





Xpert[®]
TV

Comprehensive TV Testing

 **Xpert[®] TV**

The first molecular *Trichomonas vaginalis* test for both women and men.

  In Vitro Diagnostic Medical Device

 **Cepheid[®]**
A better way.



A decade ago *Trichomonas vaginalis* infections in men were virtually ignored. More current research has associated these infections with prostatitis and male factor infertility. In addition, trichomoniasis is emerging as a risk factor for sexual transmission of HIV. Xpert® TV provides accurate actionable results that clinicians need for optimal patient management.”

David H. Persing, M.D., Ph.D.
Executive Vice President, Chief Medical & Technology Officer, Cepheid



THE NEED

Identification of *Trichomonas vaginalis* (TV) infections is problematic. The demanding nature of this fragile organism outside its ideal living conditions, compounded with the poor sensitivity of wet mount microscopy and time delays for conclusive diagnosis from culture methods, makes detection of this asymptomatic infection a challenge. Symptoms alone are insufficient to diagnose a *Trichomonas vaginalis* infection. In women, the characteristics of vaginal discharge, color and odor, are poor predictors of this commonly asymptomatic infection.¹

Trichomonas vaginalis was found in over 73% of the male partners of women with trichomoniasis.² To prevent serial reinfection, all recent and current sex partners of patients with acute, persistent, or recurrent trichomoniasis should be treated or referred for treatment regardless of symptoms.³

What would help laboratories offering TV testing?

- Accurate, reliable, and reproducible tests
- Assay indications for key male and female specimens
- Elimination of repetitive microscopy readings
- Less time preparing samples and reagents



THE SOLUTION

Now anyone can run a TV test with confidence. Each test cartridge contains everything you need, including three controls to ensure test integrity and performance. With Xpert TV, same-day patient consultation and treatment are now a reality for clinicians.

On-demand TV testing – a next generation solution:

- The first NAAT to deliver TV results for male urine samples
- Near patient easy-to-use technology
- Intended for both symptomatic and asymptomatic patients so clinicians can screen individuals at higher risk of infection
- More tests than any platform

Each self-contained Xpert cartridge has controls for three specific failure modes:

- Sample Adequacy Control (SAC) – confirms adequate patient sample collection
- Sample Processing Control (SPC) – ensures the sample is correctly processed
- Probe Check Control (PCC) – monitors reagent systems in each and every cartridge



THE IMPACT



Nucleic acid amplification tests (NAATs) offer the highest sensitivity for the detection of TV. Improve your laboratory workflow with simple, on-demand, random-access flexibility. Combine performance with the ability to run other tests (such as CT/NG, HPV, HIV, HCV, and GBS) on the GeneXpert® System to achieve proven increase in overall laboratory level service.

Shift from reactive to proactive

- Deliver high sensitivity NAAT results for accurate diagnosis in both men and women
- Deliver near patient results on-demand as soon as 40*-65 minutes
- Support patient consultations with real time results
- Help patients and their partners live healthier lives



IMPACT ON PATIENT PATHWAY: "TEST AND TREAT"

Culture Sensitivity 70%⁴



Limitations: Organisms lost during centrifuge and preparation process
 Culture is the gold standard for male urine
 Confirmation of a +/- urine sample could take days

Wet Mount Sensitivity 45-60%^{5,6}



Limitations: For diagnosis, specimens should be examined within 10 minutes to observe motile parasites
 Training and proficiency required
 Microscopist fatigue and organism viability issues⁷

Xpert® TV Sensitivity >95%⁸



* Early Assay Termination for positive results.



WORKFLOW:

3 EASY STEPS

Total hands-on time: <1 Minute

1

Obtain either urine or swab samples previously collected and stored in the Cepheid Transport Reagent



2

Transfer the sample to the cartridge



3

Insert cartridge and start test



➤ **Xpert® TV is a qualitative real-time PCR test for automated detection of *Trichomonas vaginalis* in male and female samples for same day consultation and treatment.**

CATALOG INFORMATION

Xpert TV (10 tests) GXTV-CE-10

SPECIMEN KITS REQUIRED FOR PRIMARY SAMPLE COLLECTION AND TREATMENT:

Xpert Vaginal/Endocervical Specimen Collection Kits (50 ready-to-use individual kits) SWAB/A-50
Xpert Urine Specimen Collection Kits (50 ready-to-use individual kits) URINE/A-50

References:

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2. Hobbs MM, et al. Methods for detection of *Trichomonas vaginalis* in the male partners of infected women: Implications for control of trichomoniasis. J Clin Microbiol. 2006;44:3994-9. Epub 2006 Sep 13.
3. HIV Clinical Resource. August 2012. Accessed Nov 2014. <http://www.hivguidelines.org/clinical-guidelines/womens-health/trichomoniasis/>
4. Madico G, et al. Diagnosis of *Trichomonas vaginalis* Infection by PCR Using Vaginal Swab Samples. J Clin Microbiol. 1998 Nov;3205-10.
5. Patil MJ, et al. Diagnosis of *Trichomonas Vaginalis* from Vaginal Specimens by Wet Mount Microscopy, In Pouch TV Culture System, and PCR. J Glob Infect Dis. 2012 Jan-Mar; 4(1):22-5.
6. Sharrad J, et al. United Kingdom National Guideline on the Management of *Trichomonas vaginalis* 2014. BASHH. 2014. 14 p.
7. APHL Public Health Laboratory Issues in Brief. Laboratory Detection of *Trichomonas*. 2013 Aug.
8. Cepheid Xpert TV Package Insert.

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