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March 03, 2022

Change Notification Information

Trichomonas vaginalis and *Mycoplasma genitalium* testing

Introduction

Sparrow Laboratories will be updating the method used for *Trichomonas vaginalis* and *Mycoplasma genitalium* (TV/MG) testing.

This change will go into effect on 03/21/2022

cobas[®] **TV/MG** is an FDA cleared Nucleic Acid Amplification Test (NAAT) designed to support a variety of specimen types as recommended by the CDC¹. **cobas** TV/MG testing provides the laboratory with a more efficient system that will minimize operator time and reduce time to results enabling the laboratory to better serve your needs. This highly sensitive and specific assay will provide accurate results that are minimally equivalent or better as compared to our current method.

Sample Collection Devices

As we change our testing method we will also need to change the sample collection devices.

cobas PCR Media Urine Sample kit²

The **cobas**[®] PCR Urine Sample packet includes a transfer pipet and one tube of **cobas** PCR Media. The transfer pipet is used to transfer urine from the collection cup to the **cobas** PCR Media Tube.

Urine specimens in **cobas** PCR Media are stable at 2 - 30° C for up to 1 year.

Note: If the urine specimen cannot be transferred immediately, it can be stored at 2°C to 30°C for up to 24 hrs prior to transferring to the **cobas** PCR Media Tube.

cobas PCR Media Dual Swab Sample kit⁴

This sample collection kit is intended for the collection of vaginal, endocervical or meatal specimens. It contains a polyester woven swab, a flocked swab, and one tube of **cobas** PCR Media to stabilize the specimen.

In the case of endocervical collection, the polyester woven swab is use to remove mucus from the cervical os and surrounding mucosa. This woven swab **should be discarded after cleaning**. Samples that arrive in the laboratory with the woven cleaning swab **will be rejected**. The flocked swab is used to collect the specimen from the endocervical canal.

When collecting vaginal or meatal specimens, use **only** the polyester woven swab and **discard the unused flocked swab**. Specimens that arrive in the laboratory with 2 swabs **will be rejected**.

Following specimen collection, transport and store the **cobas** PCR Media Tube containing the collection swab at 2°C to 30°C.

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Swab specimens will be rejected by the laboratory:

- If they do not contain a swab
- If they contain 2 swabs

Soon you will receive a starter kit containing sample collection kits, laminated sample collection guides and a bag for the collection of unused sample collection kits, the current Aptima collection and transport sample kits cannot be used with the new method and will be rejected.

As we move towards this method conversion we ask that you begin to use up your current stock of sample collection kits for TV testing and order on an as needed basis.

Background

T. vaginalis (TV) is the most prevalent non-viral sexually transmitted infection in the United States, with CDC estimating 1 million new cases diagnosed annually.⁵ *M. genitalium* (MG) is described as an emerging issue by CDC, but already has an estimated prevalence between that of Chlamydia and Gonorrhea.⁶

CDC's diagnostic considerations for TV and MG include:¹

- Diagnostic testing for TV should be performed in women seeking care for vaginal discharge
- Consider screening for TV in persons receiving care in high-prevalence settings and for asymptomatic persons at high risk for infection
- Routine screening for TV in all women with HIV infection is recommended at entry to care and then at least annually thereafter
- MG should be considered in cases of persistent or recurrent cervicitis, PID, or urethritis

STI testing is critical for the diagnosis and management of common urogenital disease syndromes that present with similar signs and symptoms, or no symptoms at all. In women, it is estimated that 70% of TV cases⁷ and 77% of MG cases⁸ have no symptoms and the health consequences of these undiagnosed infections are profound. TV and MG are associated with non-gonococcal urethritis in men, as well as cervicitis, Pelvic Inflammatory Disease (PID), and adverse pregnancy outcomes in women (premature rupture of membranes, preterm delivery, and low birth weight). Additionally, both diseases can increase the risk of HIV transmission in either gender.¹

Specimen types: Vaginal swab specimens (Provider-collected or self-collected in a clinical setting), Endocervical swab specimens, Meatal swab specimens (MG only), Urine specimens (male and female), Cervical specimens in PreservCyt solution (TV only).

Specimen collection kits: cobas PCR Media Urine, Uni, and Dual sample kits, ThinPrep / PreservCyt vial

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Specimen type and collection kit guide

Specimen	Collection and Transport kit
Male Urine	cobas PCR Urine sample kit
Female Urine	cobas PCR Urine sample kit
Vaginal	cobas PCR Media Dual Swab Sample kit
Endocervical	cobas PCR Media Dual Swab Sample kit
Meatal	cobas PCR Media Dual Swab Sample kit
Cervical	PreservCyt® Solution

Specimen stability:

- Urine specimens can be stored at 2°C to 30°C for up to 24 hrs prior to transferring to the **cobas** PCR media tube. Urine specimens in **cobas** PCR Media are stable at 2 - 30° C for up to 1 year.
- Transport and store the **cobas** PCR Media Tube containing the collection swab at 2°C to 30°C. Specimens in **cobas** PCR Media are stable at 2 - 30° C for up to 1 year.

For additional information, please call 517-371-9400 or email walid.khalife@sparrow.org or kara.parsons@sparrow.org

References:

1. Sexually Transmitted Diseases Treatment Guidelines, 2015MMWR Recommendations and Reports/Vol. 64 / No. 3 June 5, 2015, Centers for Disease Control and Prevention.
2. **cobas** PCR Urine Sample Kit (material number 05170486190) instructions for use
3. **cobas** PCR Media Uni Swab Sample Kit (material number 07958030190) instructions for use
4. **cobas** PCR Media Dual Swab Sample Kit (material number 07958021190) instructions for use
5. Satterwhite CL, Torrone E, Meites E, et al. Sexually transmitted infections among US women and men: prevalence and incidence estimates, 2008. Sex Transm Dis 2013;40:187–93.
6. McGowin CL, et al. PLoS Pathog. 2011; 7:e1001324.
7. Centers for Disease Control and Prevention. Trichomoniasis – CDC Fact Sheet. <https://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm>. Accessed Nov. 7, 2019.
8. Falk L., et al. Sex Transm Infect 2005; 81:73-78.

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