

To be used with multiCare reflectometer.
Instructions for use

Introduction.

With the multiCare Cholesterol strips it is possible to quickly check cholesterol levels in the blood and inform the family physician to find a suitable therapy or to check-up on an existing therapy.

The level of cholesterol in the blood is influenced by the diet, but also by: medicines, diabetes mellitus, pregnancy and severe illnesses. It is recommended to check blood cholesterol concentration on all people who are used to smoke, to drink too much alcohol and to eat fat and are over weighted or do not exercise enough. It is specially recommended to people who already had heart disease or with familial cases of heart diseases before the age of 60. Perform the test at fast for at least 9 hours.

Test principle. The test is based on a Cholesterol/Esterase Oxidase/Peroxidase/Chromogen reaction.

The intensity the colour developed from the reaction is proportional to the concentration of cholesterol in the blood.

Performing the test.

- Open the box of multiCare Cholesterol strips of green colour and take the chip of the same colour contained inside the box.

- Insert the chip into the appropriate space behind the multiCare

Reflectometer with the arrow turned upward (Picture 1).

- Open the vial, take out the strip and close it immediately.

- Insert the strip into the reflectometer, with the arrow turned towards the reflectometer and the symbol of the parameter on the up side of the strip, until you hear a click sound (Picture 2).

- Check on the display if the CH symbol appears and check that the number displayed is the same of the one printed on the strip vial label (Picture 3).
- Wash the hand with hot water and massage the finger that you choose for the pricking to increase the blood flow. Let your arm hang down for about 1 minute.

- Execute the puncture of the finger using the Lancing Device contained in the multiCare Reflectometer set and a sterile lancet.

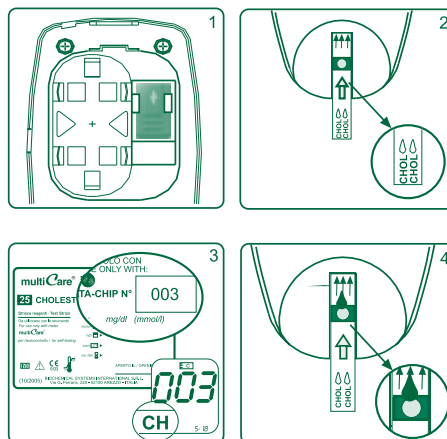
- Remove the first drop of blood and gently press the finger tip to obtain a second big drop (minimum 10 microliters). If the pression on the finger is excessive, the result could be altered.

- When blood is sufficient, (when there is a hanging drop), place the drop of blood onto the white rounded part of the strips as indicated in the picture 4 and after some seconds the result will be displayed.

Apply the drop of blood on the strip only when it is inserted on the instrument.

Only one measurement can be carried out for each blood sample!

Carefully follow the instructions contained in the multiCare user manual. Dispose properly all components of the pack, avoiding contaminations.



Correct test execution check. After each measurement, check the circular opening under the reactive area in correspondence to the opposite surface where the blood sample has been applied, the colour must be uniform. If not, repeat the measurement.

Testing the system. A check-up of the user's skill, the correct working of the multiCare instrument and its strips, must be periodically carried out through the use of the Cholesterol multiCare Control Solutions and by following the included instructions.

The expected results for this test are printed on the vial's label of the multiCare Cholesterol strips that are being used.

Cholesterol values.

Less than 200 mg/dL (5.1 mmol/l) = desirable values

From 200 (5.1 mmol/l) to 239 mg/dL (6.1 mmol/l) = high risk factor

More than or equal to 240 mg/dL (6.1 mmol/l) = high cholesterol

The analytical results have to be communicated to the physician.

The self-checking can be useful for the physician in order to formulate a diagnosis.

Table of results :

Cholesterol below 130 mg/dL (3.3 mmol/l) = LO

Cholesterol between 130 mg/dL (3.3 mmol/l) and 400 mg/dL (10.2 mmol/l) = the numerical result

Cholesterol above 400 mg/dL (10.2 mmol/l) the display = HI

Warnings

* Long exposure to air and light can alter the results. It is recommended to keep the strips in the original vial with the cap at room temperature between 10 and 35°C (50 and 95°F).

* Avoid exposing to excessive humidity, do not freeze!

* Keep the multiCare Cholesterol strips away from children.

* Do not perform any tests below 5°C (41°F) or above 45°C (113°F).

* Do not touch reacting strips with polluting agents, like for example dirty hands, the results could be seriously altered.

* Use the strip immediately after removing it from the vial.

* Make sure the vial is properly closed after removing the strip and use its original cap containing drying material. Do not place the strips in a different container.

* The multiCare strips must be used within and not after the expiry date on the package. Once the vial has been opened, use the strips within 3 months. The reactive area on the strip is white in optimal conditions. Do not use the strip if the reactive area has a different colour.

Notes for doctors and labs. To measure the cholesterol with the multiCare system, it is possible to use either fresh capillary blood or venous blood treated with heparin or K-EDTA. Do not use fluoride or oxalate as anticoagulant. Do not use serum or plasma on the strip.

Limitations.

* If the value of cholesterol after testing does not correspond to the normal sensations felt by the patient and to the basic knowledge of health conditions and symptoms, repeat the test. Read the user manual to verify the correct determination procedure and consult your physician.

* Recent illness, pregnancy and hormonal contraceptives may influence the cholesterol values. Results obtained under such conditions must be referred to the physician before any dietetic or therapeutic measures are applied.

* Should the values of cholesterol be over 240 mg/dL (6.1 mmol/l), contact a physician immediately

* Reducing agents like for example, Ascorbic acid, at normal concentrations, do not interfere. If high quantities are taken, low cholesterol values could be obtained.

* The result is affected by high levels of steroids, triglycerides and bilirubin.

* Inaccurate results can be obtained at high altitudes since the concentration of oxygen is lower.

* Abnormal values of hematocrit (higher than 50% or lower than 35%) can influence the results.

* **Minimum volume of blood sample: 10 µL.**

Accuracy. The average error of multiCare system compared to the reference method CHOD-PAP is <10%. In a series of measurements performed in a hospital, the following linear regression has been obtained $y = 1.0x - 0.5$.

Precision. Repeatability: the average imprecision is <5%, in a series of measurements performed in laboratory an average coefficient of variation of 2.48% was obtained.

Reproducibility. The average imprecision is <5%, in a series of measurements performed in laboratory an average coefficient of variation of 2.79% was obtained.

Composition. Chromogen: 0.025 mg / strip - Cholesterol esterase: 0.8 IU / strip - Cholesterol oxidase: 0.4 IU / strip - Peroxidase: 1.2 IU / strip



IVD In vitro Diagnostic
Control solutions
Level 1
Level 2

Packaging: 5 strips pack
10 strips pack
25 strips pack
Manufacturer: Biochemical Systems International srl
multiCare Customer Service: Phone +39 0575 984164
e-mail multicare@biosys.it
IN VITRO DIAGNOSTICUM