Trichomonas Vaginalis Rapid Test Cassette (Vaginal Swab) Package Insert

REF ITV-502	English

A rapid test for the qualitative detection of Trichomonas Vaginalis antigen from vaginal swabs.
For professional in vitro diagnostic use only.

INTENDED USE

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

SUMMARY

Trichomonas Vaginalis is an anaerobic, flagellated protozoan parasite and the causative agent of trichomoniasis. It is the most common pathogenic protozoan infection of humans in industrialized countries.[1] Infection rates between men and women are similar with women being symptomatic, while infections in men are usually asymptomatic. Transmission usually occurs via direct, skin-to-skin contact with an infected individual, most often through vaginal intercourse. The WHO has estimated that 160 million cases of infection are acquired annually worldwide.[2] The estimates for North America alone are between 5 and 8 million new infections each year, with an estimated rate of asymptomatic cases as high as 50%.[3] Usually treatment consists of metronidazole and tinidazole.[4]

PRINCIPLE

The *Trichomonas Vaginalis* Rapid Test Cassette (Vaginal Swab) is a qualitative, membrane based immunoassay for the detection of *Trichomonas Vaginalis* antigens through visual interpretation of color development on the internal strip. *Anti-Trichomonas Vaginalis* antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with *anti-Trichomonas Vaginalis* antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there is sufficient *Trichomonas Vaginalis* antigen 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 *Trichomonas Vaginalis* Rapid Test Cassette (Vaginal Swab) contains *anti- Trichomonas Vaginalis* antibody conjugated gold particles and *anti-Trichomonas Vaginalis* antibody 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 lot numbers.
8. Be sure to add extracted sample to the cassette's sample well. Invalid result may occur if inadequate extracted sample 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 recommend to use the swab supplied by the kits' manufacturer.

- Insert the swab into the inside of the vagina, and rotate for 20 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 may be running immediately. If immediate testing is not possible, the patient sample 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℃. 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.
- To run a culture as well as the *Trichomonas Vaginalis* Test. Separate swabs must be collected because the sample buffer will influence Trichomonas organisms.

MATERIALS

Materials Provided

- Test cassettes
- Extraction buffer
- Package insert
- Extraction tubes
- Extraction tube tips
- Workstation
- Sterile swabs

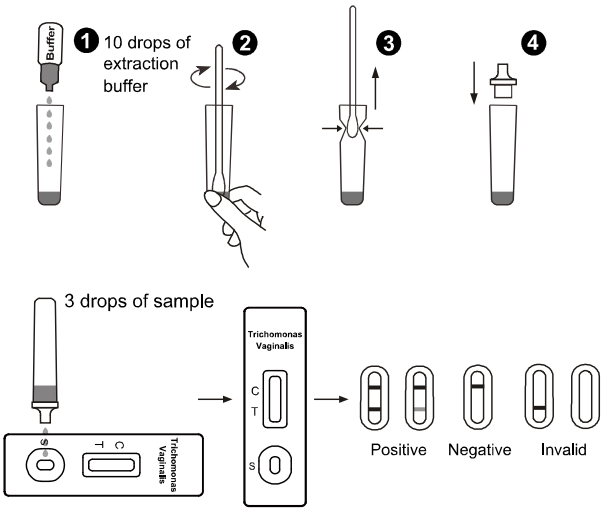
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

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

1. Place a clean extraction tube in the designated area of the workstation. Add **10 drops of extraction buffer** (approx. 560µL) into the extraction tube.
2. Put the specimen swab into the extraction tube, vigorously mix the solution by rotating the swab forcefully against the side of the tube for least 10 times (while submerged). Best results are obtained when the specimen is vigorously mixed in the solution.
3. Allow the swab to soak in the reaction 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 reaction buffer solution must remain in the tube for adequate capillary migration to occur.
4. Discard the swab in a suitable bio-hazardous waste container, 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 of extracted sample** (approx. 100µL) from the extraction tube to the specimen well(S) on the test cassette. Please note avoid trapping air bubbles in the specimen well(S) 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.



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 *Trichomonas Vaginalis* 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 *Trichomonas Vaginalis* antigen 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 *Trichomonas Vaginalis* antigen is not present in the specimen, or is present below the detectable level 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

Internal procedural controls are 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 *Trichomonas Vaginalis* Rapid Test is only for the qualitative detection of T. vaginalis antigen from vaginal swabs.
2. The performance of the *Trichomonas Vaginalis* Antigen Rapid Test with specimens other than vaginal fluid or the saline solution remaining from a wet mount of a vaginal swab 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. 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 may warrant additional patient follow up.
6. Samples contaminated with preparations containing iodine or by the immediate prior use of vaginal lubricants are not recommended.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The performance of the *Trichomonas Vaginalis* Rapid Test Cassette (Vaginal Swab) has been evaluated with 100 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 *Trichomonas Vaginalis* Rapid Test Cassette (Vaginal Swab) is 90.0% and the relative specificity is 96.3%.

***Trichomonas Vaginalis* Rapid Test Cassette vs. Other Rapid Test**

Method		Other Rapid Test		Total Results
	Results	Positive	Negative	
***Trichomonas Vaginalis* Rapid Test Cassette (Vaginal Swab)**	Positive	18	3	21
	Negative	2	77	79
Total Results		20	80	100

Relative Sensitivity: 90.0% (95%CI*: 68.3%~98.8%); *Confidence Intervals
Relative Specificity: 96.3% (95%CI*: 89.4%~>99.2%);
Overall Accuracy: 95.0% (95%CI*: 88.7%~98.4%).

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of four specimens: a negative, low positive, middle positive and high positive. The negative, low positive, middle positive and high positive 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, low positive, middle positive and high positive. Three different lots of the *Trichomonas Vaginalis* Rapid Test cassette (Vaginal Swab) have been tested over a 3-days period using negative, low positive, middle positive and high positive 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 *Trichomonas Vaginalis* Rapid Test Cassette (Vaginal Swab).

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

BIBLIOGRAPHY

1. Soper, D (2004). "Trichomoniasis: under control or undercontrolled?". American Journal of Obstetrics and Gynecology. 190 (1): 281–90.
2. Harp, Djana F.; Chowdhury, Indrajit (2011). "Trichomoniasis: Evaluation to execution". European Journal of Obstetrics & Gynecology and Reproductive Biology. 157 (1): 3–9.
3. Hook, Edward W. (1999). "*Trichomonas Vaginalis*—No Longer a Minor STD". Sexually Transmitted Diseases. 26 (7): 388–9.
4. Jump up^ W Evan Secor. "*Trichomonas Vaginalis*". MedScape.

Index of Symbols

	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/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

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

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