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StrongStep®

Trichomonas Vaginalis Antigen Rapid Test

(Dyed latex immunochromatography)

REF : 500040 **Specimen:** Swab

Language: English **Version:** 02

Effective Date: 2011-12

For professional in vitro diagnostic use only.

INTENDED USE

StrongStep® Trichomonas Vaginalis Antigen Rapid Test is intended for the qualitative detection of Trichomonas vaginalis ("Trichomonas") antigens from vaginal swabs. This kit is intended to be used as an aid in the diagnosis of Trichomonas infection.

INTRODUCTION

Trichomonas infection is responsible for the most common, non-viral sexually transmitted disease (vaginitis 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. The *StrongStep*® Trichomonas vaginalis Antigen Rapid Test is an immunochromatographic assay that detects pathogen antigens directly from vaginal swabs. Results are rapid, occurring within approximately 15 minutes.

PRINCIPLE

StrongStep® Trichomonas vaginalis Antigen Rapid Test uses dyed latex immunochromatographic, capillary flow technology. The test procedure requires the solubilization of Trichomonas 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 Trichomonas is present in the sample, it will form a complex with the primary anti-Trichomonas antibody conjugated to dyde latex particles (red). The complex will then be bound by a second anti-Trichomonas 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 inactived trichomonas and sodium azide. For external control.
1 Negative control (on request only)	Not contain trichomonas. 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.

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 manufacture 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 *StrongStep*® Trichomonas vaginalis antigen rapid test, separate swabs must be collected because the sample buffer will kill Trichomonas organisms.

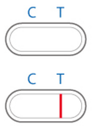
PROCEDURE

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 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 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:

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 as an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External procedural controls may 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*® Trichomonas vaginalis Antigen Rapid Test is only for the qualitative detection of T. vaginalis antigen from vaginal swabs.
2. The performance of *StrongStep*® Trichomonas vaginalis 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. Patients with vaginitis/vaginosis symptoms may have mixed infections. Therefore a test indicating the presence of T. vaginalis does not rule out the presence of Candida vulvovaginitis or Bacterial vaginosis (These can also be diagnosed by LimingBio's other two products: 500030 Candida albicans antigen rapid test; 500080 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*® Trichomonas vaginalis antigen rapid test may warrant additional patient follow up.
7. 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 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).
8. Samples contaminated with preparations containing iodine or by the immediate prior use of vaginal lubricants are not recommended.

PERFORMANCE CHARACTERISTICS

Table: *StrongStep*® Trichomonas vaginalis Antigen Rapid Test vs. Culture

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

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.

Cross-reactivity with other organisms has been studied using suspensions of 10^7 CFU/ml. The following organisms were not detected using the test:

Acinetobacter calcoaceticus	*Proteus vulgaris*
Salmonella typhi	*Acinetobacter spp.*
Staphylococcus aureus	*Candida albicans*
Neisseria catarrhalis	*Neisseria gonorrhoea*
Neisseria meningitidis	*Neiiseria lactamica*
Escherichia coli	*Gardnerella vaginalis*
Streptococcus faecalis	*Streptococcus faecium*
Pseudomonas aeruginosa	*Chlamydia trachomatis*
Ureaplasma Urealyticum	*Mycoplasma hominis*

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GLOSSARY OF SYMBOLS

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

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