**INTENDED USE**

StrongStep® Candida albicans antigen Rapid Test is intended 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.

**INTRODUCTION**

Vulvovaginal candidiasis (VVC) is thought to be one of the most common causes of vaginal symptoms. Approximately, 75% of women will be diagnosed with Candida at least once during their lifetime. 40-50% of them will suffer recurrent infections and 5% are estimated to develop chronic Candidiasis. Candidiasis is more commonly misdiagnosed than other vaginal infections. Symptoms of VVC include vaginal itching, vaginal soreness, irritation, rash on the outer lips of the vagina and genital burning that may increase during urination, are non-specific. To obtain an accurate diagnosis, a thorough evaluation is necessary. Women who complain of vaginal symptoms, standard tests should be performed, such as saline and 10% potassium hydroxide microscopy. Microscopy is the mainstay in the diagnosis of VVC, yet studies show that, in academic settings, microscopy has a sensitivity of at least 50% and this will miss a substantial percentage of women with symptomatic VVC. To increase the accuracy of diagnosis, yeast cultures have been advocated by some experts as an adjunctive diagnostic test, but these cultures are expensive and underutilized, and they have the further disadvantage that it may take up to a week to get a positive result. Inaccurate diagnosis of Candidiasis may delay treatment and cause more serious lower genital tract diseases. StrongStep® Candida albicans Antigen Rapid Test is a point-of-care test for qualitative detection of Candida vaginal discharge swabs within 10-20 minutes. It is an important advance in improving the diagnosis of women with VVC.

**PRINCIPLE**

StrongStep® Candida albicans Antigen Rapid Test uses dried latex immunochromatographic, capillary flow technology. The test procedure requires the activation of the Candida proteins from a vaginal swab by mixing the swab in Sample Buffer. Then the mixed sample buffer is added to the test cassette sample well and the mixture migrates along the membrane surface. If Candida is present in the sample, it will form a complex with the primary anti- Candida antibody conjugated to colored particles. The complex will then be bound by a second anti-Candida antibody coated on the nitrocellulose membrane. The appearance of a visible test line along with the control line will indicate a positive result.

**KIT COMPONENTS**

- 20 Individually packed test devices
- 2 Extraction Buffer vial
- 1 Positive control (on request only)
- 1 Negative control (on request only)
- 20 Extraction tubes
- 1 Workstation
- 1 Package insert

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Timer
- For timing use.

**PRECAUTIONS**

- For professional in vitro diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not re-use tests.
- This test is a qualitative test and the test result obtained cannot be quantified.
- Do not place the swab in any transport device containing medium since transport medium interferes with the assay and will not allow or tampering for the assay. Put the swab into the extraction tube, if the test may be run immediately. If immediate testing is not possible, the patient samples should be placed in a dry transport tube for storage or transportation. 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 swabs before collecting specimens.
- To run a culture as well as the StrongStep® Candida albicans antigen rapid test, separate swabs must be collected because the sample buffer will kill Candida organisms.

**PROCEDURE**

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

- Place a clean extraction tube in the designated area of the workstation add 20 drops of extraction buffer into the extraction tube.
- Put the specimen swab into the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube for at least fifteen times (while submerged). Best results are obtained when the specimen is vigorously mixed in the solution.
- Allow the swab to soak in the extraction buffer for one minute prior to the next step.
- Squeeze out as much liquid as possible from the swab by pinchling the side of the flexible extraction tube as the swab is removed. At least 1/2 of the sample buffer solution must remain in the tube for adequate capillary migration to occur.
- Put the cap on the extracted tube.
- Discard the swab in a suitable biohazardous waste container.
- The specimens extracted can retain at room temperature for 60 minutes without affecting the result of the test.
- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be permitted for 10 minutes.
- Add 3 drops (approximately 100 µl) of extracted sample from the extraction tube to the sample well on the test cassette. Avoid trapping air bubbles in the specimen well (5), and do not over fill the upper observation window. As the test begins to work, you will see color move across the membrane.
- Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.
- Discard used test tubes and Test Cassette in suitable biohazardous waste container.
INTERPRETATION OF RESULTS

POSITIVE RESULT: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE RESULT: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVAID RESULT: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE: 1. The intensity of the color in test region (T) may vary depending on the concentration of the substance present in the sample. But the substance level cannot be determined by this qualitative test. 2. Insufficient specimen volume, incorrect operation, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered as an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External procedural controls may be provided request only in the kit to ensure that the tests are functioning properly. Also, the controls may be used to demonstrate proper performance by the test operator. To perform a positive or negative control test, complete the steps in the Test Procedure section treating the control swab in the same manner as a specimen swab.

LIMITATIONS OF THE TEST

1. StrongStep® Candida albicans Antigen Rapid Test is only for the qualitative detection of Candida albicans antigen from vaginal swabs and the saline solution remaining from a wet mount of a vaginal swab.
2. The performance of the StrongStep® Candida albicans Antigen Rapid Test with specimens other than vaginal fluid has not been established.
3. The results obtained from this kit yield data that must be used only as an adjunct to other information available to the physician.
4. This test does not differentiate between viable and non-viable organisms. 5. This test does not differentiate between individuals that are carriers and individuals that have an acute infection.
5. Patients with vaginitis/vaginosis symptoms may have mixed infections. Therefore a test indicating the presence of Candida vaginovaginitis does not rule out the presence of T. vaginalis or Bacterial vaginosis (These can also be diagnosed by Limingbio’s other two products: 50040 Trichomonas vaginalis Antigen Rapid test; 50080 Bacterial Vaginosis Rapid test).
6. A negative result may be obtained if the specimen collection is inadequate or if antigen concentration is below the sensitivity of the test. A negative result of StrongStep® Candida albicans Antigen Rapid Test may warrant additional patient follow up.

- Vaginovagal candidiasis (VVC) may be caused by other candida such as C.parapsilosis, C.tropicalis, C. glabrata, C. guillermondii, C. lusitaniae, C. krusei and C. tropicalis. However, StrongStep® Candida albicans Antigen Rapid Test only detects the Candida albicans, and has no cross-reactivity with C.tropicalis, C.krusei and C.tropicalis.
- Women with vaginal discharge should be evaluated for risk factors of cervicitis and pelvic inflammatory disease and for other organisms including Neisseria gonorrhoeae and Chlamydia trachomatis (These can also be diagnosed by Limingbio’s other three products: 50010 Chlamydia trachomatis Antigen Rapid test; 500020 Neisseria gonorrhoeae Antigen Rapid test; 50050 Neisseria gonorrhoeae/Chlamydia trachomatis Antigen Combo Rapid Test)
- Samples contaminated with preparations containing iodine or by the immediate prior use of vaginal lubricants are not recommended.

PERFORMANCE CHARACTERISTICS

Table: StrongStep® Candida albicans Antigen Rapid Test vs. Culture

<table>
<thead>
<tr>
<th>Parameter</th>
<th>StrongStep®</th>
<th>Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative Sensitivity:</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>87.3% (83.5%-90.6%)</td>
<td>324</td>
<td>5</td>
</tr>
<tr>
<td>+ - Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>95.0% (93.3%-96.2%)</td>
<td>47</td>
<td>671</td>
</tr>
<tr>
<td>Overall Agreement:</td>
<td>StrongStep®</td>
<td>Culture</td>
</tr>
<tr>
<td>(%)</td>
<td>371</td>
<td>676</td>
</tr>
<tr>
<td>95% Confidence Interval:</td>
<td></td>
<td>1047</td>
</tr>
</tbody>
</table>

Analytical Sensitivity: 1×10⁶ CFU/ml Candida albicans (ATCC 5314 strain).

Analytical Specificity: Cross-reactivity with other organisms has been studied using suspensions of 10⁶ CFU/ml. The following organisms were not detected using the test.

- Acinetobacter baumannii
- Salmonella typhi
- Staphylococcus aureus
- Neisseria gonorrhoeae
- Neisseria meningitidis
- Escherichia coli
- Streptococcus faecalis
- Pseudomonas aeruginosa
- Ureaplasma urealyticum
- Candida parapsilosis
- Candida glabrata
- Candida krusei
- Cryptococcus neoformans

C. tropicalis, C. krusei have cross-reactivity over the concentration of 1×10⁵ CFU/ml.

LITERATURE REFERENCES


GLOSSARY OF SYMBOLS

- REP: Catalog number
- T: Temperature limitation
- LOT: Consult instructions for use
- BD: Batch code
- ID: In vitro diagnostic medical device
- BY: Use by
- M: Manufacturer
- CA: Contains sufficient for <x> tests
- N: Do not reuse
- CE: Authorized representative in the European Community
- CM: CE marked according to IVD Medical Devices Directive 98/79/EC

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