ACRO BIOTECH, INC

# *Candida albicans* Rapid Test Cassette (Vaginal Swab) Package Insert

| REF ICA-502 | English |
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*A rapid test for the qualitative detection of Candida albicans antigen from vaginal swabs.*
*For professional in vitro diagnostic use only.*

## INTENDED USE

The *Candida albicans* Rapid Test Cassette (Vaginal Swab) is a rapid chromatographic immunoassay for the qualitative detection of *Candida albicans*antigens from vaginal swabs. This test is intended to be used as an aid in the diagnosis of Candida infection.

## SUMMARY

*Candida albicans* is an opportunistic pathogenic yeast [1] that is a common member of the human gut flora. It does not proliferate outside the human body.[2] It is detected in the gastrointestinal tract and mouth in 40-60% of healthy adults.[3,4] It is usually a commensal organism, but can become pathogenic in immune compromised individuals under a variety of conditions.[4,5] It is one of the few species of the *Candida* genus that causes the human infection candidiasis, which results from an overgrowth of the fungus.[4,5] Candidiasis is for example often observed in HIV-infected patients.[6]*C. albicans* is the most common fungal species isolated from biofilms either formed on (permanent) implanted medical devices or on human tissue.[7,8]

*C. albicans*, together with *C. tropicalis*, *C. parapsilosis* and *C. glabrata*, is responsible for 50–90% of all cases of candidiasis in humans.[5,9,10] A mortality rate of 40% has been reported for patients with systemic candidiasis due to *C. albicans*.[11] Estimates range from 2800 to 11200 deaths caused annually in the USA due to *C. albicans* causes candidiasis.

## PRINCIPLE

The *Candida albicans* Rapid Test Cassette (Vaginal Swab) is a qualitative, membrane based immunoassay for the detection of *Candida albicans* antigens through visual interpretation of color development on the internal strip. Anti-*Candida albicans* antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-*Candida albicans* antibodies conjugated to colored particles impregnated onto the label pad of the test unit. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there is sufficient *Candida albicans* antigens in the specimen, a colored line will form at the test region of the membrane. The presence of this colored line indicates a positive result, while its absence indicates a negative result. The appearance of a colored line at the control region serves as a procedural control, indicating that proper volume of specimen has been added and membrane wicking has occurred.

## REAGENTS

The *Candida albicans* Rapid Test Cassette (Vaginal Swab) contains anti- *Candida albicans* antibody conjugated gold particles and anti- *Candida albicans* antibodies coated on the membrane.

## PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not exchange or mix buffer and test cassettes from kits of different lots.
8. Be sure to add sufficient extracted specimen to the cassette's specimen well. Invalid result may occur if inadequate extracted specimen is added.

## STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

## SPECIMEN COLLECTION AND PREPARATION

It is recommended to use the swab supplied by the kits manufacture.

- Insert the swab into the inside of the vagina, and rotate for 10 seconds. Pull the swab out carefully.
- Do not place the swab in any transport device containing medium since transport medium interferes with the assay and viability of the organisms is not required for the assay. Put the swab to the extraction tube, if the test is to be performed immediately. If immediate testing is not possible, the patient specimen should be placed in a dry transport tube for storage or transport. The swabs may be stored for 24 hours at room temperature (15-30°C) or 1 week at 4°C or no more than 6 months at -20°C. All specimens should be allowed to reach a room temperature of 15-30°C before testing.
- Do not use 0.9% sodium chloride to treat swab before collecting specimen.
- The solution remaining in the test tube used for the wet mount may also be used as the specimen for the *Candida albicans* test. To use this specimen type, add 3 drops of the solution to the specimen well directly. These saline specimens may be held at room temperature for on longer than 24 hours. These specimens may also be stored at 4°C for up to 1 week or -20°C for 6 months.
- To run a culture as well as the *Candida albicans*Rapid Test. Separate swabs must be used, because the buffer will influence Candida organisms.

## MATERIALS

**Materials Provided**

- Test Cassettes
- Extraction Buffer
- Package Insert
- Extraction Tubes
- Extraction Tube Tips
- Workstation
- Sterile Swabs

**Materials Required But Not Provided**

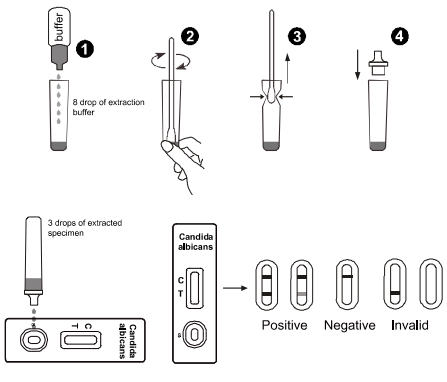
- Timer

## DIRECTIONS FOR USE

**Allow the test, specimen swab, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Place a clean extraction tube in the designated area of the workstation. Add **8 drops (approx. 450µL)** extraction buffer into the tube.
2. Put the specimen swab into the tube; vigorously mix the solution by rotating the swab forcefully against the side of the tube for least ten times (while submerged). Best results are obtained when the specimen is vigorously mixed in the solution.
3. Allow the swab to soak in the extraction buffer for 1 minute prior to the next step. Squeeze out as much liquid as possible from the swab by pinching the slide of the flexible extraction tube as the swab is removed. At least 1/2 of the extraction buffer solution must remain in the tube for adequate capillary migration to occur.
4. Discard the swab in a suitable bio-hazardous waste container, and then fit on the extraction tube tip onto the extraction tube.
5. Remove the test cassette from its sealed pouch, and place it on a clean and level surface. To obtain a best result, the assay should be performed within one hour.
6. Add **3 drops (approx. 100µL)** of extracted specimen from the extraction tube to the specimen well on the test cassette. Please avoid trapping air bubbles in the specimen well and do not drop any solution in observation window.
7. Wait for the colored line(s) to appear. The result should be read at **15 minutes**, do not interpret the results after 20 minutes.

**Note:** It is suggested not to use the buffer, beyond 6 months after opening the vial.




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**POSITIVE: * Two colored lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A positive result indicates that *Candida albicans* antigen was detected in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *Candida albicans* antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T). A negative result indicates that *Candida albicans* antigen is not present in the specimen, or is present below the detectable limit of the test.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

1. The *Candida albicans* Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of *Candida albicans*antigen in vaginal swab specimens only. Neither the quantitative value nor the rate of increase in *Candida albicans* antigen concentration can be determined by this qualitative test.
2. A negative result should be confirmed by culture. A negative result may be obtained if the concentration of the *Candida albicans* antigen present is not adequate or is below the detectable limit of the test.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

## PERFORMANCE CHARACTERISTICS

**Detection Limitation**

The *Candida albicans* Rapid Test Cassette (Vaginal Swab) can detect *Candida albicans antigen* as low as 1E+06 org/ml.

**Clinical Sensitivity, Specificity and Accuracy**

The performance of the *Candida albicans* Rapid Test Cassette (Vaginal Swab) has been evaluated with 83 clinical specimens collected from the patient symptomatic and asymptomatic in comparison with other rapid test method. The results show that the relative sensitivity of the *Candida albicans* Rapid Test Cassette (Vaginal Swab) is 92.3% and the relative specificity is 98.6%.

***Candida albicans* Rapid Test Cassette vs. Other Rapid Test**

| Method | | Other Rapid Test | | Total Results |
|---|---|---|---|---|
| ***Candida albicans* Rapid Test Cassette (Vaginal Swab)** | Results | Positive | Negative | |
| | Positive | 12 | 1 | 13 |
| | Negative | 1 | 69 | 70 |
| **Total Results** | | 13 | 70 | 83 |

Relative Sensitivity: 92.3% (95%CI*: 64%~99.8%);
Relative Specificity: 98.6% (95%CI*: 92.3%~>99.9%);
Overall Accuracy: 97.6% (95%CI*: 91.6%~99.7%). *Confidence Intervals

**Precision**

**Intra-Assay**

Within-run precision has been determined by using 3 replicates of four specimens: a negative, 1E+06org/ml, 1E+07org/ml and 1E+08org/ml. The negative, 1E+06org/ml, 1E+07org/ml and 1E+08org/ml values were correctly identified >99% of the time.

**Inter-Assay**

Between-run precision has been determined by 3 independent assays on the same four specimens: a negative, 1E+06org/ml, 1E+07org/ml and 1E+08org/ml. Three different lots of the *Candida albicans* Rapid Test cassette (Vaginal Swab) have been tested over a 3-days period using negative, 1E+06org/ml, 1E+07org/ml and 1E+08org/ml specimens. The specimens were correctly identified >99% of the time.

**Cross-reactivity**

Cross reactivity with other organisms has been studied using suspensions of $10^7$ Colony Forming Units (CFU)/test. The following organisms were found negative when tested with the *Candida albicans* Rapid Test Cassette (Vaginal Swab).

*Acinetobactercalcoaceticus*
*Salmonella typhi*
*Staphylococcus aureus*
*Neisseria catarrhalis*
*Neisseria meningitides*
*Gardenerellavaginalis*
*Streptococcus faecium*
*Chlamydia trachomatis*
*Mycoplasma hominis*
*Proteus vulgaris*
*Trichomanasvaginalis*
*Acinetobacter spp.*
*Neisseria gonorrhea*
*Escherichla coli*
*Streptococcus faecalis*
*Pseudomonas aeruginosa*
*Ureaplasmaurealyticum*

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**Index of Symbols**

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| | Consult instructions for use or consult electronic instructions for use | Σ | Contains sufficient for <n> tests | 30°C / 2°C | Temperature limit |
| IVD | *In vitro* diagnostic medical device | LOT | Batch code | REF | Catalogue number |
| EC REP | Authorized representative in the European Community | | Use-by date | | Do not re-use |
| | Do not use if package is damaged and consult instructions for use | | Manufacturer | | |


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CE

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**Statement:** Information about manufacturer of sterile swab is placed on the packaging.


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