sōna LFA Cube Reader

REF #: LFARDR-IVD

Compatible with sōna Lateral Flow Assays

IVD 10°C 35°C

INTENDED USE

The sōna LFA Cube Reader (REF #: LFARDR-IVD) is a benchtop analyzer intended for professional laboratory use as a method of interpretation for IMMY's sōna Lateral Flow Assays carrying a compatible RFID tag. Readings displayed by the reader are interpreted according to the corresponding assay's instructions for use.

PRODUCT DESCRIPTION

The sōna LFA Cube Reader illuminates the test strip with a 525 nm LED and measures the reflected light with an image sensor to interpret results from sōna LFA test strips.

A test and lot-specific RFID tag is located on the bottom of compatible sōna Lateral Flow Test Strips Tube. This RFID tag contains a program specific to the strips being tested and is required for proper analysis.

When functioning properly, the sōna LFA Cube Reader reads and displays test results specifically for that assay. Results may include 1) a value displayed numerically and/or 2) a reading of "POS", "NEG", or "INVALID".

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

COMPONENTS

- sōna LFA Cube Reader (REF #: LFARDR-IVD)
- LFA Cube Reader Adapter
- USB Power Cord
- Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Wall socket power adapter OR compatible USB slot
- Lateral Flow Assays programmed with compatible RFID tag such as IMMY's sōna Lateral Flow Assays:
  1. IMMY sōna *Aspergillus* Galactomannan Lateral Flow Assay (REF #: AF2003)
  2. IMMY sōna *Talaromyces* Ag. Lateral Flow Assay (REF #: TM2025)

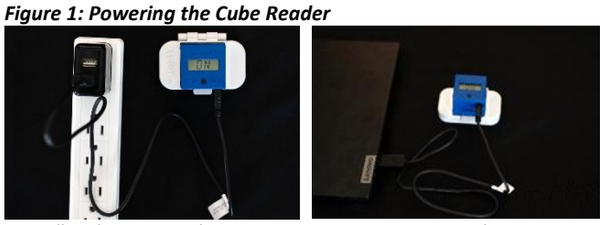
WARNINGS AND PRECAUTIONS FOR USERS

1. **For In Vitro Diagnostic Use Only.**
2. For professional use only.
3. This reader is intended to be used only with LFAs programmed with compatible RFID tags, such as IMMY's sōna Lateral Flow Assays. Ensure the corresponding 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. No other calibration is required or recommended.
10. RFID tags are provided for running each assay. Each RFID tag is assay-specific and lot-specific, 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 flat 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 and humidity 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 the corresponding sōna 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 strips 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 (Figure 1). 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.

Figure 1: Powering the Cube Reader



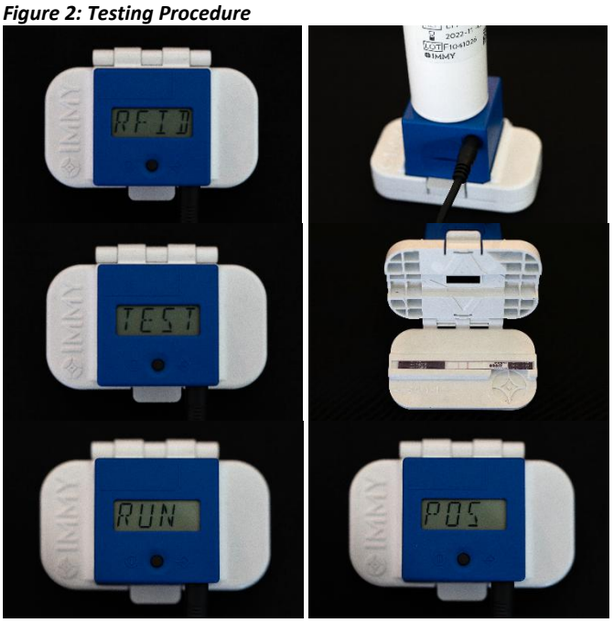
Wall Socket Power Adapter | Laptop USB Slot

TESTING PROCEDURE

1. Run the sōna LFA according to the product Package Insert.
2. Press the button on the top of the sōna LFA Cube Reader to turn the unit on.

3. Press the button on the top of the sōna LFA Cube Reader once or until the display reads “RFID” (Figure 2).
4. Scan the lot-specific RFID tag located on the bottom of the sōna Lateral Flow Tests Strip Tube by placing it over the display on the cube reader. An audible signal will confirm scanning of the RFID tag and “TEST” will appear on display.
5. Visually inspect the test strip and verify there are no interfering artifacts such as large pieces of dirt or lint in the reading frame between the test and control line.
6. When the test strip is ready to be analyzed, properly insert the LFA strip into the cube reader so the sample arrows of the strip are facing the same direction as the sample arrows on the adapter itself. If not correctly placed the test results may be invalid. Results should be read within the allowable reading window (see the corresponding sōna LFA Package Insert).
7. 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.
8. Result readout will vary depending on which product RFID is scanned. Record the displayed test results.
9. To continue testing, remove the strip and press the button on the cube reader three times until “TEST” appears on the display. Repeat Testing Procedure steps 5-8 for all strips tested.
10. When a new test or lot of strips is used, the RFID for that new lot must be scanned prior to reading strips.

Figure 2: Testing Procedure



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 corresponding sōna LFA Instructions for Use for how to determine results when using the sōna LFA Cube Reader.

Results read after the allowable reading window are invalid.

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.

ANALYTICAL PERFORMANCE – MEASUREMENT PRECISION

To demonstrate the accuracy (trueness) and inter-reader precision of results using the sōna LFA Cube Reader, a printed test strip with 6 lines of differing intensity over the entire measuring range of the reader was evaluated on 20 different reader units. Results are reported in Table 1.

Table 1: Measurement Precision	**Line 1**	**Line 2**	**Line 3**	**Line 4**	**Line 5**	**Line 6**
Mean all readers	113.96	17.85	42.08	7.15	76.40	105.55
Target value	114.68	18.02	42.51	6.92	77.22	106.04
Mean dev. from target value	0.63%	0.96%	1.01%	-3.26%	1.06%	0.46%
Standard dev.	0.39	0.14	0.21	0.20	0.43	0.65
CV	0.34%	0.81%	0.50%	2.74%	0.56%	0.62%

CLEANING THE CUBE READER

1. Remove the sōna LFA Cube Reader from the adapter by gently applying downward pressure on the adapter tab.
2. Clean the LFA Cube Reader Adapter with a disinfectant. See Warnings and Precautions for Users.
3. Clean the LFA Cube Reader lens with a lint-free cloth.
4. Place the LFA 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.

TROUBLESHOOTING GUIDE

Problem	***Solution***
Part malfunction or damage (Re-ordering information)	sōna LFA Cube Reader – Part #: D27165 LFA Cube Reader Adapter – Part #: D27164 USB Power Cord – Part #: 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 “RFID,” 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 or is placed incorrectly 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, re-scan the RFID and then repeat the testing process. If problem continues, contact techsupport@immy.com.

INTERNATIONAL SYMBOLS

	Operating Conditions 10-35°C	IVD	In Vitro Diagnostic Use Only
	Manufactured by	REF	Reference Number
	Expiration Date	LOT	Lot Number
	Don’t dispose in general trash. For disposal of device, please refer to country specific rules and laws.		

Rev. 2

For a list of IFU changes, email info@immy.com

To locate country specific IFUs, visit IMMY.com/resources

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