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LN-6000, Rev. D

lumella™

Lumella™ Preeclampsia Test Reader

User Guide for Healthcare Professionals

TABLE OF CONTENTS

Page

I. Introduction 1

II. How to Use the User Guide 2

III. General Information 3

The Lumella™ Preeclampsia Test System
RFID Tag
Guidelines for Using the RFID Tag
Test Procedure

IV. Warnings and Precautions 5

V. Set Up 6

Battery Use
Buttons

VI. Important Information 7

Blood Testing
Testing Supplies
Healthcare Professionals
How to Run a Test

VII. Care and Cleaning 11

VIII. Troubleshooting 13

IX. Reader Specifications 15

X. Warranty 17

XI. Disposal Procedure 17

XII. Explanation of Symbols 18

I. INTRODUCTION

Thank you for selecting the Lumella™ Preeclampsia Test system from DiabetOmics, Inc. The Lumella™ Preeclampsia Test System includes a Reader and Lumella™ Preeclampsia Test cartridges, and has an optional Bluetooth printer available.

This system is intended for in vitro diagnostic use to measure glycosylated fibronectin in fresh finger stick whole blood. The Lumella™ Preeclampsia Test System is intended to be used as an aid in the assessment of Preeclampsia in conjunction with other clinical and laboratory information. The system is for professional use only.

The Lumella™ Reader uses reflectance photometry to measure color changes that occur on a test cartridge after the treated blood sample has been added.

Before you begin testing, please read this entire User Guide and the Test Kit Product Insert completely. This provides the necessary information for the use of this system. To ensure you receive product updates, please remember to register each Reader at:

www.LumellaPOC.com/registration

II. HOW TO USE THE USER GUIDE

This guide includes all the information you need to properly test using the Lumella™ Preeclampsia Test System. This User Guide is arranged in the order a new user would need the information.

For questions or assistance with the Lumella™ Preeclampsia System, contact:

Diabetomics Customer Service

Tel: 877-748-9355
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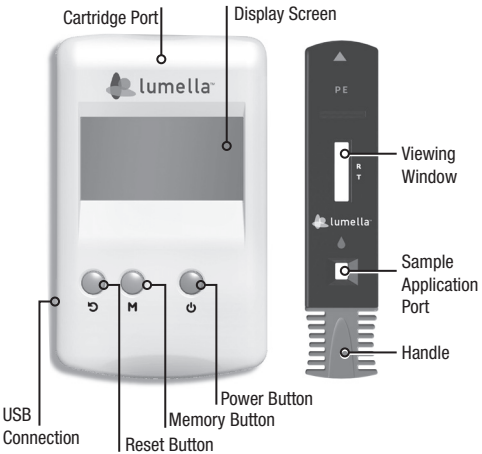
III. GENERAL INFORMATION

The Lumella™ Preeclampsia Test System:
The Lumella™ Preeclampsia Test System consists of a Reader, Preeclampsia Test cartridges and accessories needed to perform the test.



RFID Tag
Each box of Test Kits contains an RFID Tag laminated onto an RFID Card below the RFID symbol (((•))). The RFID tag contains specific information for each cartridge test lot. When the tag is scanned by the Reader, the RFID does the following:

- Reads the Test Kit lot number
- Reads the Test Kit expiration date
- Provides the lot-specific information to the Reader

Guidelines for using the RFID Tag

- The RFID Tag must be read to run a test.
- When prompted by the Reader, scan only the RFID Tag that is on the RFID card included with the Test Kits being used.
- If the cartridge has expired, the Reader will display *error 05* and the test will not continue.

Test Procedure
Each box of individual test sets contains a Product Insert that provides instructions for use. Please read the instructions completely before testing.

IV. WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For use only by trained healthcare professionals.
- Carefully follow the instructions and procedures described in this User Guide and Product Information Sheet included with the Test cartridges.
- Optimal results will be achieved by performing testing at temperatures between 18-30°C (68-86°F).
- Avoid running the test in direct light (see Care and Cleaning).
- The use of non-Lumella Controls and Calibration Verification materials will result in incorrect results.
- Patient specimens, and used lancets, Test Cartridges, blood collection micropipettes and transfer pipettes may be potentially infectious. Follow universal precautions.
- Follow the proper infection control procedures for your facility. Discard the used lancet in a closed puncture resistant container, such as a sharps container. Use a new lancet every time you test. Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.

Do not flood or submerge the reader with cleaning solution.

V. SET UP

Battery Use

The Lumella™ Preeclampsia Reader contains a rechargeable lithium ion battery that is not replaceable. To charge the battery, connect the micro USB end of the supplied charging cable into the Reader and plug the standard USB end into any standard USB charging port. It is recommended that the Reader is charged for 30 minutes prior to the first usage. The Reader should completely charge in approximately 90 minutes.

Buttons

⏻ **Power:** Press this button to turn the Reader ON. Press and hold for 3 seconds then release to turn the Reader Off. If left unattended for more than 5 minutes, the Reader will turn itself off to preserve battery life.

Reset: Press this button to reset the Reader after an error message or if you want to run another sample after the completion of a test.

Memory: Press and hold this button for 3 seconds to display the most recent 5 test results. Successive presses will scroll back through previous test results 5 at a time.

Pairing a Printer
With the Printer and Reader off, hold down the Memory button (M) and turn the Reader on (⏻). Release the Memory button only after a beep sounds. The Reader will display the previous test result then prompt to turn on the Printer. After searching for and finding the Printer (~20 seconds), the Reader will display "Printing Sample" and the Printer will print "Paired" followed by the Reader ID.

Unpairing a Printer
Hold down the Memory button (M) and turn off the Reader (⏻). Continue holding the Memory button until a beep sounds. Release the Memory button. The Reader will display the previous test result and then display "Printer Removed".

VI. IMPORTANT INFORMATION

Blood Testing
A Test Kit Product Information Sheet is included with each box of Test cartridges. Please completely and carefully read the Sheet along with this section of the User Guide before testing.

Testing Supplies and Equipment
You need the following provided items to perform a blood test:

- Lumella™ Preeclampsia Reader
- Lumella™ Preeclampsia Test Cartridge
- Lot-specific RFID Card with RFID tag
- Single use lancing device
- Blood collection micropipette
- Sample Buffer Vial
- Alcohol wipe & Bandage
- Transfer pipette

How to Run a Test

1. Obtain and dilute a blood sample as shown in the Product Information Sheet.
2. Turn on the Lumella™ Reader by pressing the power button (⏻). After a brief self-test check, the Reader will display the previous test result followed by "Scan RFID". Pair the (optional) Bluetooth

printer if printed results are desired.

3. Hold the lot-specific RFID Card positioned with the RFID tag (by the icon over the Lumella™ logo on the Reader located above the LCD (display window). After a few seconds you should hear a beep indicating that the Reader has received the RFID data.
4. After a few more seconds you should hear one long tone followed by 3 short tones.
5. "Insert Cartridge" will be displayed.
6. Remove the Lumella™ Preeclampsia Test Cartridge from the foil pouch. (Only open the foil pouch immediately prior to running the test).
7. Hold the Test Cartridge by the handle and insert it into the Reader as far as it will go. When the Test Cartridge has been detected by the Reader, "Apply Sample" will be displayed. Place the Reader on a level surface.
8. Open the Sample Buffer Vial and draw up the diluted sample using the transfer pipette. Consult the Lumella™ Quick Reference Guide for details.
9. Carefully apply the diluted sample to the Test Cartridge by touching the transfer pipette onto the Sample Application Port and gently squeezing the pipette to deliver all of the sample at once. (If the bulb is squeezed too rapidly some of the sample may spray outside of the Application Port resulting in erroneous results).
10. The test will run automatically after the addition of the specimen. When the sample has been detected a 10-minute countdown timer will be displayed and the LCD screen will be dimmed to preserve battery power. Do not move or touch the Reader while the test is running.
11. When the test is complete the Reader will beep and display the test results which will be automatically printed on a compatible printer if detected by the Reader or transferred to another recommended external Bluetooth device.
12. To run another patient sample, press the Reset button and repeat steps 1-11.
13. To turn off the Reader, press and hold the Power button, for 3 seconds then release.

VII. CARE AND CLEANING

- The Lumella™ Preeclampsia Reader is a sensitive electronic device; handle with care. The Reader should not be dropped. After cleaning, store in the supplied case when not in use. Do not store or operate the Reader in direct light, such as sunlight, spotlight, under a lamp or by a window. Direct light may adversely affect test results.
- Do not expose any of the supplies or accessories to high humidity, extreme heat, cold, dust or dirt. Store the Reader at room temperature (18–30°C, 64–86°F) and 20-80% Relative Humidity (RH). **Do not freeze.**
- Please read the Test Kit Product Information Sheet for storage and handling information that pertains to each Test Kit.
- Clean and disinfect the Reader as appropriate after each patient to prevent transmission of infectious agents. Discard gloves after cleaning and disinfecting the device and wash hands.

- To clean and disinfect the Reader's surface or buttons, use a soft wipe dampened with a 10% bleach solution. Allow the bleach solution to remain on the device for 5 minutes and then wipe off residue with a soft wipe dampened with clean water.

Do not flood or submerge the reader with cleaning solution.

Removing screws from the back of the Reader voids all warranties. There are no user serviceable parts inside the case. See Section X, WARRANTY.

Display Counter and Required Service

The Lumella™ Preeclampsia Test Reader will require service after 1500 tests have been run. A counter will be displayed at the start of a test after 1400 tests have been run indicating how many tests remain before service is required. To avoid interruption of testing capability, please contact Customer Support to arrange for service prior to reaching 1500 tests.

VIII. TROUBLESHOOTING

Message or Symptom	Description	Resolution
ERROR 01	The RFID scan failed or data is invalid.	Check that the RFID label is intact. Repeat test. If error continues, contact your local distributor.
ERROR 02	Reader self-check failed.	Repeat power up process. If error continues, contact your local distributor.
ERROR 03	Cartridge was removed before the completion of test.	Repeat test using a new cartridge. If error continues, contact your local distributor.
ERROR 04	Reader Timeout 1. RFID Tag was not scanned within 5 minutes. 2. Cartridge was not inserted within 5 minutes. 3. Sample was not added to the cartridge within 5 minutes.	Complete requested action within 5 minutes.
Battery Too Low	Not enough battery power to run a test.	Plug Reader into USB power source for at least 30 minutes before attempting to test again.
ERROR 05	Expiration Date read on RFID has passed.	Verify Expiration Date on Test Kit package. If Product is still within dating, reread the RFID label. If error continues contact your local distributor.

IX. READER SPECIFICATIONS

Battery: Lithium–Ion 3.7 V DC

Battery lifetime: Approximately 3 years

Mode of operation: Continuous

Operating temperature: 18–30°C (64–86°F)

Operating humidity: 20–80% (non-condensing)

Degree of protection against ingress of water: Ordinary equipment

Dimensions: 22.6 x 112.6 x 68.8 mm (0.89" x 4.43" x 2.7")

Weight: 120 g (0.26 lb)

Pollution degree: 2

Overvoltage category: II

Equipment is not suitable for use in the presence of flammable mixtures.

Internally powered and Class II equipment.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The Lumella™ Preeclampsia Test System has been tested for electrical safety and EMC according to the following standards:

- EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment.
- UL 61010-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements.
- EN 61326-1 Electrical equipment for measurement, control and laboratory use. EMC requirements.

Warning:

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, could cause interference to adjacent equipment. There is no guarantee that interference will not occur in a particular installation if the instructions are not followed. The user can determine if the interference is caused by the equipment by turning the unit off. If interference is caused by the reader, the equipment should be moved.

X. WARRANTY

The Reader carries a 3-year warranty from the day of receipt. Any other use of the system than recommended by the manufacturer, or opening the Reader, will void the warranty.

XI. DISPOSAL PROCEDURE

The product may come into contact with blood during testing. Used products therefore carry a risk of infection. When disposing of a Reader that has been utilized, please do so in accordance to the regulations applicable in your country. For information about correct disposal, please contact your local council or authority.

XII. EXPLANATION OF SYMBOLS


Consult Instructions for Use


Storage Temperature

For *in vitro* Diagnostic Use

Serial Number


Manufacturer


Do Not Dispose of in Trash


Radio Frequency ID


Caution

Component Number

Authorized Representative in the European Community


Battery Strength


European Conformity

NOTES