Breaking Down Barriers to STI Testing & Treatment

CSC C RAPID TEST

MILLION CASES OF **CHLAMYDIA** MILLION CASES OF **TRICHOMONAS** MILLION CASES OF **GONORRHEA** MILLION CASES OF **SYPHILIS**

448 MILLION NEW CURABLE STIS EACH YEAR

Trichomoniasis:Under diagnosed and under treated?

TRICHOMONAS VAGINALIS is estimated to be the most common, curable, non-viral sexually transmitted infection.² It is a motile parasite, approximately the size of a white blood cell, and is estimated to cause 20% of vaginitis complaints. Historically thought of as a nuisance infection, it can have serious health implications and has been largely under diagnosed and under treated.

WHAT THE EXPERTS ARE SAYING

"Wet mount alone is insufficient for the reliable diagnosis of TV infection in women." 3

"Syndromic management according to the vaginal discharge algorithm would lead to substantial under-diagnosis and over-treatment of Trichomonas vaginalis."4

"Increased vaginal and endocervical inflammation in women and urethral inflammation in men with Trichomoniasis likely contributes to enhanced HIV transmission." ⁵

DIAGNOSTIC CHALLENGES

There are a number of diagnostic options available. However, choices may have to be made in terms of:



GA ACCURACY

Patient receives correct diagnosis



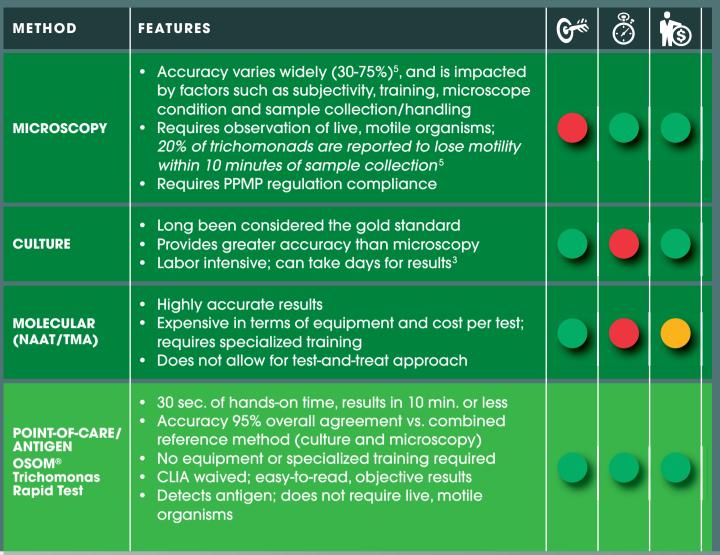
TIME

Patient receives correct diagnosis in a timely manner



COST

Diagnosis is obtained cost-effectively and affordably





WHY IS POINT-OF-CARE ANTIGEN TESTING IMPORTANT? RESULTS WHILE THE PATIENT WAITS—A PATH TO BETTER PATIENT CARE

"Rapid antigen testing is equivalent to culture, and it compares favorably with the sensitivity of TMA for the detection of TV."3

"The OSOM® Trichomonas Rapid Test will be an important addition to the repertoire of techniques available for T. vaginalis detection, especially for facilities without access to a microscope or incubator and in settings where difficult patient follow-up makes point-of-care testing attractive."2

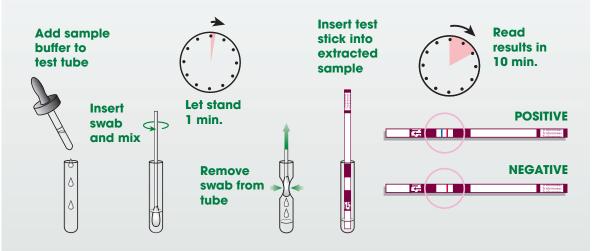
"The OSOM® Trichomonas Rapid Test is a simple, objective test that can be expected to improve the diagnosis of T. vaginalis, especially where culture and PCR are unavailable."8

"The decreased hands-on time of performing the OSOM® test significantly decreased the amount of labor devoted to microscopy. The projected labor savings can be utilized to perform other laboratory procedures." 18

OSOM® Trichomonas Rapid Test Procedure



Visit www.osomtraining.com for online multilingual product training.



ORDER	CONFIGURATION	CATALOG #
OSOM® TRICHOMONAS RAPID TEST KIT	25 TESTS	181
OSOM® TRICHOMONAS POSITIVE CONTROL KIT	10 SWABS	182 (CE MARKED)
OSOM® VAGINITIS SWAB TRANSPORT SYSTEM	50 SWAB SETS	185

In a recent independent study, the sensitivity and specificity were 100% and 99.6% for the OSOM® test when compared to culture.

In the same study, when using NAAT as the reference standard, the sensitivity was 95.5%. ¹⁷

The ability of the **OSOM® Trichomonas Rapid Test** to accurately, quickly and cost effectively detect Trichomonas offers significant benefits to the patient and clinician alike:

- Begin immediate and proper treatment
 - Avoid misuse of unnecessary antibiotics
- Provide opportunity for appropriate sexual health education during the visit
- Help prevent further spread of Trichomonas and reduce associated health risks



PRETERM LABOR & BIRTH®

INCEDTILITY 12.13

INCREASED RISK OF HIV/HSV^{6,10,11}

PELVIC INFLAMMATORY DISEASE 14

CERVICAL CANCER 15

PROSTATE CANCER IN MEN¹⁶

ONLINE TRAINING

View a simple animation of the test procedure, take a quiz, and print your personalized training certificate online, anytime. To get started, visit www.osomtraining.com. May be used for:

- New operators
- Validating a new test
- Refresher training



Highly-trained Technical Service Specialists, all medical technologists with clinical laboratory backgrounds, are available to assist you with:

- Concerns or questions about any of our products
- Assay use, adoption and staff training
- Record keeping, regulations, and reimbursement
- Evaluation of new methods: remote or onsite assay verification program







REFERENCES

- Prevalence and Incidence of Selected Sexually Transmitted Infections, World Health Organization 2011 Huppert JS, Batteiger BE, Braslins P, Feldman JA, Hobbs MM, Sankey HZ, Sena AC and Wendel KA. Use of an Immunochromatolographic Assay for Rapial Detection of *Trichomonas vaginalis* in Vaginal Specimens. Journal of Clinical Microbiology 2005; 43 (2): 684-687 Huppert, Jill S., Joel E. Mortensen, Jennifer L. Reed, Jessica A. Kahn, Kimberty D. Rich, William C. Miller, and Marcia M. Hobbs. "Rapid Antigen Testing Compares Favorably with Transcription Mediated Amplification Assay for the Detection of in Young Women." *Clinical Infectious Diseases* 45.2 (2007): 194-98 Romoren, Maria, M. Velauthapillal, M. Rahman, J. Sundby, E. Klouman, and P. Hjortdohl. "Trichomoniais and Resteid Vaginasis in Prepanary." *Pulletin act the World*.
- Romoren, Maria, M. Velautinapillai, M. Rahman, J. Sundby, E. Klouman, and P. Hjortdall. "Inchomoniasis and Bacterial Vaginosis in Pregnancy: Inadequately Managed with the Syndromic Approach." *Bulletin of the World Health Organization* 85.4 (2007): 297-304

 Hobbs, M. M., D. M. Lapple, L. F. Lawing, J. R. Schwebke, M. S. Cohen, H. Swygard, J. Atashili, P. A. Leone, W. C. Miller, and A. C. Sena. "Methods for Detection of Trichomonas Vaginalis in the Male Partners of Infected Women: Implications for Control of Trichomoniasis." Journal of Clinical Microbiology 44,11 (2006): 3994-999
- Schwebke, Jane R.; Trichomoniasis care today: A clinician's guide to timely diagnosis and successful treatment,
- Swygard H, Sena AC, Hobbs MM, Cohen MS: Trichomoniasis: clinical manifestations, diagnosis and management Sexually Transmitted Infections 2004, 91-5
- Zaki, Mayssa M., Hanaa M.E. Moussa, and Omayma M. Hassanin. "Evaluation of the OSOM Trichomonas Rapid Test for Detection of Trichomoniasis." PUJ 4.2 (2011): 177-84
- Wendel KA. Trichomonicsis: What's New? Current Infectious Disease Reports 2003;5;129-34
 Chesson, HW, et al; Estimates of the Annual Number and Cost of New HIV Infections Among Women Attributable to Trichomoniasis in the US, SexTransDiseases, Vol. 31, No. 9, Sep 2004, 547-551

 11. Gottlieb SL, Douglas JM Jr, Foster M, Schmid DS, Newman DR, Baron AE, Bolan G, latesta M, Malotte CK, Zenilman
- J, Fishbein M, Peterman TA, Kamb ML; Project RESPECT Study Group. Incidence of herpes simplex virus type 2 infection in 5 sexually transmitted disease (STD) clinics and the effect of HIV/STD risk-reduction counseling. J Infect Dis. 2004 Sep 15;190(6):1059-67. Epub 2004 Aug 5

 12. Sherman KJ, Daling JR, Weiss NS. Sexually transmitted diseases and tubal infertility. Sex Transm Dis. 1987
- Jan-Mar;14(1):12-6
- 13. Grodstein F. Goldman MB. Cramer DW. Relation of tubal infertility to history of sexually transmitted diseases. Am J
- Godsteil F, Godarda Mar 1; 137(5):577-84
 Moodley P, Wilkinson D, Connolly C, Moodley J, Sturm AW. *Trichomonas vaginalis* is associated with pelvic inflammatory disease in women infected with human immunodeficiency virus. Clin Infect Dis. 2002 Feb 15:34(4):519-22. Epub 2002 Jan 7
- 15. Gram IT, Macaluso M, Churchill J, Stalsberg H. Trichomonas vaginalis (TV) and human papillomavirus (HPV) infection and the incidence of cervical infraepithelial neoplasia (CIN) grade III. Cancer Causes Control. 1992
- Stark, Jennifer R., et al. Prospective Study of Trichomonas Vaginalis Infection and Prostate Cancer Incidence and Mortality: Physicians' Health Study. J Natl Cancer Inst 101.20 (2009): 1406-411 17. Nathan B, Heron D, Appiah J, Saunders P, Bru, R, Nichols T, Alexander S, Baraister P, Ison C: Evaluation of NAAT and
- POCT for detecting T. vaginalis 18. Campbell L., Woods V., Lloyd T., et al. Evaluation of the OSOM Trichomonas Rapid Test versus Wet Preparation Examination for Detection of *Trichomonas vaginalis* Vaginitis in Specimens from Women with a Low Prevalence of Infection. Journal of Clinical Microbiology. Oct 2008, 3467-3469





THE AMERICAS

Sekisui Diagnostics, LLC 31 New York Avenue Framingham, MA 01701 Phone: 800 332 1042 Fax: 800 762 6311 Email: osomrapidtests@sekisui-dx.com ISO 13485:2003 Certified

INTERNATIONAL

Sekisui Diagnostics (UK) Limited 50 Gibson Drive Kings Hill, West Malling, Kent, ME19 4AF, UK Phone: +44 (0) 1732 220022 Fax: +44 (0) 1732 220024 Email: info@sekisui-dx.com ISO 9001:2000 Certified, ISO 13485:2003 Certified