sōna LFA Cube Reader

REF LFARDR

Compatible with sōna *Aspergillus* GM Lateral Flow Assay

FOR IN VITRO DIAGNOSTICS USE ONLY

INTENDED USE

The sōna LFA Cube Reader (REF LFARDR) is a benchtop analyzer intended to be used as an aid in the interpretation of results of the sōna *Aspergillus* GM Lateral Flow Assay (REF AF2003).

PRODUCT DESCRIPTION

The sōna LFA Cube Reader uses an LED light source at 525 nm to interpret results from sōna LFA test strips.

A lot-specific RFID tag is located on the bottom of the sōna *Aspergillus* GM Lateral Flow Test Strip Tube (REF LFAF50). This RFID tag contains the program specific to the strips being tested and is required for proper analysis.

When functioning properly, the sōna LFA Cube Reader displays test results specifically for that assay. Results will include 1) a value displayed numerically and 2) as "POS" or "NEG."

In each test, the control line should be visually read to ensure that the sample flows correctly and sample preparation (if applicable) steps were followed.

COMPONENTS

1. sōna LFA Cube Reader (REF LFARDR)
2. LFA Cube Reader Adapter
3. USB Power Cord
4. Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

IMMY sōna *Aspergillus* Galactomannan Lateral Flow Assay (REF AF2003)

WARNINGS AND PRECAUTIONS FOR USERS

1. **For In Vitro Diagnostic use only.**
2. For professional use only.
3. This reader is intended to be used only with the sōna AGM LFA (REF AF2003). Ensure the LFA kit is not expired before use.
4. Wear protective clothing, including a lab coat, eye/face protection, and disposable gloves.
5. Handle patient samples with requisite Good Laboratory Practices.
6. Wash hands thoroughly after using the cube reader to read patient specimens.
7. Dispose of all specimens and materials used during testing as though they contain an infectious agent.
8. Laboratory chemical and biohazardous wastes must be handled and discarded in accordance with all local, regional, and national regulations.
9. The cube readers are produced, calibrated, and checked before shipping under strict quality control measures to guarantee a high degree of quality.
10. RFID tags are provided for running the assay. Each RFID tag is assay-specific and lot-specific type being conducted and test-specific information is transferred wirelessly by the RFID tag to the reader before each measurement. Using an RFID tag that is meant for use with another assay or lot can affect the measurement result.
11. Do not use the cube reader in direct sunlight or exposed to bright light while reading results.
12. Metal surfaces can influence the RFID tag. Always place the RFID tag on top of the cube reader's display to ensure optimal reading of the RFID information.
13. Protection provided by this equipment may be impaired if the equipment is used in a manner not consistent with the instructions in this package insert.
14. The cube reader must be plugged in through the power source.
15. The cube reader is designed for use on a straight and horizontal surface.
16. Always ensure that the cube reader is inserted correctly into the LFA Cube Reader Adapter. A wrong or improper insertion can lead to incorrect results.
17. The cube reader can be operated at 10° to 35°C (50° to 95°F) between 20% and 85% humidity. Ensure that the cube reader is brought to operating temperature before use.
18. Protect the cube reader from any liquids. Any liquids entering the reader enclosure can damage the reader permanently.
19. The cube reader has a sleep timer that will automatically power-down the unit after about 55 seconds of inactivity. If the cube reader powers down during testing, it is necessary to re-scan the lot-specific RFID tag on the LFA tube being tested prior to continuing analysis.
20. During strip analysis, quickly press and release the button on top of the cube reader to switch between display screens. If the button is held down for longer periods of time it may interfere with proper testing procedures as described here.
21. Results read after the allowable reading window (see sōna *Aspergillus* GM LFA Package Insert) are invalid.
22. Please follow the instructions on the product insert provided with the test kit regarding the disposal of the test devices containing hazardous or infectious material.
23. The cube reader itself contains no biological hazards. However, contamination due to biological hazards is possible and the reader should be handled accordingly.
24. The LFA Cube Reader Adapter should be cleaned and disinfected regularly according to good lab practices. Disinfectants that can be used include (but are not limited to) a solution of 10% bleach or 1% Lysol brand I.C.™

POWERING THE CUBE READER

Plug the provided USB Power Cord into a wall socket power adapter (not provided) or plug USB Power Cord into a compatible USB slot. The sōna LFA Cube Reader will automatically turn on with the first connection to the power cord. Following initial power-on, press the button on the cube reader once to power on.

TESTING PROCEDURE

1. Run the sōna *Aspergillus* GM LFA according to product Package Insert.
2. Press the button on the top of the sōna LFA Cube Reader twice until the display reads "RFID".
3. Scan the lot-specific RFID tag located on the bottom of the *Aspergillus* GM Lateral Flow Test Strip Tube by placing it over the display on the cube reader. An audible signal will confirm scanning of RFID tag and "TEST" will appear on display.
4. When the test strip is ready to be analyzed, properly insert the LFA strip into cube reader so the sample arrows of the strip are facing the same direction as the sample arrows on the adapter itself. Results should be read within the allowable reading window.
5. While "TEST" is still displayed on the cube reader, press the button once to run. "RUN" will appear on the display while the strip is being read.
6. Result readout will vary depending on which product RFID is scanned. Record displayed test results.
7. To continue testing, remove the strip and press the button on the cube reader three times until "TEST" appears on display. Repeat Testing Procedure steps 4-6.

sōna LFA Cube Reader

REF LFARDR

Compatible with sōna *Aspergillus* GM Lateral Flow Assay

FOR IN VITRO DIAGNOSTICS USE ONLY

QUALITY CONTROL

It is recommended to run a positive control and a negative control each day of use. The cube reader should display "POS" after the positive control is analyzed and "NEG" after the negative control is analyzed.

INTERPRETATION OF RESULTS

The control line must be present for a valid test. If the control line is not present, "INVALID" will appear on display of the cube reader once analyzed. If the cube reader displays, "INVALID", remove the LFA strip and visually inspect it for the presence of a control line. If a control line is not present, the test is invalid and must be run again.

Refer to the sōna *Aspergillus* Galactomannan Lateral Flow Assay Package Insert for how to determine results using the sōna LFA Cube Reader.

Results read after the allowable reading window are invalid.

PERFORMANCE – PRECISION

In order to evaluate the precision of results using the sōna LFA Cube Reader, 7 different dilutions of fungal antigen were tested using a sōna LFA test. A total of 12 readings across 4 readers (for each dilution) were obtained to establish the Inter-reader precision, while a total of 10 readings using a single reader (for each dilution) were obtained to establish the Intra-Reader precision.

	Range
Inter-Reader Precision	2-10%
Intra-Reader Precision	1-11%

CLEANING THE CUBE READER

1. Remove the sōna LFA Cube Reader from the adapter by gently applying downward pressure on the adapter tab and lifting the cube reader out of the adapter.
2. Clean the LFA Cube Reader Adapter with a disinfectant. See Warnings and Precautions for Users.
3. Clean the cube reader lens with a lint-free cloth.
4. Place the cube reader back in the adapter by matching the angled corner of the cube reader with the angled corner of the cube reader adapter. Gently apply downward pressure to the adapter tab and insert the cube reader, backside first. Press the cube reader firmly into place and release the adapter tab. The cube reader should be firmly seated into the adapter before use.

POWERING THE sōna LFA CUBE READER

Plug the provided USB Power Cord into a wall socket power adapter (not provided) or into a compatible USB slot. The sōna LFA Cube Reader will automatically turn on with first insertion of batteries/connection to power cord. Following initial power-on, press the button on the cube reader once to power on.

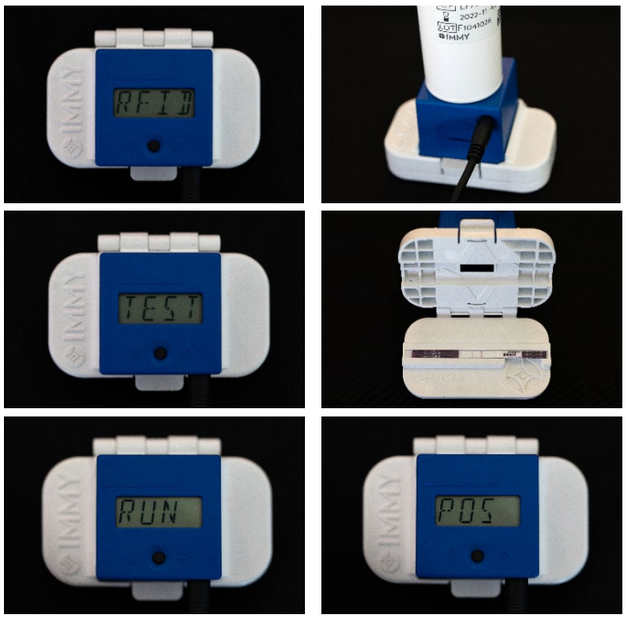
Wall Socket Power Adapter

Laptop USB Slot

IMMY
2701 Corporate Centre Drive
Norman, OK 73069 U.S.A.
405.360.4669 | 800.654.3639
Fax: 405.364.1058
orderproducts@immy.com
www.immy.com

CUBE READER PROCEDURE OVERVIEW

1. Run sōna *Aspergillus* GM Lateral Flow Assay according to product Package Insert.
2. Press button on Cube Reader twice display "RFID".
3. Scan lot-specific RFID tag on bottom of LF Test Strip Tube by placing it on cube reader. An audible signal will confirm scanning of RFID tag and display will read "TEST".
4. Properly insert the LFA strip into cube reader.
5. While "TEST" is still displayed on the cube reader, press the button once to run. "RUN" will appear on display as strip is being **read.**
6. Refer to the sōna *Aspergillus* GM Lateral Flow Assay Package Insert for how to determine results using the Cube Reader. Record displayed test results.
7. To test another strip of same lot, remove strip, press button on cube reader three times until display reads "TEST". Repeat steps 4-6.



TROUBLESHOOTING GUIDE

PROBLEM	SOLUTION
Part malfunction or damage (Re-ordering information)	• sōna LFA Cube Reader – REF D27165 • LFA Cube Reader Adapter – REF D27164 • USB Power Cord – REF D27167
"ERR" appears on display of cube reader	• The RFID tag may not have been fully placed over the display screen of the cube reader. Press button until the display shows "ON," then Center the RFID over the display. An audible signal should follow to indicate a successful acceptance of the RFID program.
"INVALID" appears on display of cube reader	• If no strip is in the cube reader adapter when the button is pressed to run/analyze, "INVALID" will appear on display. Place a strip in the adapter as shown and repeat the testing procedure. • If an LF test strip does not have a control line present, "INVALID" will appear on the display. Visually inspect the strip for a control line. If there is no control line, the test is invalid. If there is a control line present, run the calibration procedure and then repeat the testing process.

INTERNATIONAL SYMBOLS

10°C 35°C	Operating Conditions 10-35°C	LOT	Lot Number
	Manufactured by	REF	Reference Number
	Expiration Date	IVD	In Vitro Diagnostic Use Only

Rev. Date 2023-02-01
Rev. 1