

MYCOVIEW STUDIOBOX

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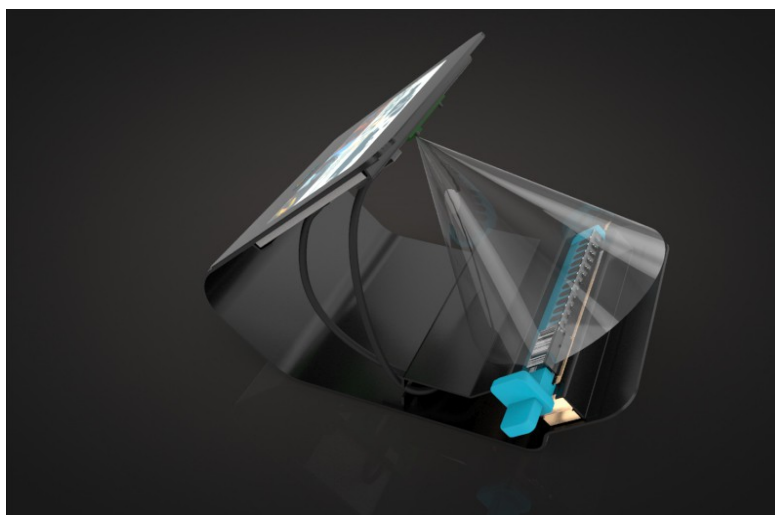
1- INTENDED USE

Mycoview StudioBox is dedicated to the reading of MycoView (12 wells) & MycoView ID (5 wells) strips in either classical or Quantum versions, to give the final report of the urogenital mycoplasma diagnosis, offering rapid recording & printing of the results. Mycoview StudioBox allows the reading & interpretation of the results from different types of specimens: urethral and endocervical swabs, urine and other types such as semen and less common specimens.

It allows also the reading of the vial used for the screening of the presence of urogenital mycoplasma – UGM (see § 5.6)

2- MEASUREMENT PRINCIPLE

Mycoview StudioBox uses an image analysis algorithm. A picture of the test is taken, then analyzed, allowing to discriminate a positive reaction from a negative one from a strip well or a screening vial.



Positive result + : Inside the test-strip, the growth of UGM is indicated when the medium turns red or bright pink (alkaline pH);

Negative result - : The medium remains yellow-orange or turns yellow if there is no growth of urogenital mycoplasma.

3- DESCRIPTION OF THE SYSTEM

3-1. General view of Mycoview StudioBox



3-2. Technical Specifications

Standards	CE (:IVDD 98/79/EC) Low Tension (2006/95/EC) – Test Standard EN60950 ECM (EN55022) ROHS 2 (2011/65/EU)
Dimensions	Depth: 270 mm Width: 190 mm Height: 230 mm
Weight	4 kg
Power supply	EN 61000-3-2, EN 61000-3-3, EN 61000-4-2, EN 6100-4-3, EN 6100-4-4, EN 61000-4-5, EN 61000-4-6, EN 61000-4-8, EN 61000-4-11. Input Voltage: AC 100 – 240 V Output Voltage : 12V/2A/24W 6 DC PLUG 2.1x5.5S
Conditions for use	Temperature: +10°C ~ +30°C Relative humidity : 45%RH ~ 75%RH Atmosphere pressure: 86Kpa ~ 106Kpa Light : normal Surrounding conditions: clear, without strong EMI, without strong noise, without strong vibration ,without strong amycytic gas, avoid direct light from sun
Measurment principle	- Image analysis software
Management des données	- LINUX – Specific Algorithm - EEPROM v1.26

4- START-UP

4-1. Unpacking of the device

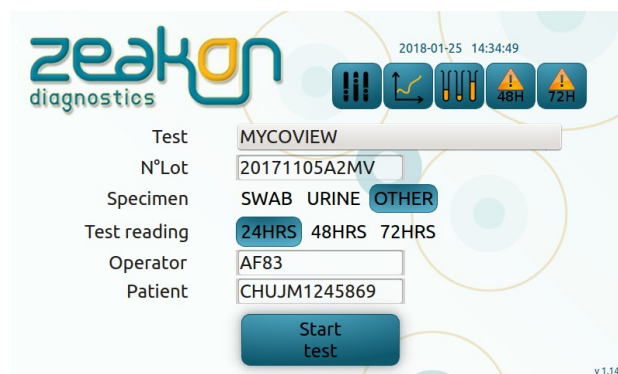
Open the carton box and check its contents :

- Carton foamed pouch containing 2 carriers (1x test strip carrier & 1x screening vial carrier)
- Power supply cable 12V/2A/24W 6 DC PLUG,
- MycoView StudioBox reader ; A very thin protective film is sticked to the touch screen, it can be left or removed,
- Touch sensitive screen stylus,
- Separated packaging : USB barcode scanner for direct upload of the patient ID and the kit lot N°.

Optional printer: Dymo LabelWriter 450 with Dymo Label REF # 11354 for direct printing of the test reports.

4-2. Installation procedure

- Plug the power supply cable into the Mycoview StudioBox device (back side), then into the main socket.
- Switch on the Mycoview StudioBox (1 second pressure) with the On/Off button located in the left side of the reader.
- The main menu will be loaded as follows :



- Software version is indicated on the bottom right side of the screen.

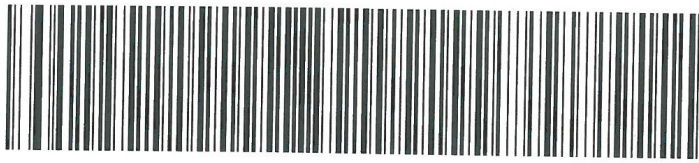
4-3. Barcode scanner setting

The barcode scanner is automatically detected by the MycoView StudioBox. However, to avoid to press the “Enter” key after each scan, the barcode scanner can be set :

Connect the barcode scanner to the USB port of the MycoView StudioBox. Open the barcode scanner instructions and scan the following barcode to set up automated Enter key after each scan (you could also scan the hereunder barcode if the printing quality is correct) :

ADD AN ENTER KEY (Carriage Return/Line Feed)

To add an Enter key after scanned data, scan the bar code below.



ADD AN ENTER KEY (CARRIAGE RETURN/LINE FEED)

Note : This step can be carried out only once. No need to repeat it for each use.

4-4. Settings menu

zeakon diagnostics

2018-02-28 16:50:03

Test MYCOVIEW

N°Lot 20171105A2MV

Specimen SWAB URINE OTHER

Test reading 24HRS 48HRS 72HRS

Operator AF83

Patient CHUJM1245869

Start test

v1.14

- Click on the icon box in red to reach the settings menu.

Settings (192.168.0.104)

Printer off auto manu

Barcode reader yes no

Operator mode on off

Date 2018-02-13 17:02:43

Password

MAC e4:11:5b:fc:e3:41

Save Cancel

- Printer** : **off** to deactivate the optional printer DYMO LabelWriter™ 450 - Ref# LW450 – **auto** : for a systematic printing of the report– **manu** : for a printing step determined by the technician.
- Barcode reader** : to use or not the barcode reader.
- Operator mode** : to activate or not the field allowing to fill in the information identifying the operator.
- Date** : To set date & time.
- Password** : Securised access, for back up & updates. Restricted access to IT administrator.

4-5. Barcode / Manual acquisition setting

For traceability purposes, the kit lot number can be recorded and associated to the test report (ticket report). If the field is not filled in, no lot N° will be recorded.

The lot N° can be added manually or with the barcode scanner.

In the main menu, click on the field box in red to add the lot N°

zeakon diagnostics

2018-02-28 16:50:03

Test MYCOVIEW

N°Lot 20171105A2MV

Specimen SWAB URINE OTHER


Test reading 24HRS 48HRS 72HRS

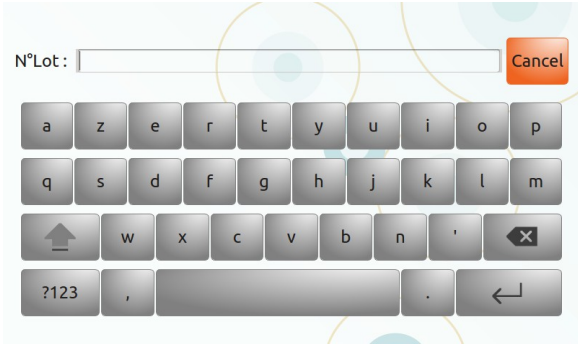
Operator AF83

Patient CHUJM1245869

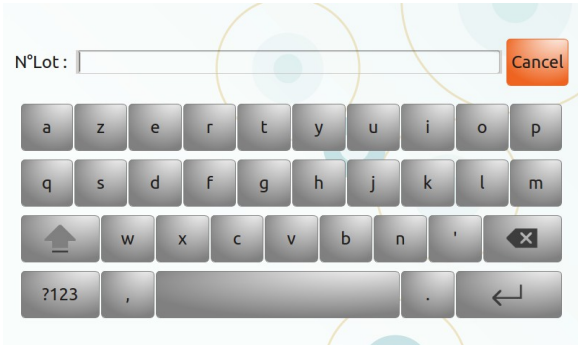
Start test

v1.14

- **Manual acquisition :** Fill in the field using the keyboard and click on the Enter key  to validate.



- **Acquisition with the barcode scanner :** Scan the kit box lot N° barcode. Automatic return to main menu (§4.3).



Proceed to the acquisition of any new batch number before proceeding to the test reading for any test coming from any new kit lot N°.

4-6. Operator field

If activated, fill in the operator field with the information identifying the operator. The last recorded operator will remain recorded.



5- READING OF THE TEST STRIP (5 OR 12 WELLS) AND OF THE SCREENING VIAL

MycoView StudioBox can read both strips and vials. It differentiates vials from strips.

It can read swab, urine and other type of specimens.

Refer to the instructions for use of MycoView Ref# 2040, MycoView ID Ref# 2030, MycoView Quantum Ref# 2040Q MycoView ID Quantum Ref# 2030Q kits for all steps concerning the use of these kits.

For the screening vial, refer to the instructions for use of the kits MycoView Medium Ref# 2060, MycoView Screening Quantum Ref# 2060Q, for all steps concerning the use of these kits.

Note: select the type of test as well as the type of specimen before reading the test.

5-1. Selection of the type of test

Select a test type from the drop down menu : MycoView, MycoView ID, MycoView Quantum ou MycoView ID Quantum. The particular case of Mycoview Medium or Mycoview Screening Quantum is explained in the next paragraph.

A screening vial can be issued either from a Mycoview Medium / Mycoview Screening Quantum kit, or from a MycoView, MycoView ID, MycoView Quantum or MycoView ID Quantum.

When the vial is issued from Mycoview Medium / Mycoview Screening Quantum kit, select from the list one of these kits to associate its lot number.

When the vial is issued from MycoView, MycoView ID, MycoView Quantum ou MycoView ID Quantum kit select from the list one of the kit used to associate its lot number. Mycoview StudioBox detect automatically the presence of vial or of a strip.

5-2. Selection of the type of specimen

MycoView StudioBox can read different types of specimens classified in 3 groups :

- **SWAB**
- **URINE** : to select also when using ESWAB (Copan) or Sigma-VCM (MWE)
- **OTHER** : Semen and any other less frequent liquid specimen.

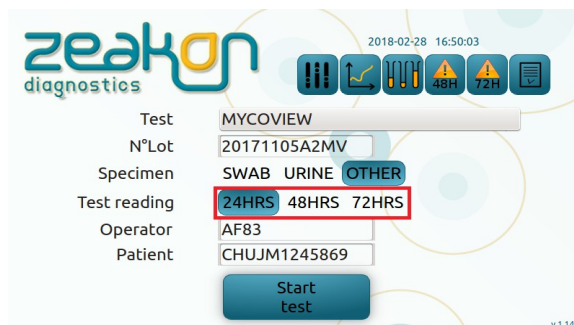
Select the specimen that will be enclosed in the test report.

The diagnostic criteria differ between the 3 groups: Threshold and incubation time are different.

Test	Incubation	24H		48H		72H	
		Usp	Mh	Usp	Mh	Usp	Mh
MycoView Quantum	SWAB	Yes	Yes	NA	Yes	NA	NA
MycoView Quantum	URINE	Yes	Yes	Yes	Yes	NA	NA
MycoView Quantum	OTHER	Yes	Yes	Oui	Yes	Yes	Yes
MycoView	SWAB	Yes	Yes	NA	Yes	NA	NA
MycoView	URINE	Yes	Yes	Yes	Yes	NA	NA
MycoView	OTHER	Yes	Yes	Yes	Yes	Yes	Yes
MycoView ID Quantum	SWAB	Yes	Yes	NA	Yes	NA	NA
MycoView ID Quantum	URINE	Yes	Yes	Yes	Yes	NA	NA
MycoView ID Quantum	OTHER	Yes	Yes	Yes	Yes	Yes	Yes
MycoView ID	SWAB	Yes	Yes	NA	Yes	NA	NA
MycoView ID	URINE	Yes	Yes	Yes	Yes	NA	NA
MycoView ID	OTHER	Yes	Yes	Yes	Yes	Yes	Yes

5-3. Selection of the reading time (T=24, 48 ou 72h)

Select the reading time, ex. 24h.



The screenshot shows the Zeakon diagnostics software interface. At the top, the logo 'zeakon diagnostics' is visible. Below it, there are several icons representing different test types and a date/time stamp '2018-02-28 16:50:03'. The main form contains the following fields:

- Test: MYCOVIEW
- N°Lot: 20171105A2MV
- Specimen: SWAB URINE OTHER
- Test reading: 24HRS 48HRS 72HRS (24HRS is highlighted with a red box)
- Operator: AF83
- Patient: CHUJM1245869

A 'Start test' button is located at the bottom of the form.

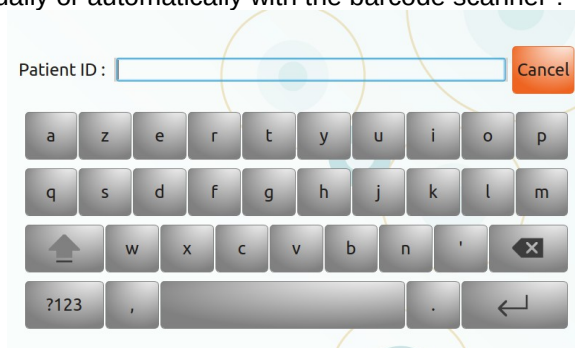
For tests requiring more than 24h incubation reading, you can select among 2 menus 48h or 72h to find out the tests in process requiring a 48h or 72h reading to re-edit them in the main menu.



This screenshot is similar to the previous one, but the '48HRS' and '72HRS' options are highlighted with a red box instead of '24HRS'.

5-4. Patient ID setting

Patient ID can be settled manually or automatically with the barcode scanner :

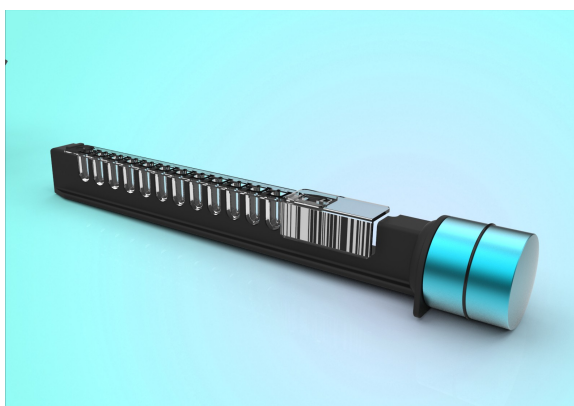


The screenshot shows the 'Patient ID' setting screen. At the top, there is a text input field labeled 'Patient ID :'. To the right of the field is a 'Cancel' button. Below the input field is a virtual keyboard with the following keys:

- Row 1: a, z, e, r, t, y, u, i, o, p
- Row 2: q, s, d, f, g, h, j, k, l, m
- Row 3: ↑, w, x, c, v, b, n, ', <X>
- Row 4: ?123, , , ., ←

5-5. Reading of the test strip

Check that all the 12 wells of the test strip are limpid; cloudy appearance in a well indicates bacterial or yeast contamination. Under these conditions, the test should be repeated; Use the test strip carrier dedicated to 12 and 5 wells strips.



- Set your test parameters (test type/specimen/reading time).
- Scan or enter manually the patient ID.

- Place the test strip 5 or 12 wells on the carrier, **the side with the extension (to be held or to receive the plastic clip for barcodes) always on the side of the handling part of the carrier**
Option : The clip-on plastic for barcode can remain clipped to the strip during the reading step.
- Insert the carrier with the test inside the reader rail with a 45° angle.



- Push the carrier to its maximum position inside the reader.



- Select START TEST.

zeakon diagnostics

2018-02-28 16:50:03

Test MYCOVIEW

N°Lot 20171105A2MV

Specimen SWAB URINE OTHER

Test reading 24HRS 48HRS 72HRS

Operator AF83

Patient CHUJM1245869

Start test

v1.14

- The reader displays a photo of the test and a test report showing all necessary informations.

Reading report

2018-01-26 15:26:21

AF83

TEST: MYCOVIEW

URINE

LOT N: 20171105A2MV

ID: CHUJM1245869

RESULT: 24HRS

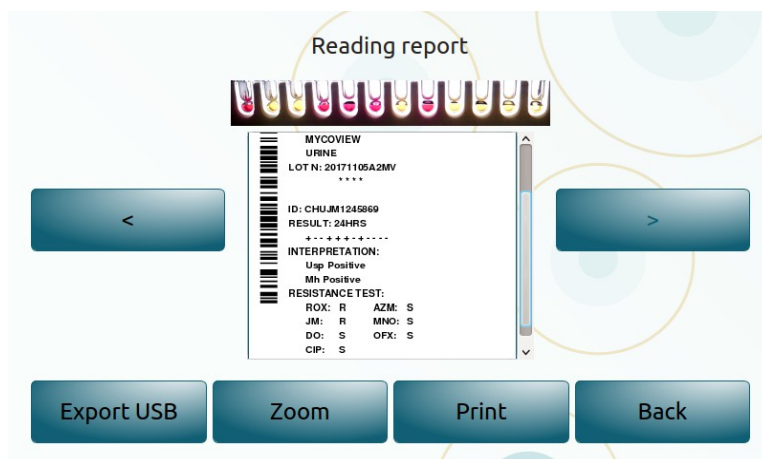
INTERPRETATION:

Usp Positive

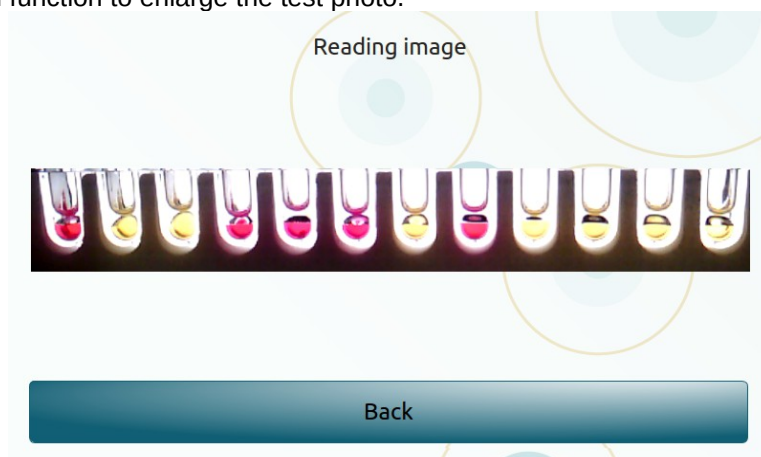
Mh Positive

Export USB Zoom Print Back

- The result for each well (+/-) is indicated along with the interpretation of the test with, in the case of the 12 wells strip, the resistancy profile to antibiotics (using the drop down bar).
Note: When the swab specimen and 48h reading time are selected, MycoView StudioBox will not interpret the results concerning wells N°2 & 4 as these wells concern the identification, differential titration of *Ureaplasma spp.* which incubation cannot last longer than 24 hours in the case of swab specimen.



- Print immediately the results or later using the back button.
- A barcode identical to the one from the patient ID is generated and printed on the test report to allow an easy identification of the patient file in another computer. The result is automatically recorded. See Achieved results § 6.
- Use the Zoom function to enlarge the test photo.



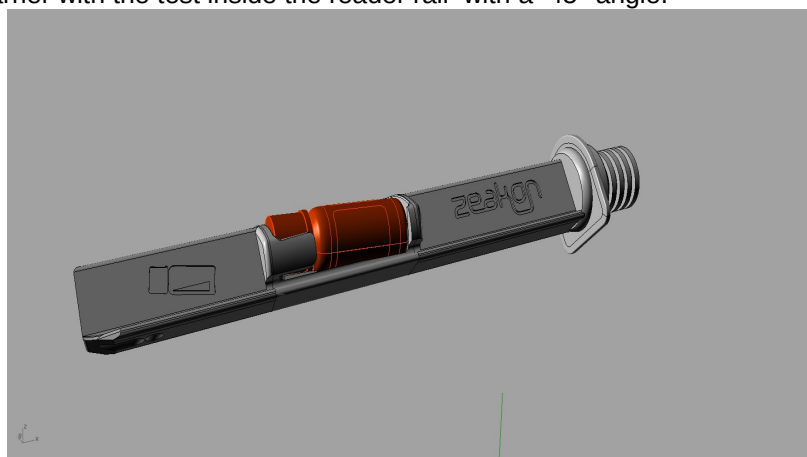
Note: 400 test results can be stored in the MycoView StudioBox.

5-6. Reading of the screening vial

MycoView StudioBox can read the 0.5 mL screening vial with its dedicated carrier. The positioning of the vial label is not important.

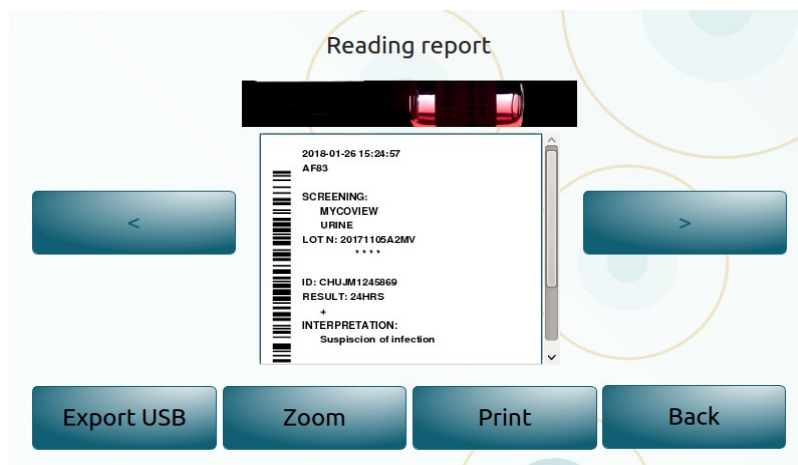
The vial must be placed following the information engraved on the carrier : the bottom of the vial always on the side of the handling part of the carrier for a correct reading.

- Set your test parameters (test type/specimen/reading time).
- Scan or enter manually the patient ID.
- Insert the carrier with the test inside the reader rail with a 45° angle.



- Press on START TEST.
- The reader displays a photo of the test and a test report showing all necessary informations.

It is indicated on the report that the test is a screening test provided in that case from a Mycoview kit. This example shows a positive screening (+) : **Suspicion of infection**. The sample should be tested on a test strip



to get further informations.

- Print immediately the results or later using the back button.
- A barcode identical to the one from the patient ID is generated and printed on the test report to allow an easy identification of the patient file in another computer.
- The result is automatically recorded. See Achieved results § 6.
- Use the Zoom function to enlarge the test photo.

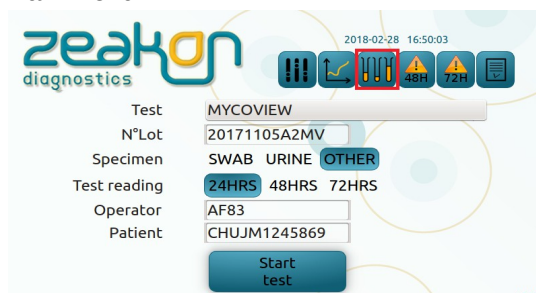
5-7. Data export

400 test results can be stored in the MycoView StudioBox.

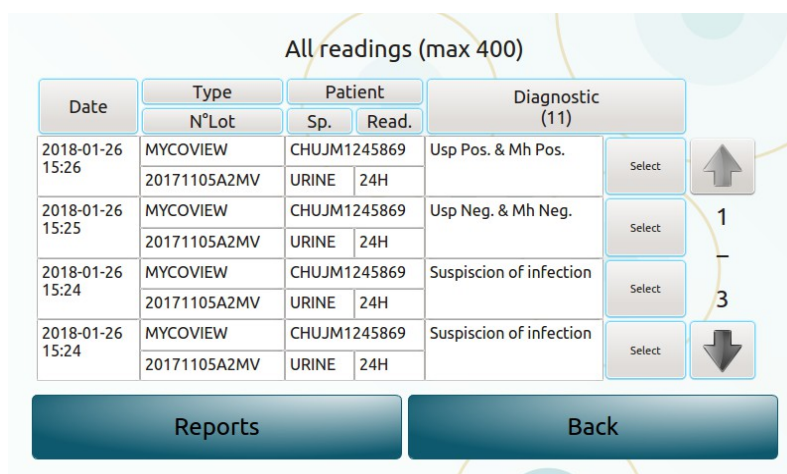
Use the Export USB function (active when a USB device is connected to the reader) to export all data under .csv file format. A folder is also generated on the USB device. It contains all test photos along with the ticket reports .pdf files.

6- ACHIEVED RESULTS

Select the icon box in red in the main menu :



- Click on **Select** to upload the data from the patient into the main menu.



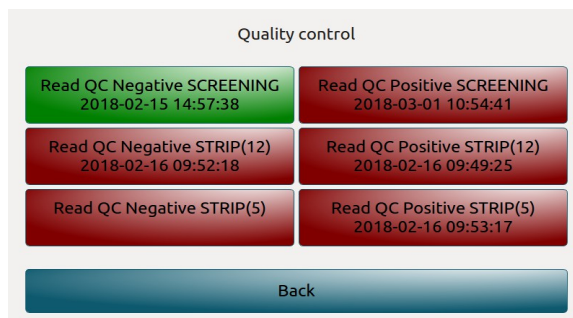
- Click on **Reports** to display the reports individually to print, to export and to check them.

7- QUALITY CONTROL

- From the main menu, select the icon in red :



By default, the 3 pairs (negative & positive) of quality controls have a red background. Once the control is done, date & time of the control will be displayed. If the control result matches with the expected result, the control background will turn to green. If not, it will remain with a red background.



Select the control to run according to the type of kit used in routine :

Reference	Kit designation	Negative control to run	Positive control to run
Ref# 2040	MycoView	Read QC Negative strip (12)	Read QC Positive strip (12)
Ref# 2030	MycoView ID	Read QC Negative strip (5)	Read QC Positive strip (5)
Ref# 2040Q	MycoView Quantum	Read QC Negative strip (12)	Read QC Positive strip (12)
Ref# 2030Q	MycoView ID Quantum	Read QC Negative strip (5)	Read QC Positive strip (5)
Ref# 2060	MycoView Medium	Read QC Negative Screening	Read QC Positive Screening
Ref# 2060Q	MycoView Screening Quantum	Read QC Negative Screening	Read QC Positive Screening

The control principle is to check the correct reading of the test wells individually, and/or the correct reading of the screening vial.

- A 5 or 12 wells strip (all negative) along with a 5 or 12 wells strip (all positive) must be tested.
- Moreover, 0.5mL positive and negative screening vials must be tested if the screening test is carried out in routine.

The controls references to order depending on the kit used in routine are described in the following table :

Reference	Kit designation	Control kit reference	Control kit designation
Ref# 2040	MycoView	Ref# 3080	StudioBoxControl 12 (1 set)
Ref# 2030	MycoView ID	Ref# 3090	StudioBoxControl 5 (1 set)
Ref# 2040Q	MycoView Quantum	Ref# 3080	StudioBoxControl12 (1 set)
Ref# 2030Q	MycoView ID Quantum	Ref# 3090	StudioBoxControl 5 (1 set)
Ref# 2060	MycoView Medium	Ref# 4000	StudioBoxControl screening (1 set)
Ref# 2060Q	MycoView Screening Quantum	Ref# 4000	StudioBoxControl screening (1 set)

The composition of each control kit is described in the following table :

Control reference	Control kit designation	Control kit composition
Ref# 3080	StudioBoxControl12 (1 set)	1 x strip 12 + / 1 x strip 12 - / 1 x strip 12 Usp + / 1 x strip 12 Mh +
Ref# 3090	StudioBoxControl 5 (1 set)	1 x strip 5 + / 1 x strip 5 - / 1 x strip 5 Usp + / 1 x strip 5 Mh +
Ref# 4000	StudioBoxControl screening (1 set)	1 x screening + / 1 x screening -

- Place the test strip or the screening vial into its dedicated carrier. Insert the carrier into the MycoView StudioBox.
- Click on the control to run :

The control results are recorded in the menu achieved results (all readings menu).

8- PRECAUTIONS / LIMITATIONS

The MycoView StudioBox is strictly designed for *in vitro* use;

- The MycoView StudioBox is strictly designed to be combined to the following kits :

Reference	Kit designation
Ref# 2040	MycoView
Ref# 2030	MycoView ID
Ref# 2040Q	MycoView Quantum
Ref# 2030Q	MycoView ID Quantum
Ref# 2060	MycoView Medium
Ref# 2060Q	MycoView Screening Quantum

- Make sure to have enough space around MycoView StudioBox to allow the correct loading of the carriers.
- Avoid touching the sides of the wells of the strips while handling the test.
- As with all methods used for microbial testing, results depend largely on how the specimen was collected. A positive result with MycoView StudioBox indicates that urogenital mycoplasmas are present, but detection of mycoplasmas from genital tract is not necessarily equivalent to infection. Those positive results must be correlated to the clinical situation of the patient and estimated likelihood that urogenital mycoplasmas are playing a role in the infection process.

9- MAINTENANCE

Clean the outside of MycoView StudioBox regularly with a 70% alcohol solution.

Both carriers can be cleaned with a 5% bleach solution.

No other particular maintenance is required.



ZEAKON Diagnostics

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