

1-INTENDED USE

The A8 Reader Control kit enables the control of the good functioning of the reading chamber (12 LEDS) of the A8 Reader by means of one positive control and one negative control.

2- KIT CONTENTS

Mycoview empty strip x2

Adhesive film x2

Regeneration solution x2 (Distilled water – 0.05% azide)

Freeze-dried A8 Control x2 (Colloidal gold conjugate – Sodium Phosphate buffer – 0.1% azide)

3- PRINCIPLE

The A8 reader consists of 12-pairs of photo-electric components, which are used to detect the light intensity of transmitted light through the wells of the MycoView test-strip. The transmitted light differs when there is presence or absence of urogenital mycoplasma (UGM) : inside the MycoView test-strip, the growth of UGM is indicated when the medium turns red or bright pink (alkaline pH); The medium remains yellow-orange or turns yellow if there is no growth of urogenital mycoplasma. Each pair of LED/photodiode is driven to work one by one with a multi-switcher, threshold cut-off values have been determined for each LED/photodiode, the operation menu and test results are shown in the LCD monitor. One LED/photodiode will read one well of the MycoView strip. By preparing a negative and a positive control solution (with given colours) and inoculating a Mycoview strip with the solution and proceeding to the reading of the strip, each well profile should be well read by the A8 Reader.

4- PRECAUTIONS

Bring the reagents to room temperature before using the test;

Refer to the protocol enclosed in the A8 Reader kit (Ref. 2010) for all steps concerning handling of the instrument

The test is strictly designed for *in vitro* use;

Read these instructions carefully before using the test;

Do not use the kit reagents after the expiry date;

Never use reagents from different kits together;

Use a new pipette tip for each test;

5- PREPARATION AND READING

Positive Control :

Reconstitute one freeze-dried medium with 1.3 mL of the Regeneration Solution

Gently mix the reconstituted solution.

Add 100 µL into each well of the Mycoview 12 wells strip.

Optional : Close the 12 wells with the adhesive film.

Negative Control :

Reconstitute one freeze-dried medium with 3 mL of the Regeneration Solution

Gently mix the reconstituted solution.

Add 100 µL into each well of the Mycoview 12 wells strip.

Optional : Close the 12 wells with the adhesive film.

Reading :

In the A8 Reader main menu, select Mycoview Test and Swab Specimen and proceed to the Test Reading at 24 hours.

The A8 Reader must read positive (+) each well of the 12 wells of the Mycoview test strip when reading the positive control solution.

The A8 Reader must read negative (-) each well of the 12 wells of the Mycoview test strip when reading the negative control solution.

If any well is read as discordant, contact your representative.

6- STORAGE

The reagents may be stored at +2°C/+8°C until expiry date indicated on the vials.

When reconstituted with the regeneration solution, the reagents should be used within the same day and should not be stored.

7- MATERIALS REQUIRED BUT NOT PROVIDED

- Pipettes and tips;

8- SYMBOLS USED



In Vitro diagnostic use



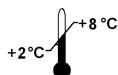
Expiry date



Technical insert included in the kit, information to read



Lot number



Store between +2°C / +8°C



Catalogue reference



Manufactured by



Zeakon Diagnostics

11 Rue Alfred de Vigny
25000 Besancon - FRANCE