



LIMING BIO

diagnostics are ASSURED

StrongStep®

Candida Albicans Antigen Rapid Test (Dyed latex immunochromatography)

REF : 500030	Specimen: Swab
Language: English	Version: 02
Effective Date: 2011-12	

For professional in vitro diagnostic use only.

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 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. To obtain an accurate diagnosis, a thorough evaluation is necessary. In 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 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 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 dyed latex immunochromatographic, capillary flow technology. The test procedure requires the solubilization 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	Each device contains a strip with colored conjugates and reactive reagents pre-coated 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 Candida albicans and sodium azide. For external control.
1 Negative control (on request only)	Not contain Candida albicans. 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.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer	For timing use.
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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 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.**

STORAGE AND STABILITY

- 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.

SPECIMEN COLLECTION AND STORAGE

Use only Dacron or Rayon tipped sterile swabs with plastic shafts. It is recommend to use the swab supplied by the kits 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). 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*® 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.



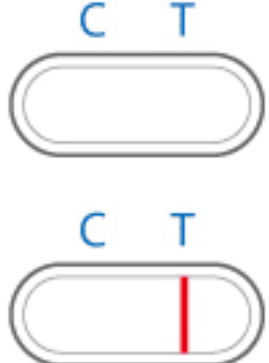
- Place a clean extraction tube in the designated area of the workstation. Add 20 drops of extraction buffer into the extraction tube.
- Put the specimen swab into the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube for at least fifteen times (while submerged). 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 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 the 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 the 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.

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).
INVALID 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:**
- 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.
 - 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 as 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

- 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.
- The performance of the *StrongStep*® Candida albicans Antigen Rapid Test with specimens other than vaginal fluid has not

- been established.
- The results obtained from this kit yield data that must be used only as an adjunct to other information available to the physician.
 - This test does not differentiate between viable and non-viable organisms.
 - This test does not differentiate between individuals that are carriers and individuals that have an acute infection.
 - Patients with vaginitis/vaginosis symptoms may have mixed infections. Therefore a test indicating the presence of Candida vulvovaginitis does not rule out the presence of T. vaginalis or Bacterial vaginosis (These can also be diagnosed by LimingBio's other two products: 500040 Trichomonas vaginalis Antigen Rapid test; 500080 Bacterial Vaginosis Rapid test).
 - 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.
 - Vulvovaginal candidiasis (VVC) may be caused by other candida, such as C.parapsilosis, C.tropicalis, C.glabrata, C.krusei, C.kefyr, C.lusitaniae, C.zeilanoideis etc.. However, *StrongStep*® Candida albicans Antigen Rapid Test only detects the Candida albicans, and has cross-reactivity with C.tropicalis, C.zeilanoideis.
 - 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/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

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		
	StrongStep® Candida Test		+	-	Total
			324	5	329
		-	47	671	718
			371	676	1047

Analytical Sensitivity: 1*10⁵ CFU/ml Candida albicans (ATCC 5314 strain).

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.












<i>Acinetobacter calcoaceticus</i>	<i>Proteus vulgaris</i>
<i>Salmonella typhi</i>	<i>Acinetobacter spp.</i>
<i>Staphylococcus aureus</i>	<i>Trichomonas vaginalis</i>
<i>Neisseria catarrhalis</i>	<i>Neisseria gonorrhoea</i>
<i>Neisseria meningitidis</i>	<i>Neisseria lactamica</i>
<i>Escherichia coli</i>	<i>Gardnerella vaginalis</i>
<i>Streptococcus faecalis</i>	<i>Streptococcus faecium</i>
<i>Pseudomonas aeruginosa</i>	<i>Chlamydia trachomatis</i>
<i>Ureaplasma urealyticum</i>	<i>Mycoplasma hominis</i>
<i>Candida parapsilosis</i>	<i>Candida kefyr</i>
<i>Candida glabrata</i>	<i>Candida lusitaniae</i>
<i>Candida krusei</i>	<i>Cryptococcus neoformans</i>

C. tropicalis, C. zeylanoides have cross-reactivity over the concentration of 1*10⁷ CFU/ml.

LITERATURE REFERENCES

- Egan M.E., Lipski M.S., Diagnosis of Vaginitis,American Family Physician, September 2000, pp 1-14.
- Sobel J.K. et. Al., Volvovaginal candidiasis: Epidemiologic, diagnostic and therapeutic considerations. American Journal of Obstetrics and Gynecology V178(2), 1998.

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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