1) No significant effect was observed to the following concentration for each substance.
   - Ascorbic acid 10 mg/dL (0.57 mmol/L)
   - Bilirubin 10 mg/dL (170 μmol/L)
   - Hemoglobin 0000 mg/L
   - Total protein 45–85 g/L
   - Uric acid 2–9 mg/dL (119–536 μmol/L)
(2) Dobutamine hydrochloride (cardiotonic reagent) and dopamine hydrochloride (cardiotonic reagent) give minus bias. These results are representative;
   - Test condition may have some influence on your results.
   - Interferences from other substances are not predictable.

[Performance characteristics]
1. Dynamic range
   - 50–450 mg/dL (1.29–11.64 mmol/L)
2. Accuracy
   - Serum 78 0.992 1.8 0.997
3. Precision
   - Within ± 15 %
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.
[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

[Contents]

Slide : 24
QC card : 1

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

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[Symbols]

Do not touch the center part of the slide.

Warmed up to room temperature before opening the individual packages.

SLIDE CODE

Do not reuse

Lot number

Use by

Contains sufﬁcient for <n> tests

Temperature limitation

Consult instructions for use

In vitro diagnostic medical devices

Manufacturer

Authorized representative in the European Community