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Candida Albicans Test Disk
 For Swab Specimen



Catalog No. R11-624



For Research Use Only

INTENDED USE

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

PRECAUTIONS

The Immunospec 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.

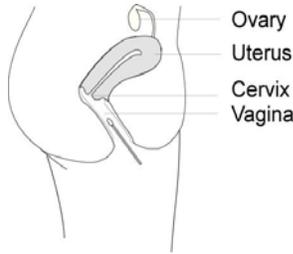
MATERIALS PROVIDED

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

1. Test cassette.
2. Disposable sample dropper.
3. Instructions.
4. Mixing tube
5. Swabs
6. Extraction buffer.

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 will result in poor visual reading and may cause invalid results.



WARNINGS

1. For in research use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. 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.

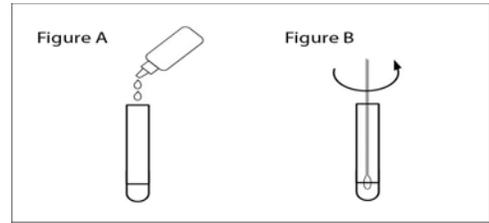
SPECIMEN STORAGE

If a swab 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

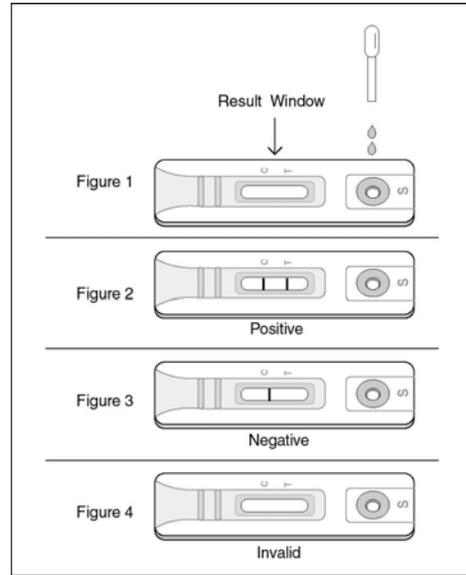
1. Bring all samples to room temperature prior to testing.

2. Add 6 to 8 drops of the extraction buffer 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. The swab extract can be tested immediately or remain at room temperature for up to 3 hours without affecting test results.



PROCEDURE OF THE TEST

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk, squeeze 2 drops of the extracted specimen 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 reading the test results at room temperature of 15 to 30 °C. If your room temperature is significantly lower than 15 °C, then the interpretation time should be properly increased.

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

The presence of only one purple color band within the Result Window indicates a negative result (Figure 3).

INVALID RESULT:

If after performing the test no band is visible within the result 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: A positive result will not change once you have established your answer at 10 to 20 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 30 minutes.

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.

SPECIFICITY AND INTERFERENCE STUDY

Determine the Specificity of Immunospec *Candida Albicans* test. An in-house study is conducted with 3 separate lots of the Immunospec *Candida Albicans* Swab specimen Test. Specimens tested include specimen added triglyceride concentrations up to 500 mg/ml, Bilirubin concentrations up to 10 mg/100ml, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml. All of the above were analyzed and did not show interference or cross reactivity with the test.

REFERENCES

1. Reed BD, Zazove P, Pierson CL, Gorenflo DW, Horrocks J. *Candida* transmission and sexual behaviors as risks for a repeat episode of candida vulvovaginitis. *J Wom Health* 2003; 12: 979-989.
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3. Christensson, B., G. Sigmundsdottir, and L. Larsson. 1999. D-Arabinitol- a marker for invasive candidiasis. *Med. Mycol.* 37:391-396
4. Kevin B. Laupland, Daniel B. Gregson, Deirdre L. Church, Terry Ross, and Sameer Elsayed. Invasive *Candida* species infections: a 5 year population-based assessment. *J. Antimicrob. Chemother.*, Sep 2005; 56: 532 - 537.



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