

QUICK GUIDE IMMUVIEW[®] READER



ENGLISH (UK)

Instrument for automated interpretation of results for ImmuView[®] lateral flow test



IMMUVIEW® READER

Introduction

This short ImmuView® Reader Quick Guide provides an overview of how to perform a test with the ImmuView® Reader, and an ImmuView® strip. The ImmuView® Reader is an instrument for automated interpretation of results for ImmuView® lateral flow test.

This ImmuView® Reader is pre-set for basic daily use. You can customise your ImmuView® Reader to fit your personal settings and quality assurance requirements.

Please refer to the ImmuView® Reader manual for more detailed information about the different functions of the reader.



Scan the QR code to access ImmuView® Reader Manual via hyperlink or use the following link to access it manually by entering this hyperlink in your browser:
<http://ssidiagnostica.com/manualimmuvierreader/>

Intended use

The ImmuView® Reader is an adjunctive instrument for automated reading and interpretation of results for ImmuView® lateral flow immunochromatographic *in vitro* diagnostics test strips.

Materials provided

The following content are supplied with the ImmuView® Reader:

- ImmuView® Reader
- 1 x Instrument check cartridge
- 2 x Strip-Carriers
- Power supply (With adaptors for US, EU, UK, Canada, and AUS)
- 3 x Ferrites (clip on for accessories only)
- 1 x Quick guide
- 1 x Certificate of Analysis (CoA)

The ImmuView® Reader, consumables, and its ports

Figure 1 ImmuView® Reader - Front View

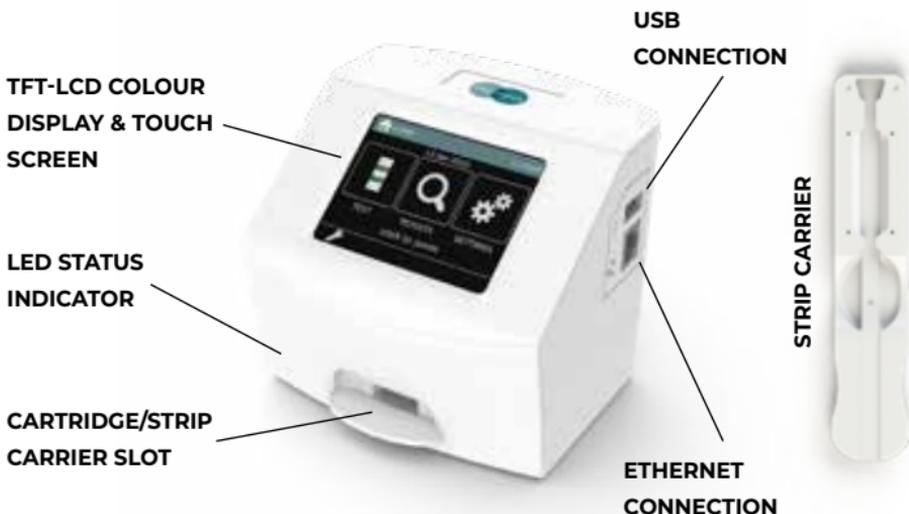
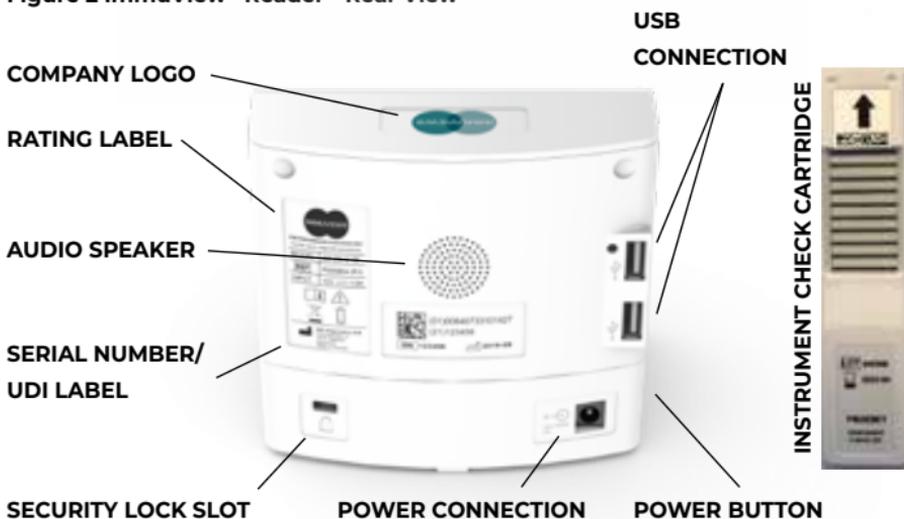


Figure 2 ImmuView® Reader - Rear View



Start up the ImmuView® Reader

Turn on the reader by pressing and holding the power button for 2-3 seconds (until a tone sounds). The power button is found on the left side of the ImmuView® Reader (see picture of reader on page 3).

The start-up sequence is an automated test that is performed to verify correct internal system functionality of the reader. If the reader is left turned on, the self-test is automatically performed every 24hrs. The startup sequence takes around 3 minutes.

This is how the startup sequence appears on the ImmuView® Reader:

- Hourglass icon appears
- Loading bar appears and begins to load till full
- “ImmuView®” logo is displayed with indication of start-up progress



Main menu

Once the start-up sequence is completed, the first screen you will see is “The Home menu screen”. You are per default logged-in as Default User. To log-in push the “key” button (lower left corner) and type in your initials. The Home menu screen gives you the following options:

- **Test**, for running a test
- **Results**, for reviewing previously run test results
- **Settings**, for configuring the instrument



Further details and options for “Results” or user/admin “Settings” can be found in the user manual.

How to run a test

Step 1: Press “TEST” on the Screen

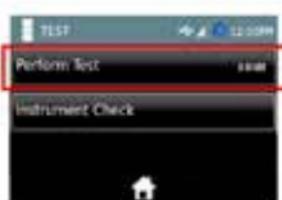
The Test menu shows the different types of tests that can be performed on the ImmuView® Reader:

- *Perform Test*
- *Instrument Check*



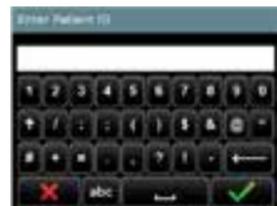
For further test settings, please refer to section 8.7 in the user manual

Step 2: Press “Perform Test” on the screen



Step 3: Enter Patient ID

- Enter a unique patient ID using the onscreen keyboard, or a scanner*.
- Press ✓ [Accept] to save the patient ID.



NB: If you Press X [Cancel] it cancels the test and test data is not saved.

**A handheld scanner can be attached to the reader.
We recommend Datalogic QuickScan QD2430 2D*

Step 4: Insert the strip into the Strip Carrier



Strip placement

Make sure "P&L" is visible & placed as shown in the picture.

Please refer to the section "How to insert the ImmuView® strip in the Strip Carrier", at the end of this quick guide, for a detailed description.

Step 5: Insert the Strip Carrier in the ImmuView® Reader

Insert the Strip Carrier (including the ImmuView® strip) in the ImmuView® Reader when the screen says, "Insert Test". When you hear/feel a "click", the Strip Carrier is in place and the ImmuView® Reader will start to analyse the strip.



Once you have inserted the Strip Carrier, no further actions are required.

The reading takes around 40 seconds.

When the reading is done, the test result will automatically be shown on the screen.

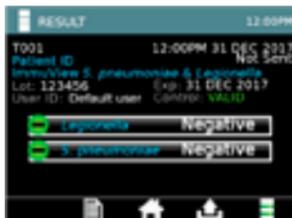
The Strip Carrier must be left inserted in the ImmuView® Reader during this phase of analysis.



Result

After the analysis, the ImmuView® Reader makes a sound, to indicate that the analysis is finished.

This example shows that both *Legionella* and *S. pneumoniae* are negative. Please also notice the text "Control: VALID", which indicates that the test is valid.



You can remove the Strip Carrier from the ImmuView® Reader now.

ImmuView® Reader results outcomes:



A positive result will display a “Red Plus” next to the text.



A negative result will display a “Green Minus” next to the text.

Boil & Re-test Sample; and an IFU icon: Please refer to the ImmuView® IFU interpretation of result section for further explanation.

Invalid; and an IFU icon: Potential error related to the Strip Carrier or the ImmuView® strip. Refer to “How to insert the ImmuView® strip in the Strip Carrier” section of this Quick Guide, and/or the ImmuView® IFU interpretation of result section.

The ImmuView® Reader will automatically save the result, which can be accessed in the “Results” – please refer to section 8.12 in the ImmuView® Reader user manual for more information.

To perform another test, press this icon.



To export the test result, press this icon.

Only possible if the ImmuView® Reader is connected to LIS or an USB key is inserted into one of the ImmuView® Reader USB ports



If you want to go back to the main menu, press this icon (home)



To print the results, press this icon:

You need an external printer for this. We recommend the Seiko Smart Label 620 Labelprinter.



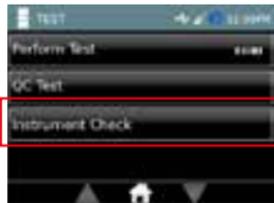
Other essential features

Performing an Instrument Check

To perform an Instrument Check:

Follow step 1 and in step 2

[on page 5 in this Quick Guide] press the 'Instrument Check'.



Unpack the Instrument Check Cartridge.

Follow Step 5 and insert the Instrument Check Cartridge in the reader. The arrow on the Instrument Check Cartridge needs to enter the ImmuView® Reader first.



Instrument Check Cartridge

The ImmuView® Reader will perform the Instrument check.

The result will either be a pass or fail.

A pass describes that the ImmuView® Reader is within the specifications.

A fail describes that the ImmuView® Reader is outside the specifications, and the reader is to be put in quarantine and sent to the supplier (please refer to the manual).

Note: The ImmuView® Reader is by default pre-set to prompt the user every 7 days for an Instrument Check.

LIS integration and other tasks

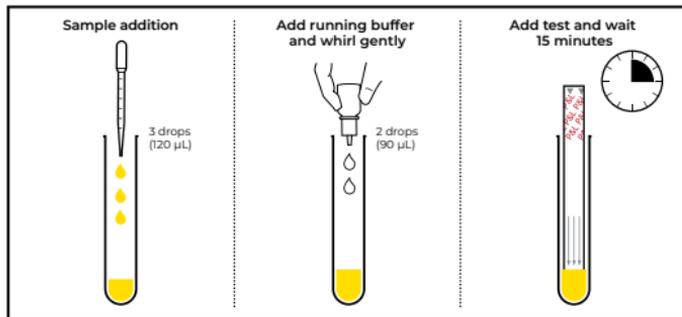
The ImmuView® Reader can be connected to the LIS system. Please refer to section 9.19 (Data connectivity) in the manual to learn how to transfer data from the ImmuView® Reader to LIS.

Other features

Refer to the manual for detailed information of other ImmuView® Reader features like printing results, storing data etc.

How to insert the ImmuView® strip in the Strip Carrier

Step 1: Follow the procedure as described in the ImmuView® *S. pneumoniae* & *Legionella* IFU

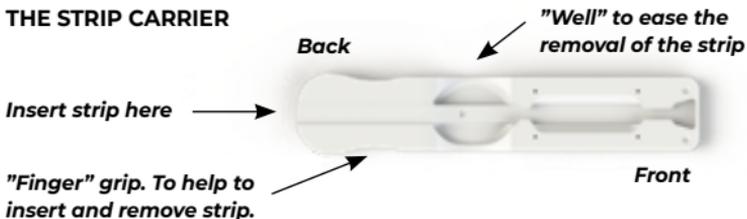


Step 2: After 15 minutes remove the ImmuView® strip from the test tube, and gently dap off excess sample fluid, e.g. in a napkin.



Step 3: Insert the ImmuView® strip in the Strip Carrier. Firstly, have a look at the design of the Strip Carrier, pictured belloved.

THE STRIP CARRIER



Next, follow step A, B and C, and you are ready to insert the Strip Carrier in the ImmuView® Reader

- A.** Gently insert the ImmuView® strip in the Strip Carrier. Make sure “arrows” go in first, and the “P&L” text is at the back.



- B.** Continue to gently push the ImmuView® strip in the Strip Carrier.



- C.** Once the ImmuView® strip reaches the front of the Strip Carrier, the ImmuView® strip is in place, and you can now insert the Strip Carrier in the ImmuView® Reader.



NOTICE THE ARROW.

The arrow always needs to be visible when it is inserted in the reader or the reader may report invalid results

Step 4: Insert the Strip Carrier in the ImmuView® Reader (please see section 5 in the Quick Guide for correct sequence).

On the reader it will say “insert test” when it is time to insert the Strip Carrier.

Back **Front**

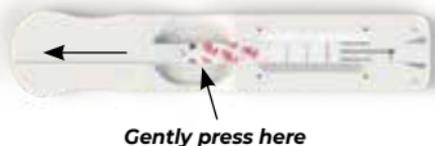


Strip placement
Make sure “P&L” is visible & placed as in the picture.



Removal of ImmuView® strip

A. To remove the ImmuView® strip, simply slide it back from the Strip Carrier and gently remove it. You can use your thumb for this.



B. Next, continue to remove the strip from the Strip Carrier.



C. Discard the used strip and clean the Strip Carrier.



Cleaning the Strip Carrier:

Cleaning with 70% Isopropanol and 10% Bleach. See manual for further details.

Quality certificate

SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 13485.



Quality System
DS/EN
ISO 13485



Information and ordering

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