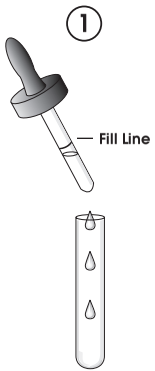
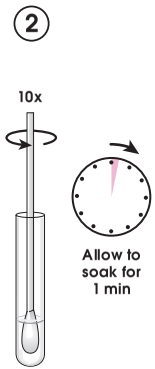
osom® Trichomonas Rapid Test

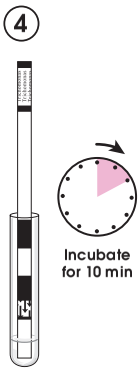


Add Sample Buffer
Fill the dropper to the line indicated on the barrel and expel entire contents into tube.

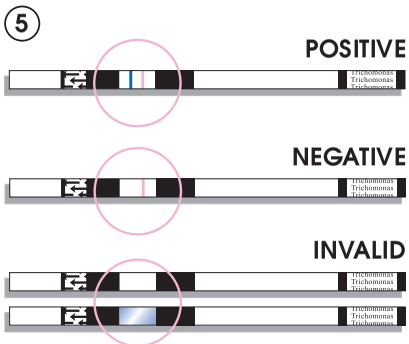


Mix Swab in Buffer
Add swab to tube and mix vigorously (approx. 10 times).

Squeeze Liquid from Swab
Squeeze side of tube to express as much liquid from swab as possible.



Add Test Stick and Incubate
Place absorbent end of test stick into the solution.



- **Positive:** A blue Test Line and a red Control Line.
- **Negative:** A red Control Line but no blue Test Line.
- **Invalid:** If no red Control Line appears or background color makes reading the red Control Line impossible.

QUALITY CONTROL (QC)

Internal Procedural Controls

1. The appearance of the control line in the results window is an internal positive procedural control.
2. The clearing of the background in the results area may be documented as an internal negative procedural control.

External Controls

ASC recommends that positive and negative external controls be run with each new lot and with each new untrained operator. One positive control swab (pink shaft) is included with each kit. For a negative control, run one of the sterile swabs supplied with the kit. Run controls in the same manner as patient swabs.

AmericanScreening™

OSOM®

Trichomonas Rapid Test

CLIA Complexity: Waived

FOR LABORATORY AND PROFESSIONAL USE ONLY

INTENDED USE

The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of *Trichomonas vaginalis* ("Trichomonas") antigens from vaginal swabs or from the saline solution prepared when making wet mounts from vaginal swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the Trichomonas pathogen.

SUMMARY AND EXPLANATION OF TEST

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.[1,2] Effective diagnosis and treatment of Trichomonas infections have been shown to eliminate symptoms.[2] 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,[3] a process that can take 24–120 hours. Wet mount microscopy has a reported sensitivity of 58% versus culture.[4] The OSOM® Trichomonas Rapid Test is an immunochromatographic assay that detects pathogen antigens directly from vaginal swabs. Results are rapid, occurring within approximately 10 minutes.

PRINCIPLE OF TEST

The OSOM® Trichomonas Rapid Test uses color immunochromatographic, capillary flow, "dipstick" technology. The test procedure requires the solubilization of Trichomonas proteins from a vaginal swab by mixing the swab in Sample Buffer. The OSOM® Trichomonas Rapid Test Stick is then placed in the sample mixture 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 colored particles (blue). The complex will then be bound by a second anti-Trichomonas antibody coated on the nitrocellulose membrane. The appearance of a visible blue test line along with the red control line will indicate a positive result.

REAGENTS AND MATERIALS PROVIDED

25 Test Sticks
25 Sterile Swabs
25 Test Tubes
1 Sample Buffer vial, 25 ml (saline buffer with 0.01% sodium azide)
1 Sample Buffer dropper top
1 Positive control swab (contains sodium azide and a desiccant tablet)
1 Workstation
1 Directional Insert
Note: Extra components (swabs, tubes) have been provided for your convenience
Warning: Contains Sodium Azide

MATERIAL REQUIRED BUT NOT PROVIDED

A timer or watch

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow your clinical and/or laboratory safety guidelines in the collecting, handling, storing, and disposing of patient specimens, and all items exposed to patient specimens. Swabs, test tubes, and Test Sticks are for single use only.
- The Sample Buffer contains saline solution with a preservative (sodium azide) and a detergent at low concentrations. If solution comes in contact with the skin or eyes, flush with lots of water.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
- Do not use or mix components from different kit lots.

STORAGE CONDITIONS

- Store Test Sticks and reagents tightly capped at room temperature (15°–30° C).
- Do not freeze.
- Do not use Test Sticks and reagents after expiration date.
- Discard unused Test Sticks that have been removed from the canister after 1 hour.

SPECIMEN COLLECTION AND PREPARATION

- Collect specimens from the vaginal cavity with a sterile rayon swab from the kit.
- Use of the swabs supplied in the kit or BD BBL™ CultureSwab™ (sterile or with Liquid Stuarts Media) is recommended. Swabs from other suppliers have not been validated. Swabs with cotton tips or wooden shafts are not recommended.

- Process the swab as soon as possible after collecting the specimen. Specimens may be held at room temperature for no longer than 24 hours. Swabs may also be stored at 4° C or -20° C for up to 36 hours.
- To transport patient samples place swab in a clean, dry container such as a plastic or glass tube.
- The solution remaining in the test tube used for the wet mount may also be used as the sample for the OSOM® test. **To use this sample type, soak a new kit swab in this solution. Using this swab, perform the complete test procedure detailed below.** There must be enough solution left after the wet mount to soak the new swab completely. These saline specimens may be held at room temperature for no longer than 24 hours. These specimens may also be stored at 4° C or -20° C for up to 36 hours.
- To run a culture as well as the OSOM® Test, separate swabs must be collected because the Sample Buffer will kill Trichomonas organisms.

QUALITY CONTROL (QC)

The OSOM® Trichomonas Rapid Test provides two methods of control for the assay: internal controls to aid in determining test validity, and external controls to demonstrate proper test function.

Internal Procedural Controls

Several controls are incorporated into each Test Stick for routine quality checks.

1. The appearance of the control line in the results window is an internal positive procedural control. **Test System:** The appearance of the control line assures that adequate sample volume was present. It also assures that adequate capillary migration of the sample has occurred and verifies proper assembly of the Test Stick.
   Operator: The appearance of the control line indicates that enough sample volume was present for capillary flow to occur. If the control line does not appear at the read time, the test is invalid.
2. The clearing of the background in the results area may be documented as an internal negative procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light grey and not interfere with the reading of the test. The test is invalid if the background fails to clear and hides the appearance of a distinct control line.
   If the background color does not clear and interferes with the test result, the test may be invalid.

External Quality Control Testing

OSOM® Test kits include a Positive Control Swab for external quality control testing. Kit swabs may be used as negative controls. Additional Positive Control Swabs may be purchased separately. The Trichomonas Positive Control Kit is catalog number 182. Use the Controls to ensure that the Test Sticks are functioning properly. Also, the Controls may be used to demonstrate proper performance by the test operator. Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, ASC recommends that positive and negative external controls be run with each new lot, and with each new untrained operator.

QC Testing Procedures

The Positive Control Swab is impregnated with sufficient Trichomonas antigen to produce a visible positive test result. 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.

EXPECTED RESULTS

Studies have shown that the incidence of Trichomonas infections by culture in women presenting to STD clinics is between 8–37%.[1,2] In a clinical trial involving the OSOM® Trichomonas Rapid Test at seven sites, including STD clinics, hospital emergency departments, and public health clinics, the prevalence of Trichomonas Infections detected by culture or wet mount ranged from 13% to 29%. Up to 50% of women infected with Trichomonas may not be aware of symptomology. The highest incidence of this disease is found in women with at-risk factors that predispose them to acquiring sexually transmitted diseases. Trichomoniasis also has a high likelihood of co-infection with other STDs, including those that also result in symptoms of vaginitis.

LIMITATIONS OF THE PROCEDURE

- The OSOM® Trichomonas Rapid Test is only for the qualitative detection of *T. vaginalis* antigen from vaginal swabs and the saline solution remaining from a wet mount of a vaginal swab.
- The performance of the OSOM® Trichomonas 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.
- The results obtained with 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 *T. vaginalis* does not rule out the presence of Candida vulvovaginitis or Bacterial vaginosis.
- 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 OSOM® Trichomonas Rapid Test result may warrant additional patient follow up.
- Women with vaginal discharge should be evaluated for risk factors of cervicitis and pelvic inflammatory disease and for other organisms including *Neisseria gonorroeae* and *Chlamydia trachomatis*.
- Samples contaminated with preparations containing iodine or by the immediate prior use of vaginal lubricants are not recommended.
- *Staphylococcus aureus* in specimens at concentrations higher than $1x10^8$ organisms per mL may interfere with the test results in negative samples. These concentrations of *S. aureus* are higher than would be expected to be present in normal patient samples.[5]

PERFORMANCE CHARACTERISTICS

Vaginal samples were collected from a total of 449 consenting adult patients presenting to one of seven adult health centers. The specimens were tested for Trichomonas by wet mount microscopy, culture (InPouch™ TV BioMed Diagnostics, Inc., San Jose, CA) and the OSOM® Trichomonas Rapid Test.

Diagnostic Sensitivity and Specificity—Versus Wet Mount Microscopy Standard Analysis

The performance of the OSOM® Trichomonas Rapid Test was determined using the accepted calculations for comparative sensitivity and specificity against the results from wet mount microscopy.[6] The results from this analysis (with 95% confidence intervals in parenthesis) are summarized in Table 1.

Table 1
COMPARISON OF OSOM® TRICHOMONAS RAPID TEST TO WET MOUNT MICROSCOPY

		Wet Mount Microscopy		
		+	-	Total
OSOM® Trichomonas Rapid Test (vaginal swab)	+	69	20*	89
	-	3	345	348
	Total	72	365	437

Sensitivity: 69/72 = 96% (95% CI, 91–100%)
Specificity: 345/365 = 95% (95% CI, 92–97%)
Agreement: 414/437 = 95% (95% CI, 93–97%)

*Of the 20 samples negative by wet mount 16 were positive by culture - 4 were negative.

Diagnostic Sensitivity and Specificity—Composite Reference Standard Analysis

The relative insensitivity of wet mount microscopy versus culture has been reported in the literature.[4] Therefore, the performance of the OSOM® Trichomonas Rapid Test was analyzed using a composite reference standard (CRS)[7] calculation, which includes the results from wet mount microscopy and culture (InPouch™ TV, BioMed Diagnostics, Inc., San Jose, CA). In this analysis, any sample with a positive result from either wet mount or culture was defined as positive. Accordingly, samples that were negative in both wet mount and culture tests were defined as negative. The results of the comparison of the OSOM® Trichomonas Rapid Test using a standard vaginal swab sample to the CRS are shown in Table 2; 95% confidence intervals in parenthesis.

The results of the comparison of the OSOM® Trichomonas Rapid Test using the saline remaining from a wet mount sample are shown in Table 3. The comparative sensitivity of each method to the CRS is shown in Table 4.

Table 2
COMPARISON OF OSOM® TRICHOMONAS RAPID TEST TO COMPOSITE REFERENCE STANDARD

		Composite Reference Standard		
		+	-	Total
OSOM® Trichomonas Rapid Test (vaginal swab)	+	85	4*	89
	-	17	331	348
	Total	102	335	437

Sensitivity: 85/102 = 83% (95% CI, 76–91%)
Specificity: 331/335 = 99% (95% CI, 98–100%)
Agreement: 416/437 = 95% (95% CI, 93–97%)

*Of the 20 samples negative by wet mount 16 were positive by culture - 4 were negative.

Table 3
COMPARISON OF OSOM® TRICHOMONAS RAPID TEST SALINE FROM WET MOUNT SAMPLE TO COMPOSITE REFERENCE STANDARD

		Composite Reference Standard		
		+	-	Total
OSOM® Trichomonas Rapid Test (saline from wet mount)	+	79	5	84
	-	26	337	363
	Total	105	342	447

Sensitivity: 79/105 = 75% (95% CI, 67–84%)
Specificity: 337/342 = 99% (95% CI, 97–100%)
Agreement: 416/447 = 93% (95% CI, 91–95%)

Table 4
SENSITIVITY OF EACH METHOD VERSUS COMPOSITE REFERENCE STANDARD

Method	**Sensitivity**
OSOM® Trichomonas Rapid Test (vaginal swab)	83%
OSOM® Trichomonas Rapid Test (saline from wet mount)	75%
Wet Mount Microscopy	71%
Culture (InPouch™ TV)	99%

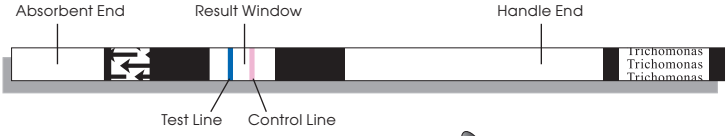
POL Studies
An evaluation of the OSOM® Trichomonas Rapid Test was conducted at four physician offices. Each site tested a randomly coded panel of negative (6), low positive (3), and high positive samples (3). Three operators at each site ran all 12 samples, which produced the following results:

Sample	Agreement	
Negative	100%	(95% CI, 95–100%)
Low	97%	(95% CI, 85–100%)
High	100%	(95% CI, 90–100%)

Assay Reproducibility
Intra-assay and inter-assay reproducibility studies demonstrated 100% agreement with expected results. Testing was performed by two operators, on three lots of OSOM® Trichomonas Rapid Test kits, using laboratory preparations of high positive, low positive and negative *T. vaginalis* samples. For intra-assay reproducibility each sample was tested twenty times within one run. For inter-assay reproducibility samples were tested in duplicate, two runs per day, over five consecutive days.

Analytical Sensitivity
The OSOM® Trichomonas Rapid Test detected antigen derived from as few as 2500 organisms per mL, a concentration lower than that expected in the vaginal discharge of most positive patients.[8] For these studies the analytical sensitivity of three representative lots of the OSOM® Trichomonas Rapid Test was determined using antigen prepared from cultured *T. vaginalis* organisms.

TEST PROCEDURE



When opening kit for the first time, unscrew the cap from the Sample Buffer bottle and replace it with the dropper top included in the kit. Discard the original Sample Buffer cap.

STEP 1: ADD SAMPLE BUFFER
Using the supplied dropper top, add 0.5 mL of Sample Buffer to each test tube. Fill the dropper to the line indicated on the barrel of the dropper top and expel entire contents into tube. **Note: Add Sample Buffer to the tube before putting in the specimen swab to prevent contaminating the Sample Buffer vial.**

STEP 2: MIX SWAB IN BUFFER
Put the specimen swab into the tube.

Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least ten times (while submerged). Best results are obtained when the specimen is vigorously mixed in the solution.

Allow the swab to soak in the Sample Buffer for one minute prior to Step 3.

STEP 3: SQUEEZE LIQUID FROM SWAB
Squeeze out as much liquid as possible from the swab by pinching the side of the flexible test tube as the swab is removed. At least ¼" of Sample Buffer solution must remain in the tube for adequate capillary migration to occur.

Discard the swab in a suitable biohazardous waste container.

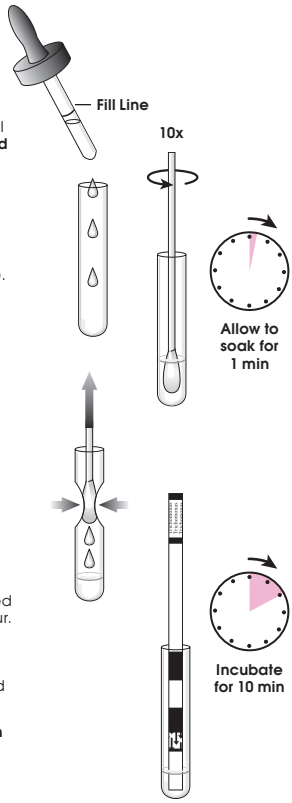
STEP 4: ADD TEST STICK AND INCUBATE
Remove the OSOM® Test Stick from the canister package. Recap the canister immediately.

Place the absorbent end (indicated with arrows, see picture) of the Test Stick into the Sample Buffer solution in the tube. Unused sticks removed from the canister should be discarded after 1 hour.

STEP 5: READ RESULTS
Read results at 10 minutes (some positive results may be seen earlier). See interpretation of results section. Test is invalid beyond the stated read time.

Note: To see the Result Window clearly, remove the Test Stick from the test tube while reading results.

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



Analytical Specificity
The OSOM® Trichomonas Rapid Test has been shown to be non-reactive with normal vaginal flora and infectious agents (including *Gardnerella vaginalis* and Candida species).

Positive and negative control samples were tested against the following potential interferents with no affect on the performance of the OSOM® Trichomonas Rapid test:

Organisms

Bacteriodes merdae	*Gardnerella vaginalis*	*Mobuluncus curtsii*	*Shigella flexneri*
Candida albicans	*Tritrichomonas foetus*	*Monella choleraesuis*	*Staphylococcus aureus*
Chlamydia trachomatis	*Neisseria gonorrhoeae*	*Salmonella typhimurium*	*Streptococcus agalactiae*
Escherichia coli			

T. foetus, C. trachomatis, and *C. albicans* samples tested at approximately 0.5×10^5. All other samples tested at approximately 1×10^6 organisms/mL. *Staphylococcus aureus* in specimens at concentrations higher than 1×10^8 organisms per mL may interfere with the test results in negative samples. These concentrations of *S. Aureus* are higher than would be expected to be present in normal patient samples.[5]

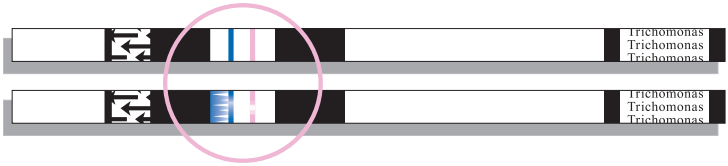
Other Substances

Condoms, with spermicide	HeLa cells	Human blood	Vaginal yeast treatment
Douche (vinegar)	HVEC cells	TYM Culture Medium	(Monistat® brand)

Samples contaminated with preparations containing douche medicated with iodine may interfere with negative samples (please refer to Limitations section).

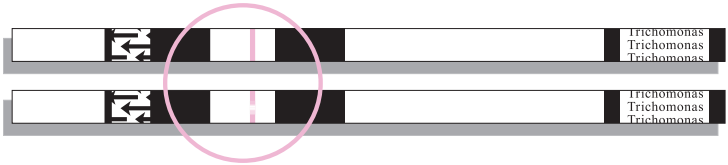
INTERPRETATION OF TEST RESULTS
The appearance of a red Control Line, with or without a blue Test Line, indicates a valid result. A blue or red line that appears uneven in color shading is still considered a valid line. In cases of moderate or high positive specimens, some color behind the Test Line may be seen. As long as the Test Line and the Control Line are visible, the results are valid.

Positive



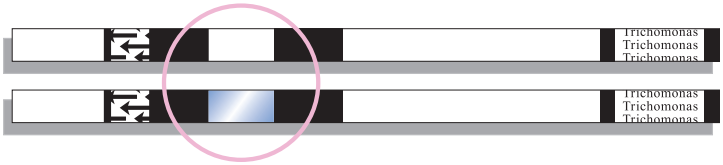
A blue Test Line and a red Control Line is a positive result for the detection of Trichomonas antigen. **Note that the red and blue lines can be any shade of that color and can be lighter or darker than the line in the picture.**

Negative



A red Control Line but no blue Test Line is a presumptive negative result. A negative result means that no Trichomonas antigen was detected, or that the level of the antigen in the sample was below the detection limit of the assay.

Invalid



If no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test on a new Test Stick or contact ASC Technical Assistance.

REFERENCES

1. Cates, W., Estimates of the incidence and prevalence of sexually transmitted diseases in the United States, *Sex Transm Dis 26*: S2–S7, 1999.
2. World Health Organization, An overview of selected curable sexually transmitted diseases, pp. 2–27, in *Global Program on AIDS*, Geneva, Switzerland, World Health Organization, 1995.
3. Ohlemeyer, C., Homberger, L., Lynch, D. and Swierkosz, E., Diagnosis of Trichomonas vaginalis in adolescent females: InPouch™ TV culture versus wet-mount microscopy, *J Adolesc Health,* 22:205–208, 1998.
4. Wiese, W., Patel, S.R., Patel, S.C., Ohl, C., and Estrada, C., A meta-analysis of the Papanicolaou smear and wet mount for the diagnosis of vaginal trichomoniasis, *Am J Med*,108:301–8, 2000.
5. Hochwalt, A., Berg, R., Meyer, S., and Eusebio, R. Site-specific prevalence and cell densities of selected microbes in the lower reproductive tract of menstruating tampon users, *Infect Dis Obstet Gynecol,* 10:141–151, 2002.
6. Galen, R. and Gambino, S., *Beyond Normality: The Predictive Value and Efficiency of Medical Diagnoses*, New York, John Wiley & Sons, 1975.
7. Alonzo, T. & Pepe M., Using a Combination of Reference Tests to Assess the Accuracy of a New Diagnostic Test, *Statistics in Medicine,* 18: 2987–3003, 1999.
8. Philip, A., Carter-Scott, P., and Rogers, C., An Agar Culture Technique to Quantitate *Trichomonas vaginalis* from Women, *J Infect Dis* 155:304, 1987.

ASSISTANCE

For technical assistance, call ASC Technical Assistance at 318-798-3306 .

AmericanScreening
9742 St. Vincent AVE
Suite 100
Shreveport, LA 71106
1-318-798-3306

EC REP Ltd

EC REP

5 Fitzwilliam Square East
Dublin 2, Ireland
Tel: +353 1 2 544 944
Info@ecrep.ie
www.ecrep.ie

KEY TO COMPONENT LABELING


Use by YYYY-MM

Batch code

Catalog number

Contents sufficient for <n> tests

In vitro diagnostic medical device


Temperature limitation


Manufacturer/Manufactured by

Consult instructions for use

Authorized representative
in the European Community

Caution, consult accompanying
documents.