



REAGENT STRIPS FOR THE LIPID MEASUREMENT

INTRODUCTION

LUX lipid test strips measure total cholesterol, HDL cholesterol and triglycerides in capillary blood when used with the LUX multiparameter device.

A code chip is provided with each pack of strips and must be properly inserted into the meter before performing the test. The code chip contains code number; the results are displayed in three minutes.

INTENDED USE

Lipids are made of lipoproteins low density (LDL), lipoproteins high density (HDL) and triglycerides (TG). LUX reagent strips are used to measure cholesterol, triglycerides and HDL cholesterol from capillary blood. The strips are used also for the calculation of low density lipoprotein (LDL), of the cholesterol/HDL cholesterol ratio (CHOL/HDL) and the cholesterol LDL/cholesterol HDL ratio (LDL/HDL). The strips are for in-vitro diagnostic use and give information on the lipoprotein metabolism.

TEST PRINCIPLE

Lipid test results are based on the reading of light reflected from the reagent strip that has changed color after applying of the sample. The intensity of the color developed from the reaction is proportional to the concentration of that parameter in the blood. LUX device converts this reading into a numerical result and show it on the display.

PREANALYTICAL PHASE

To obtain a drop of blood from a fingerstick, follow the steps below:

Use of lotion and handcream should be avoided before testing.

Hands should be washed in warm water with antibacterial soap and rinsed thoroughly.

If you use an alcohol wipe, be sure that the alcohol dries completely before pricking the finger.

Let your arm hang down along the body for about one minute.

Massage the finger to increase blood flow.

Use a sterile, disposable lancet to prick the side of the fingertip.

Wipe away the first drop of blood with a clean piece of gauze.

Gently, without force, apply pressure to the fingertip to accumulate a drop of blood.

Attention! Excessive squeezing of the finger may alter test results.

MEASUREMENT PROCEDURE

- 1- Use the pipette of 15µL included in the meter kit in order to collect the sample.
- 2- Fill the tip very gently, in order to avoid bubbles, paying attention to not aspirate air.
- 3- Apply the blood on the first round well of the strip. You will see the segments related to the first line move on the display.
- 4- Repeat the points 3, 4 and 5 to fill the second and the third well.
- 5- Wait about three minutes for the results.

Attention! Discard the used materials in the proper way. Handle and dispose all the materials that have been in contact with the blood basing on the actual norms and guidelines.

TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL) or in millimoles per liter (mmol/L). The LUX meter is preset by the manufacturer in mg/dL.

EXPECTED VALUES

The expected or reference ranges recommended from the US National Cholesterol Education Program (NCEP) 2006 are the following:

EXPECTED VALUES OF CHOLESTEROL (TOTAL)

< 200 mg/L (5,18 mmol/L)	desiderable
between 200 and 239 mg/L (5,18-6,20 mmol/L)	borderline
> or = 240mg/L (6,21 mmol/L)	high

EXPECTED VALUES OF HDL CHOLESTEROL

< 40 mg/L (1,04 mmol/L)	low HDL cholesterol (high risk of CHD*)
> or = 60 mg/L (1,55 mmol/L)	high HDL cholesterol (low risk of CHD*)

* CHD-Coronary Heart Disease

EXPECTED VALUES OF TRIGLYCERIDES

< 150 mg/L (1,70 mmol/L)	normal
between 150 and 199 mg/L (1,70-2,25 mmol/L)	borderline
between 200 and 499 mg/L (2,26-5,64 mmol/L)	high
>or = 500 mg/L (5,65 mmol/L)	very high

EXPECTED VALUES OF LDL CHOLESTEROL

<100 mg/L (2,59 mmol/L)	optimal
between 100 and 129 mg/L (2,59-3,34 mmol/L)	near optimal
between 130 and 159 mg/L (3,36-4,12 mmol/L)	borderline
between 160 and 189 mg/L (4,14-4,90 mmol/L)	high
> or =190 mg/L (4,92 mmol/L)	very high

The LDL cholesterol can be calculated using the following equation:

$$\text{LDL (CALCULATED)} = \text{TOTAL CHOLESTEROL} - \text{HDL} - (\text{TRIGLYCERIDES}/5)$$

The calculated LDL cholesterol is an estimation of LDL and it is valid only if triglycerides level is lower than 350 mg/dL. The cholesterol/HDL Ratio (TC/HDL ratio) and the LDL cholesterol/HDL cholesterol (LDL/HDL) ratio are calculated.

LIMITATIONS

Studies were performed to test for substances that may interfere with the lipid tests. The results of these tests are below reported:

1. DRUGS: Dopamine and methylidopa decreased the results of all the lipids.
2. METABOLITES: Extremely high doses of ascorbic acid (Vitamin C) decreased the results of all the lipids.
3. HEMATOCRIT: No hematocrit effect was observed for samples between HCT 30 and 50%.
4. NEONATAL USE: There has been no data generated to validate the use of this system with neonatal samples.
5. Cosmetics such as hand creams or lotions often contain glycerol. Use of these products may cause inaccurate results.
6. Displayed results are rounded.

MEASURING RANGE

When we use the LUX lipid strips, the results will be displayed as a numeric results in the following ranges:

Cholesterol: 100-400 mg/dL (2,59 - 10,36 mmol/L)

HDL Cholesterol: 20-80 mg/dL (0,52-2,07 mmol/L)

Triglycerides: 50-600 mg/dL (0,57 - 6,78 mmol/L)

When the results are below the range LOW (less than the measuring range) will be displayed. When the results are above the range, "HIGH" will be displayed (more than the measuring range). IMPORTANT: if you get a result "LOW" or "HIGH" or an unexpected result for any test, test again with a new reagent strip.

PERFORMANCE CHARACTERISTICS

ACCURACY : Comparing studies of LUX system with the Cholesterol Reference Method Laboratory Network (CRMLN) are listed below:

LUX CHOLESTEROL STRIPS VS LABORATORY CRMLN.

n = 110 samples
examined samples: from 100 to 400 mg/L
 $y = 0,99 \times -1,53$
r = 0,96

LUX HDL CHOLESTEROL STRIPS VS LABORATORY CRMLN

n = 110 samples
examined samples: from 20 to 80 mg/L
 $y = 1,05 \times -3,1$
r = 0,90

LUX TRIGLYCERIDES STRIPS VS LABORATORY CRMLN

n = 110 samples
examined samples: from 50 to 600 mg/L
 $y = 0,98 \times 1,8$
r = 0,95

PRECISION: Two levels for cholesterol, HDL cholesterol and triglycerides were tested by laboratory people with the LUX reagent strips for the measurement of lipids. The results are following:

TOTAL CHOLESTEROL

N. of measurements (n)	80	80
Average cholesterol concentration (mg/dL)	140,3	235,5
Standard Deviation (mg/dL)	3,0	8,0
Coefficient of variation (%)	2,1	3,4

TRIGLYCERIDES

N. of measurements (n)	80	80
Average Triglycerides concentration (mg/dL)	102,8	312,4
Standard Deviation (mg/dL)	4,1	12,4
Coefficient of variation (%)	4,0	4,0

HDL CHOLESTEROL

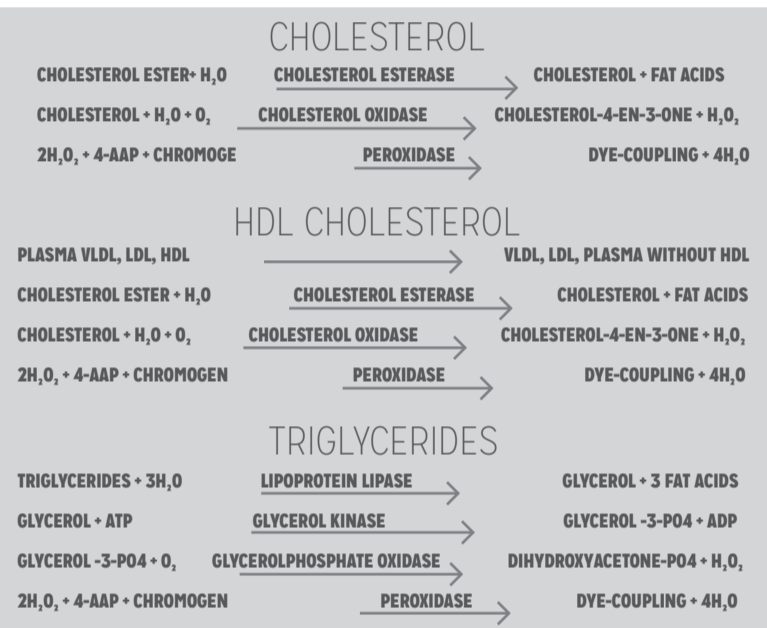
N. of measurements (n)	80	80
Average HDL cholesterol concentration (mg/dL)	45,5	70,1
Standard Deviation (mg/dL)	1,7	3,4
Coefficient of variation (%)	3,7	4,8

REFERENCE

1. NCCLS Evaluation of Precision Performance of Clinical Chemistry Devices: Approved Guideline. 1999;19(2):1-48.EP5-A.
2. National Cholesterol Education program 2001 Guidelines, National Institutes of health, National heart, Lung and Blood Institute . May, 2006
3. NCEP Guidelines for CHD Risk. JAMA. 2001. 285:2486-2509.
4. Friedewald et al. Clin Chem. 1972. 18(6):499-502.

SYMBOL DESCRIPTION

SYMBOL	DESCRIPTION
	READ INSTRUCTIONS FOR USE
	STORE AT TEMPERATURE BETWEEN
	USE WITHIN
	MNAUFACTURER
	LOT NUMBER
	FOR IN VITRO DIAGNOSTIC USE
	THIS PRODUCT COMPLIES THE REQUIREMENTS OF THE DIRECTIVE 98/79/CE FOR THE IN VITRO DIAGNOSTIC DEVICE.



NECESSARY MATERIALS

- Pipette (15µL) for the collecting of the capillary blood, included in the LUX meter kit
- LUX meter
- Single use lancets or lancing device and lancets adapted for measurements on many people
- Alcohol wipes

COMPOSITION

Each LUX lipid reagent strips contains the following active ingredients:

- Cholesterol Esterase(Pseudomonas sp.) ≥ 0.2 Unit
 - Cholesterol Oxidase (Microorganism) ≥ 0.2 Unit
 - Peroxidase (Horseradish) ≥ 0.3 Unit
 - 4-aminoantipyrine ≥ 500 µg
 - Chromogen ≥ 536 µg
 - Phosphotungstic acid ≥ 525 µg
 - Lipoprotein lipase(Pseudomonas sp.) ≥ 0.4 Unit
 - L-a-Glycerophosphate Oxidase (Pediococcus sp.) ≥ 0.38 Unit
 - Glycerol Kinase(Microorganism) ≥ 0.38 Unit
 - ATP(Microorganism) ≥ 462 µg
- Each vial contains not more than 5g powder desiccant.

STORAGE AND HANDLING

- Store test strip package in a cool, dry place at room temperature of 8-30°C (46.4-86°F). Do not freeze.
- Keep away from heat and direct sunlight.
- Do not remove the desiccant from the vial.
- Always replace vial cap immediately after removing a test strip.
- Use reagent strip as soon as you have removed it from the vial.
- Keep the code chip either in the analyzer or stored with the original pack of reagent strips.
- Store the reagent strips in the original vial. Do not combine with other strips and do not store the code chip in the reagent strip vial.
- After opening, the reagent strips are stable until expiry date if the vial is properly stored and always closed with his original cap.

PRECAUTIONS

- For in vitro diagnostic use.
- Make sure that the code chip number and the reagent strips lot numbers matches each other. Do not use a code chip from a different the test strip.
- Do not use expired or long time opened reagent strips. Check the strips vial or the pack for expiry date.
- Apply the right quantity of blood to the reagent strip once. If you do not get all of the minimum blood quantity on the strip, do not add more blood to the same strip. Repeat the test with a new reagent strip and use a fresh blood sample.
- Discard reagent strip after use. Strips can be read once. Do not use used strips for the test.
- Do not ingest.

PREPARATION OF THE TEST

The reagent strips for the measurement of the lipids are designed to be used with capillary blood. Prepare the pipette of 15 µL included in the meter kit by inserting the tip included in the strip pack. After that, insert the strip in the LUX meter and then switch on the LUX meter.



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