LUX

# REAGENT STRIPS FOR THE HEMOGLOBIN MEASUREMENT

## INTRODUCTION
LUX hemglobin reagent strips are useful for the measurement of total hemoglobin in the whole blood when used with 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 five seconds.

## INDICATION FOR USE
The LUX reagent strips are used for the quantitative measurement of the hemoglobin in whole blood (from fingerpicking or venous blood) in first aid department using LUX device.

## TEST PRINCIPLE
When the blood is applied on the strip, hemoglobin reacts developing color that is read by the device. The reaction is the following:

HEMOGLOBIN

Whole blood → Surfactant → Emolysis

## NECESSARY MATERIALS
• Pipette (7 µL) for the collecting of the capillary blood, not included in the LUX meter kit
• LUX meter
• Single use lancets or lancing device and lancets adapted for measurements on many people
• Alchol wipes

## COMPOSITION
LUX reagent strip for hemoglobin contains following reagents:
**SURFACTANT ≥ 150 µG / POLYMER ≥ 7 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). The strips are stable 3 months after opening.
• Use the strips before the expiry date indicated on the pack
• Keep away from heat and direct sunlight.
• Do not remove the desiccant from the vial.
• Always close the 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.
• The reagent strips are stable until expiry date if the vial is properly stored and always closed with his original cap.

## WARNINGS
• 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 hemoglobin are designed to be used with capillary blood. It is possible to use venous blood.
Prepare the pipette of 7 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.

## PREANALITICAL 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 soap and rinsed dried thoroughly.
If you use a alcohol wipe, be sure that the alcohol dries completely before prick 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 7µL in order to collect the sample.
2- Fill the tip very slowly, in order to avoid bubbles, paying attention to not aspirate air.
3- Apply the blood on the first well where is visible the white membrane.
You will see the segments related to the first line move on the display.
4- Repeat the points 3, 4 and 5 to fille 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 (g/dL) or in millimoles per liter (mmol/dL). The LUX meter is preset by the manufacturer in g/dL.

## EXPECTED VALUES
The expected or reference ranges recommended from the H15-A del US National Committee for Clinical Laboratory Standards (NCCLS).

**EXPECTED VALUES OF HEMOGLOBIN**

| | |
|---|---|
| < 12 g/dL (7,45 mmol/L) | Low |
| between 13 and 17 g/dL (8,07-10,55 mmol/L) | normal (male) |
| between 12 and 15 g/dL (7,45-9,31 mmol/L) | normal (female) |
| between 16 and 23 g/dL (9,94-14,27 mmol/L) | high |
| > or = 24 g/dL (9,94-14,27 mmol/L) | very high |

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

1. PRESERVANT: EDTA and heparin contained in the tube for collecting of the venous blood does not affect the results.
2. INTERFERENTS: acetaminophen (20 mg/dL), ascorbic acid (4 mg/dL), conjugated bilirubin (8,4 mg/dL for Hb < 10 g/dL, 20,3 mg/dL for Hb> 10 g/dL), cholesterol (340 mg/dL), creatinine (30 mg/dL), HbCO (25%), emolysis (25%), ibuprofen (40 mg/dL), triglycerides about (500 mg/dL), metahemoglobin (14%), tetracicline (20 mg/dL), urea (500 mg/dL), uric acid (20 mg/dL) does not affect the results. The concentration of the tested substances are indicated bewteen parenthesis. The studies on interferences were performed following the norm NCCLS EP7.
3. PH values between 6.3 to 9.0 do not interfere with the system.

## ADDITIONAL CONSIDERATION
1. Cosmetics such as hand creams or lotions often contain glycerol. Use of these products may cause inaccurate results.
2. Displayed results are rounded.

## MEASURING RANGE
When we use the LUX hemoglobin strips, the results will be displayed as a numeric results in the following ranges: 5-25 g/dL (3,1-15,51 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 for the hemoglobin measurement with the Hemocue microcuvette are listed below:

hemoglobin strips LUX vs Hemocue microcuvette Hb 301.
n = 80 samples
range of examined samples: da 5 a 25 g/dL

**ACCURACY**

| Range | Equation | R2 |
|---|---|---|
| 5 - 25 g/dL | y = 1,0291x – 0,4816 | 0,9809 |

**PRECISION**: Two different levels of hemoglobin were tested on whole blood by laboratory people with the LUX reagent strips for the measurement of hemoglobin. The results are following:

**PRECISION**

| | | |
|---|---|---|
| N. of measurements (n) | 20 | 20 |
| Average hemoglobin concentration (g/dL) | 12 | 17 |
| Standard Deviation (g/dL) | 0,3 | 0,4 |
| Coefficiente of variation (%) | 2,2 | 2,5 |

## SYMBOLS

| SYMBOLS | DESCRIPTION |
|---|---|
| | READ INSTRUCTIONS FOR USE |
| | STORE AT TEMPERATURE BETWEEN |
| | USE WITHIN... |
| | MANUFACTURER |
| LOT | LOT NUMBER |
| IVD | FOR IN VITRO DIAGNOSTIC USE |
| CE 0344 | THIS PRODUCT COMPLIES THE REQUIREMENTS OF THE DIRECTIVE 98/79/CE FOR THE IN VITRO DIAGNOSTIC DEVICE. |

BSI Biochemical Systems International
www.biosys.it

*Via G. Ferraris, 220*
*52100 AREZZO - ITALY*
*Tel. +39 0575 984164*
*biosys@biosys.it*

CE 0344

lux.fi.emo.ita/eng-ED.07-15