Rapid test for Candida Albicans infection diagnosis

INTENDED USE

Quick Candida Test is a simple one step immunochromatographic assay for the rapid, qualitative detection of Candida Albicans infection (candidiasis) in vaginal swab specimens. Quick Candida Test is an in vitro diagnostic device intended also for not professional use (self-testing).

PERFORMANCE CHARACTERISTICS

- Sensitivity: $1.5 \times 10^5$ CFU.
- Relative Sensitivity: 100 %.
- Relative Specificity: 100 %.
- Specimen: vaginal swab.
- Certification: CE 0483.

PRINCIPLE

Quick Candida Test is an in vitro diagnostic device that uses the immunochromatographic system Lateral Flow Immuno Assay (LFIA) for the qualitative detection of Candida Albicans in vaginal swab specimens. This test uses a pair of monoclonal antibodies which specifically binds to Candida Albicans, one antibody is also attached to a visible gold particle and the other antibody is attached to the membrane in the test window. When Candida Albicans is detected and bonded to the antibodies, a test line becomes visible indicating a positive result. Regardless of the outcome, if the test responded correctly, a line appears in the C region of the device.

MATERIALS PROVIDED

- Quick Candida Test cassette device, individually packed.
- Package insert.
- Swabs.
- Mixing Tube.
- Extraction buffer.
- Disposable sample dropper.

SPECIMEN COLLECTION AND PREPARATION

1. Open the sterile collection swab.
2. 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 will result in poor visual reading and may cause invalid results.
3. As the swab is extracted run a test immediately.
4. Add 6 to 8 drops of the extraction buffer into the test tube (Figure 2.A).

Figure 1. Specimen collection.
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5. Place the specimen swab in the tube and swirl it vigorously to mix the reagents for about 15 seconds (Figure 2.B). Then incubate the mixture at room temperature for 10 minutes with the swab in the tube.

6. Swirl the swab vigorously for 15 seconds and then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the tube.

7. Discard the swab.

8. Mix the contents of the tube by gentle swirling. The swab extract can be tested immediately or remain at room temperature for up to 3 hours without affecting test results.

**PROCEDURE**

1. Bring tests, specimens, buffer to room temperature (15-30 °C) before use.
2. Remove the test cassette from the foil pouch, and place it on a flat, dry surface.
3. Holding the sample dropper above the test cassette, squeeze 2 drops of the extracted specimen into the sample well (S).
4. Interpret test results at 10 to 20 minutes. Do not interpret after 30 minutes.

**INTERPRETATION OF RESULTS**

**Positive**
Presence of two colored bands: one at the T region of the test and one in correspondence of the C region. A positive result indicates that the sample contains Candida Albicans.

**Negative**
Presence of a single colored band at the C region. A negative result may indicate that the candidiasis infection is not present, or that Candida Albicans concentrations are too low to be detected.

**Invalid**
Absence of a colored band at the C regions: it is necessary to repeat the test using a new device.
Note
1. The intensity of color in the test region (T) may vary depending on the concentration of Candida Albicans present in the specimen. Therefore, any shade of color in the test region should be considered positive.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

STORAGE AND STABILITY
• The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
• The test must remain in the sealed pouch or closed canister until use.
• Do not freeze.
• The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS
• For in vitro diagnostic use only.
• Do not reuse tests.
• Do not use after the expiration date indicated on the package.
• Do not use the test if the foil pouch is damaged.
• Read the entire procedure carefully prior to testing.

LIMITATIONS OF THE TEST
The test is limited to the detection of Candida Albicans in swab specimens. 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.

CROSS REACTIVITY
Other organisms commonly found in the vaginal flora were tested, and no cross reactivity (interference) were found. Other organisms tested are:
• Lactobacillus: ATCC # 314 a 1 x 10^5 CFU/ml
• Gardnerella vaginalis: ATCC # 14018 a 5 x 10^5 CFU/ml
• Mycoplasma hominis: ATCC # 15056 a 1 x 10^3 CFU/ml
• Ureaplasma urealyticum: ATCC # 27814 a 1 x 10^5 CFU/ml
• Chlamydophila polomonit: ATCC 53592 a 1 x 10^7 CFU/ml
• Chlamydia trachomatis: ATCC: VR-1500 a 1 x 10^7 CFU/ml
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- Chlamydiophila psittaci: ATCC VR-1369 a 1 x 10^7 CFU/ml
- Mycoplasma polmonite: ATCC: 29342 a 1 x 10^7 CFU/ml
- E. coli: ATCC: 25922 a 1 x 10^8 CFU/ml

QUESTIONS AND ANSWERS

Q: If I see two bands appear, but one band is much darker than the other, can I confirm that there are two lines?
A: Yes. Even if the line is a slightly different color, the test should be interpreted as showing two lines.

Q: Can the result change after standing for a certain length of time?
A: A positive or negative result will not change after the test is completed at 20 minutes. However, in order to prevent any incorrect readings, the test result should not be interpreted after more 30 minutes.

Q: If the test result is positive, what do I do?
A: If the test result is positive, you should consult your doctor. The earlier you see your doctor, the better it is for your health.

Q: If the test result is negative, but I still have the symptoms, what do I do?
A: If the test result is negative, but you still have symptoms, you should consult your doctor.

Q: Can I run the test at any time of a day?
A: Yes, you can.