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Test Rapido a dischetto Candida Albicans per autocontrollo
One Step Candida Albicans Test Disk for self-diagnosis
Test d'identification rapide sur cassette de Candida Albicans pour autocontrôle
Test Rápido en disco Candida Albicans para autocontrol

MANUALE D'USO
OPERATOR'S MANUAL
MANUEL D'UTILIZATION
MANUAL DE USO

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*
AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*
ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*

CE
0483

M29106-M-Rev.1-06.10

INTENDED USE

The one step Candida Albicans test is a simple one step immunochromatographic assay for the rapid, qualitative detection of the presence of Candida Albicans in virginal swab specimens.

PRECAUTIONS

The One Step Candida test devices should be stored at room temperature 4-30°C (40-86°F). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

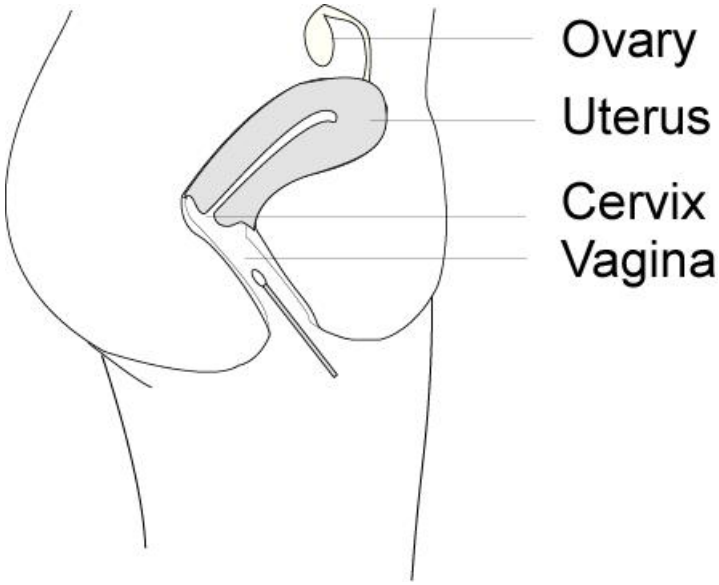
MATERIALS PROVIDED

The Candida test kit contains the following items to perform the assay:

1. Test device.
2. Disposable sample dropper.
3. Instructions.
4. Sterile swabs
5. Test tube.
6. Extraction solution.

VAGINAL SPECIMEN COLLECTION AND PREPARATION

Open the sterile the collection swab. Gently open the vaginal opening, and insert the swab about two to three inches into the vagina. Use extreme care if the patient is pregnant. Improper collection of the specimen will result in poor visual reading and may cause invalid results.



WARNINGS

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling the specimen.
3. Wear protective gloves while handling the specimen. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

SPECIMEN STORAGE

If the swab with the specimen is not extracted immediately, store it refrigerated for up to 5 days, preferably in a transportation tube. Do not freeze. Swabs may be transported to the test site under ambient conditions. Transport media should not be used.

SPECIMEN PREPARATION

1. Bring all samples to room temperature prior to testing.
2. Add 6 to 8 drops of the extraction solution into the test tube (Figure A). Place the specimen swab in the tube and swirl it vigorously to mix the reagents for about 15 seconds (Figure B). Then incubate the mixture at room temperature for 10 minutes with the swab in the tube.
3. Swirl the swab vigorously for 15 seconds, then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the tube. Discard the swab. Mix the contents of the tube by gentle swirling.
4. Take mixture with sample dropper.

Figure A

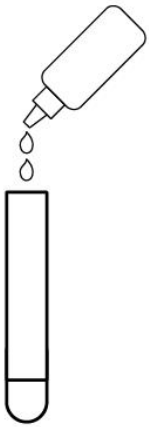
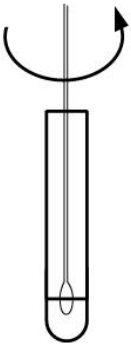


Figure B



PROCEDURE OF THE TEST

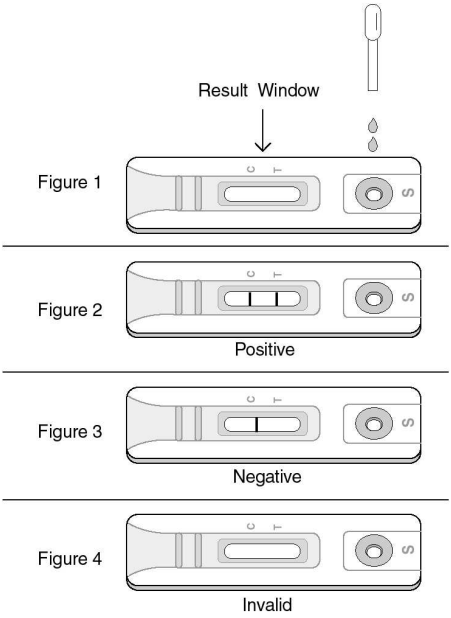
1. Remove the test device from the foil pouch, and place it on a flat, dry surface.

2. Holding the sample dropper above the Disk (S), squeeze 2 drops of the mixture into the sample well (Figure 1).

3. As the test kit begins to work, you will see purple color move across the Result Window in the center of the test disk.

4. Interpret test results at 10 to 20 minutes. Do not interpret after 30 minutes.

Caution: The above interpretation time is based on a reading of the test results at a room temperature between 15 to 30 °C.



INTERPRETATION OF THE TEST

1. As the test kit begins to work, a color band will appear in the left section of the Result Window to show that the test is working properly. This band is the Control Band (C).
2. The right section of the result window indicates the test results. If another color band appears in the right section of the Result Window, this band is the Test Band (T).

POSITIVE RESULT: TWO COLOR BANDS
The presence of two color bands (“T” band and “C” band) within the result window, regardless of which band appears first indicates a positive result (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the “T” band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the “T” band will be very faint.

NEGATIVE RESULT: ONE COLOR BAND IN ZONE C
The presence of only one purple color band in the Zone C of the Window indicates a negative result (Figure 3).

INVALID RESULT:
If after performing the test the band is not visible in the Zone C of the Window, the result is considered invalid (Figure 4). The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

Note: to avoid producing false results, the result of the test must not be considered if 30 or more minutes have passed from when the 2 drops of the mixture were dropped in the specific section (S).

Limitations of the test

The test is limited to the detection of Candida Albicans in the sample taken using the swab. Although the test is very accurate in detecting Candida Albicans a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

SPECIFICITY AND INTERFERENCE STUDY

No cross reactivity was found with the common bacterial flora in the vaginal tract.

QUESTIONS AND ANSWERS

1. Q: If I see 2 colored strips appear and one is darker than the other, do I have to consider both valid?
A: Yes they must be considered valid. Even if the two strips are slightly different, both must be considered valid.

2. Q: Can the result of the test change after a while?
A: Yes. To avoid changes in the result, read the result within 20 minutes from when the two drops of mixture were put in the specific section (S). Do not consider result if 30 or more minutes have passed.

3. Q: If the result of the test is POSITIVE what must I do?
A: If the result of the test is POSITIVE, we suggest seeking the advice of your doctor and discussing the issue with him/her.

4. Q: If the result of the test if NEGATIVE but there are signs of Candida Albicans, what must I do?
A: If the result of the test if NEGATIVE but there are signs of Candida Albicans, seek doctor's opinion.

5. Q: Can I perform the test at any time of the day?
A: Yes.

INDEX OF SYMBOLS

	Carefully read the instruction for use		Disposable device, do not re-use	CE 0483	Product compliant with European Directive no. 98/79/EC on I vitro diagnostic devices
IVD	Only for *in vitro* use		Expiration date (see box/ package)		
4°C 30°C	Keep at a temperature between 4°C and 30°C	LOT	Batch number (see box/ package)	REF	Product code (see box)

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98208, USA

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Swabs:

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