

Reagent strips for the determination of Triglycerides concentration

To be used only with multiCareⁱⁿ instrument

Instructions for use

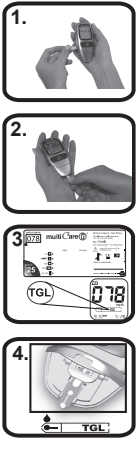
Introduction
Using the "multiCare-in" Triglycerides strips it is possible to quickly check triglycerides level in the blood. The level of triglycerides in the blood is influenced from fat feeding or from alterations of the metabolism of lipids but also from diabetes mellitus, nephrotic syndromes, pancreas problems, acute alcoholism. It is important to inform the family physician to find a suitable therapy or to check-up on an existing therapy. Perform the test when you have not had anything to eat or drink (except water) for at least 12 hours.

Test principle
The test is based on Lipase/Glycerol Kinase/ Phosphate Oxidase Glycerol /Peroxidase/Cromogen reaction. The intensity the colour develops from the reaction is proportional to the concentration of triglycerides in the blood.

Composition
The reactive area of each strip contains: chromogen min. 0.017 mg; lipase: 1.02 U; glycerol 3-phosphate oxidase 0.31 U; Glycerol kinase 0.41 U; Peroxidase: 1.2 U.

PROCEDURE

- Open the pack of "multicare -in" Triglycerides strips, pull out the data-chip of yellow color.
- Insert the data-chip into the proper space on the side of the meter (picture 1).
- Open the vial, take a strip and immediately close it.
- Insert the strip in the strip holder of the meter (picture 2), with coloured side visible, till to hear an acoustic signal ("bip").
- Check that TGL symbol appears on the display and check that the number on the strip vial label is the same of the one on the display (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 one minute
- Execute the puncture of the finger using the lancing device and a sterile lancet.
- Remove the first drop with a sterile gauze and gently press the finger to obtain a second drop (10 microliters)
- Apply the drop on the white circular area of the strip that comes out from the meter. The sample of blood will be automatically aspirated by the strip. Do not remove the finger until the moving segments will appear on the display (the instrument will emit an acoustic signal "bip").
- After some seconds the result will be displayed
- Use the ejector key on the backside of the meter to remove the used strips in order to avoid contaminations.



Only one measurement has to be carried out for each finger pricking! Carefully follow the instructions contained in the user manual. All components of the pack has to be disposed properly, avoiding contaminations.

Testing the system

A check-up of the user's skills, the correct working of the "multiCare-in" Triglycerides instrument and its strips, must be periodically carried out through the use of the "multiCare-in" Triglycerides Control Solutions and by following the included instructions.
The expected results for this test are printed on the vial's label of the "multiCare-in" Triglycerides strips that are being used.

Storage and expiry date

Keep the reactive strips at temperatures between 5°C (41°F) and 30°C (86°F) and keep them in the original vial. Do not expose to direct sun light. Close the vial with the original cap immediately after pull out the strip. In this way, the strips will last up to 3 months after the first opening. The expiry date on the package of strips refers to a new unopened vial. The use of expired strips can cause wrong results. Do not expose to excessive humidity. Do not freeze!

Table of results displayed:	Below 50 mg/dL (0.5 mmol/L) = LO* Between 50 mg/dL (0.5 mmol/L) and 500 mg/dL (5.6 mmol/L) = the numerical result Above 500 mg/dL (5.6 mmol/L) = HI**
*Repeat the test.	
**Such results mean that the Triglycerides concentration in the sample is very elevated and it indicates a serious risk. CONTACT A PHYSICIAN IMMEDIATELY	

Triglycerides values:	Less than 150 mg/dl (1.7mmol/L) = Normal Borderline High= 150-199 mg/dL (1.7-2.2 mmol/L) High= 200-499 mg/dL (2.3-5.6 mmol/L) Very High= 500 mg/dL (5.6 mmol/L) or above
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.	

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 5 and 30°C (41°F and 86°F).
- *Avoid exposing to excessive humidity, do not freeze!
- *Keep the "multiCare-in" Triglycerides strips away from children.
- *Do not perform any tests bellow 10° C (50°F) or above 40°C (104°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 siccative material. Do not place the strips in a different container.
- *The "multiCare-in" Triglycerides 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 Triglycerides with the "multiCare-in" system, it is possible to use fresh capillary blood. Do not use serum or plasma on the strip.

Limitations

*If the value of triglycerides 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.

- *The result is affected by high levels of hemoglobin, bilirubin and ascorbic acid.
- *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 30%) can influence the results.
- *Minimum volume of blood sample: 10 µL.

Accuracy

The average error of the "multiCare-in" Triglycerides system compared to the reference method GPO is <10%. In a series of measurements performed in a hospital, the following linear regression has been obtained
 $y=0.9814x + 3.8374$.

Precision

Repeatability: the average inaccuracy is <5%, in a series of measurements performed in laboratory an average coefficient of variation of 4.66% was obtained.
Reproducibility: the average inaccuracy is <5%, in a series of measurements performed in laboratory an average coefficient of variation of 4.62% was obtained.

References

Onat A, Sari I, Yazici M, Can G, Hergenc G, Avci GS. Plasma triglycerides, an independent predictor of cardiovascular disease in men: A prospective study based on a population with prevalent metabolic syndrome. Int J Cardiol. 2005 Aug 4; [Epub ahead of print].

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