



For professional in vitro diagnostic use only.

StrongStep® Candida albicans/Trichomonas vaginalis Antigen Combo Rapid Test is intended for the qualitative detection of *Candida albicans* and/or *Trichomonas vaginalis* antigens from vaginal swabs. This kit is intended to be used as an aid in the diagnosis of *Candida albicans* and/or *Trichomonas vaginalis* infection.

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 (*Trichomonas* and bacterial vaginosis). Symptoms of VVC which include: acute itching, vaginal soreness, irritation, rash on the outer lips of the vagina and genital burning that may increase during urination, are non specific. Clinicians should keep in mind that a broad variety of infectious and noninfectious diseases can cause a similar array of symptoms. To obtain an accurate diagnosis, a thorough evaluation is necessary. In women who complain of vaginal symptoms, the 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 best 50% and thus 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

Trichomonas infection is responsible for the most common, non-viral sexually transmitted disease (vaginosis or trichomoniasis) worldwide. Trichomoniasis is a significant cause of morbidity among all infected patients. Effective diagnosis and treatment of Trichomonas infections have been shown to eliminate symptoms. Conventional identification procedures for Trichomonas from vaginal swabs or vaginal washes involve the isolation and subsequent identification of viable pathogens by wet mount microscopy or by culture, a process that will cost 24 - 120 hours. Wet mount microscopy has a reported sensitivity of 58% versus culture.

StrongStep® *Candida albicans*/*Trichomonas vaginalis* Antigen Combo Rapid Test is an immunochromatographic assay that detects pathogen antigens directly from vaginal swabs. Results are rapid, occurring within approximately 15 minutes.

StrongStep® *Candida albicans*/Trichomonas vaginalis Antigen Combo Rapid Test uses dyed latex immunochromatographic, capillary flow technology. Two strips are contained in each device, one for *Candida albicans* detection while the other one for Trichomonas vaginalis detection.

The test procedure requires the solubilization of *Candida albicans*/*Trichomonas vaginalis* 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(s) and the mixture migrates along the membrane surface. If *Candida albicans*/*Trichomonas vaginalis* is present in the sample, it will form a complex with the primary anti-*Candida albicans*/*Trichomonas vaginalis* antibody conjugated to dyed latex particles (red). The complex will then be bound by a second anti-*Candida albicans*/*Trichomonas vaginalis* antibody coated on the nitrocellulose membrane. The appearance of a visible red test line along with the blue control line will indicate a positive result.

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|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| 20 Individually packed test devices | Two test strips are contained in each device. Each strip contains colored conjugates and reactive reagents precoated at the corresponding regions. |
| 2 Extraction Buffer vial | 0.01 M Phosphate buffered saline (PBS) and 0.02% sodium azide. |
| 1 positive control (on request only) | Contain inactivated <i>Candida albicans</i> and <i>Trichomonas vaginalis</i> . For external control. |

| | |
|-----------------------------------------|-------------------------------------------------------------------------------------------------|
| 1 negative control (on request only) | Not contain <i>Candida albicans</i> and <i>Trichomonas vaginalis</i> . For external control. |
| 20 Extraction tubes | For specimens preparation use. |
| 1 Workstation | Place for holding buffer vials and tubes. |
| 1 Package insert | For operation instruction. |

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|-------|-----------------|
| Timer | For timing use. |
|-------|-----------------|

- 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 reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.

- Humidity and temperature can adversely affect results.
- When the assay procedure is completed, dispose the swabs carefully after autoclaving them at 121°C for at least 20 minutes. Alternatively, they can be treated with 0.5% sodium hypochloride (or house-hold bleach) for one hour before disposal. The used testing materials should be discarded in accordance with local, state and/or federal regulations.
- **Do not use cytology brushes with pregnant patients.**

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.

- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

Use only Dacron or Rayon tipped sterile swabs with plastic shafts. It is recommended to use the swab supplied by the kit manufacturer (The swabs are not contained in this kit, for the ordering information, please contact the manufacturer or local distributor, the catalog numbers are 207000-female swab, 208000-male swab). Use the swab provided with the kit. Swabs from other suppliers have not been validated. Swabs with cotton tips or wooden shafts are not recommended.

- Insert the swab into the inside of the vagina, and rotate for 20sec. 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 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 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 month 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*® Test, separate swabs must be collected because the sample buffer will kill *Candida albicans*/*Trichomonas vaginalis* organisms.

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 to 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 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 pinching 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 a cap onto 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 performed within one hour.
 - Add 3 drops (approximately 100 µl) of extracted sample from the extraction tube to each sample well on the test cassette.
- Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in 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 15 minutes. Do not interpret the result after 20 minutes.

Discard used test tubes and Test Cassettes in suitable biohazardous waste container.

StrongStep®
Candida

C T

Trichomonas

StrongStep®
Candida

C T

Trichomonas

Candida negative(-)
Trichomonas negative(-)

Candida positive(+)
Trichomonas positive(+)



Candida positive(+)
Trichomonas negative(-)

Candida negative(-)
Trichomonas positive(+)

Note: Control band fails to appear should be regarded as **invalid** results.

- NOTE:**
- 1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. But the substances level can not be determined by this qualitative test.
 - 2. Insufficient specimen volume, incorrect operation procedure, 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 an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External procedural controls may be provided(on request only) in the kits 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/Trichomonas vaginalis Antigen Combo Rapid Test is only for the qualitative detection of Candida albicans and/or Trichomonas vaginalis 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/Trichomonas vaginalis Antigen Combo 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. Candida albicans test does not differentiate between individuals that are carriers and individuals that have an acute infection.
- 6. Patients with vaginitis/vaginosis symptoms may have mixed infections. Therefore a test indicating the presence of Candida albicans/Trichomonas vaginalis does not rule out the presence of Bacterial vaginosis (This can also be diagnosed by LimingBio’s another product:500080 Bacterial vaginosis rapid test).
- 7. 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 /Trichomonas vaginalis antigen combo rapid test may warrant additional patient follow up.

- 8. 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: 500010 Chlamydia trachomatis antigen rapid test; 500020 Neisseria gonorrhoeae antigen rapid test; 500050 Neisseria gonorrhoeae and Chlamydia trachomatis antigen combo rapid test).
- 9. Samples contaminated with preparations containing iodine or by the immediate prior use of vaginal lubricants are not recommended.

PERFORMANCE CHARACTERISTICS

Table1: *StrongStep*® Candida albicans Rapid Test vs. Culture

| | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|---|---------|-----|-------|
| Relative Sensitivity: 87.3% (83.5%–90.6%)* Relative Specificity: 99.3% (98.3%–99.8%)* Overall Agreement: 95.0% (93.5%–96.3%)* *95% Confidence Interval | | | Culture | | |
| | | | + | - | Total |
| | StrongStep® Candida Test | + | 324 | 5 | 329 |
| | | - | 47 | 671 | 718 |
| | | | 371 | 676 | 1047 |

Table2: *StrongStep*® Trichomonas vaginalis Rapid Test vs. Culture

| | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|---|---------|-----|-------|
| Relative Sensitivity: 93.6% (89.3%-96.6%)* Relative Specificity: 99.2% (98.3%-99.7%)* Overall Agreement: 98.1% (97.1%-98.8%)* *95% Confidence Interval | | | Culture | | |
| | | | + | - | Total |
| | StrongStep® Trichomonas Test | + | 190 | 7 | 197 |
| | | - | 13 | 837 | 850 |
| | | | 203 | 844 | 1047 |

Analytical Sensitivity:1*10⁵CFU/ml Candida albicans (ATCC 5314 strain).
NOTE: Since *StrongStep*® Trichomonas vaginalis antigen test detects the trichomonal secretion proteins which expressed very little in typical culture environment, it may show negative results when test with cultured Trichomonas vaginalis.

Analytical Specificity: Cross-reactivity with other organisms has been studied using suspensions of 10⁷ CFU/ml. The following organisms were not detected using the test.

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|------------------------------------|-----------------------------|
| <i>Acinetobacter calcoaceticus</i> | <i>Proteus vulgaris</i> |
| <i>Salmonella typhi</i> | <i>Acinetobacter spp.</i> |
| <i>Staphylococcus aureus</i> | <i>Neisseria gonorrhoea</i> |
| <i>Neisseria catarrhalis</i> | <i>Neiiseria lactamica</i> |

| | |
|-------------------------------|--------------------------------|
| <i>Neisseria meningitidis</i> | <i>Gardnerella vaginalis</i> |
| <i>Escherichia coli</i> | <i>Streptococcus faecium</i> |
| <i>Streptococcus faecalis</i> | <i>Chlamydia trachomatis</i> |
| <i>Pseudomonas aeruginosa</i> | <i>Mycoplasma hominis</i> |
| <i>Ureaplasma Urealyticum</i> | |
| <i>Candida parapsilosis</i> | <i>Candida kefy</i> |
| <i>Candida glabrata</i> | <i>Candida lusitaniae</i> |
| <i>Candida krusei</i> | <i>Cryptococcus neoformans</i> |

C. tropicalis, C. zeylanoides have cross-reactivity with the Candida albicans rapid test over the concentration of 1*10⁷ CFU/ml.

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GLOSSARY OF SYMBOLS

| | |
|--|---------------------------------------------------------------|
| | Catalog number |
| | Temperature limitation |
| | Consult instructions for use |
| | Batch code |
| | In vitro diagnostic medical device |
| | Use by |
| | Manufacturer |
| | Contains sufficient for <n> tests |
| | Do not reuse |
| | Authorized representative in the European Community |
| | CE marked according to IVD Medical Devices Directive 98/79/EC |

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