**MICRO.KIT.11.0 TRICHOMONAS RAPID TEST**

# PRINCIPLE

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 or by culture, a process that can take 24-120 hours. Wet mount microscopy has a reported sensitivity of 58% versus culture. The OSOM® Trichomonas Rapid Test is an immunochromatographic assay that detects pathogen antigens directly from vaginal swabs in a decreased turnaround time.

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.

# OWNERS

Supervisor, Regional Microbiology

Microbiology Best Practice Team

# RELATED DOCUMENTS

MICRO.KIT.1.1 BV and TRICH Log

QA.QC.1.1 External QC Log Sheet

# SPECIMEN

**NOTE:** Specimens should be processed as soon as possible after collection. A separate swab must be used if a culture is requested.

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| Vaginal swabs   | Dacron or rayon tipped swab transported in sterile tube with no preservatives or swab in red-capped Liquid Stuarts culturette. Swabs in saline are unacceptable. (Cotton swabs and wooden shafts are unacceptable.)  |
|  Storage requirement  | If:  | Then:  |
| < 24 hours  | Room temperature (15-30ºC)  |
| >24 - 36 hours  | Refrigerate (2º-8°C) or Freeze (-20ºC)  |

# REAGENTS

Store Test Sticks and reagents tightly capped at room temperature (15-30ºC) until the expiration date on the test kit box. Do not freeze. Discard unused Test Sticks that have been removed from the canister after one hour.

1. OSOM® Trichomonas Rapid Test Sticks
2. Sterile Swabs (cotton and wooden shaft unacceptable)
3. Test Tubes
4. Sample Buffer (25 mL saline with 0.01 sodium azide)
5. Positive Control Swab (contains sodium azide)

**Note:** The Sample Buffer contains a 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 ample volumes of water. Solutions that contain sodium azide may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded solutions down a sink.

# QUALITY CONTROL

1. Parallel testing of New Lots is performed and documented prior to the release of the lots to the Network Laboratories. All tested lots are marked with a yellow sticker.
2. External QC must be performed with each New Lot or New Shipment, whichever is most frequent.
3. External QC may be performed at the discretion of the technologist.

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| --- | --- |
| **Step**  | **Action**  |
|  1.  | Add 0.5 mL of Sample Buffer to two tubes, labeled positive and negative. (0.5 mL fill line is indicated on the barrel of the dropper top.) **Note:** Add Sample Buffer to the tubes before putting in the swabs to prevent contaminating the Sample Buffer vial.   |
|  2.  | Place the Positive Control Swab (provided in kit) and a Negative Control Swab (sterile rayon swab supplied with kit) in the appropriately labeled tube.   |
|  3.  | Continue with Test Procedure Step 2.   |

1. Internal QC (test system and procedural controls; evaluated and recorded by Hospital-based Labs on each performed test).

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| Positive Control  | Appearance of a red control band in the result area.   |
| Negative Control  | A clear to light grey background in the result area.   |

# PROCEDURE

**NOTE:** Test performed by the Hospital-based Labs (Misys only)

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| **Step**  | **Action**  |
| 1.  | Using the supplied dropper top, add 0.5 mL of Sample Buffer to each test tube (0.5 mL fill line is indicated on the barrel of the dropper top.) **Note:** Add Sample Buffer to the tube before putting in the specimen swab to prevent contaminating the Sample Buffer vial.   |
| 2.  | 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 mixing again.   |
| 3.  | Express as much liquid as possible from the swab by squeezing the side of the flexible test tube as the swab is withdrawn. At least 0.3 mL of Sample Buffer solution must remain in the tube for adequate capillary migration to occur. Discard the swab in a biohazardous waste container.   |
| 4.  | Remove the Trichomonas Rapid Test Stick from the canister package. Recap the canister immediately. Place the absorbent end (indicated with arrows) of the Test Stick into the Sample Buffer solution in the tube. Unused sticks removed from the canister should be discarded after 1 hour.   |
| 5.  | Read results at 10 minutes (some positive results may be seen earlier). Test is invalid beyond the stated read time. Interpret results following the criteria in Interpretation Of Results (below).   |

# INTERPRETATION OF RESULTS

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| --- | --- |
| Reaction:  | Result:  |
| The appearance of a blue Test Line and a red Control Line in the result area. (The lines can be any shade or intensity of that color.)   | Positive  |
| A red Control Line is visible in the result area. No blue Test Line is visible in the result area.   | Negative  |
| No red Control Line is visible in the result area.  | Invalid (repeat test)  |

# REPORTING RESULTS

POS: Positive

NEG: Negative—A negative result does not exclude the possibility of infection. Diagnosis on Misys should be made in conjunction with clinical symptoms.

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| **IF**  | **THEN**  |  |
| Result is negative  | a.  | Function MEM  |
|  | b.  | <Enter> to worksheet prompt.  |
|  | c.  | At worksheet prompt, type site specific worksheet.  |
|  | d.  | <Enter> to accession prompt. Type accession number, and <enter>.  |
|  | e.  | Type NEG at the TRR prompt, <enter>, and accept.  |
| Result is positive  | a.  | Function MEM  |
|  | b.  | <Enter> to worksheet prompt.  |
|  | c.  | At worksheet prompt, type site specific worksheet.  |
|  | d.  | <Enter> to accession prompt. Type accession number, and <enter>.  |
|  | e.  | Type POS at the TRR prompt, <enter>, and accept.  |
| BVTRS (Bacterial Vaginosis and Trichomonas Screen) is requested  | a. b. c. d.  | Function MEM <Enter> to worksheet prompt. At worksheet prompt, type site specific worksheet. <Enter> to accession prompt. Type accession number, and <enter>.  |
|  | e.  | Type appropriate response, POS or NEG, at each test prompt, <enter>, and accept.  |

# LIMITATIONS

1. The OSOM® Trichomonas Rapid Test is only for the qualitative detection of *T. vaginalis* antigen from vaginal swabs.

1. The performance of the OSOM® Trichomonas Rapid Test with specimens other than vaginal fluid has not been established.

1. The results obtained with this kit yield data that must be used only as an adjunct to other information available to the physician.

1. This test does not differentiate between viable and non-viable organisms.

1. This test does not differentiate between individuals that are carriers and individuals that have an acute infection.

1. 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 vulvo-vaginitis or Bacterial vaginosis.

1. 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.

1. 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.*

1. Samples contaminated with preparations containing iodine or by the immediate or prior use of vaginal lubricants are not recommended.

1. *Staphylococcus aureus* in specimens at concentrations higher than 1 x 108 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.

# REFERENCES

A. Package insert for the OSOM® Trichomonas Rapid Test, April, 2005.