Marshfield Labs™
A division of Marshfield Clinic

Laboratory News

VOL. 37, NO. 11 - SEPTEMBER 24, 2014

Inside This Issue

NEW CENTERS FOR DISEASE CONTROL (CDC) RECOMMENDATIONS FOR THE LABORATORY-BASED DETECTION OF *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEAE* — 2014

Timothy S. Uphoff, PhD, DABMG, Molecular Pathology Laboratory

On March 14, 2014 the CDC released new recommendations for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (MMWR Vol. 63 / No. 2) [1]. These updated recommendations were deemed necessary because of the growing evidence indicating superior performance of nucleic acid amplification tests (NAATs) over traditional culture and probe based methods.

These new recommendations are summarized as follows:

- Nucleic acid amplification tests that are cleared by the Food and Drug Administration (FDA) are recommended for detection of genital tract infections caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in men and women with and without symptoms. For detecting these infections of the genital tract, optimal specimen types for NAATs are vaginal swabs from women and first catch urine from men. Older non-culture tests and non-NAATs have inferior sensitivity and specificity characteristics and no longer are recommended.
- NAATs have not been cleared by FDA for the detection of rectal and oropharyngeal infections caused by *C. trachomatis* and *N. gonorrhoeae*. CDC is recommending NAATs to test for these extragenital infections based on increased sensitivity, ease of specimen transport and processing. Because these specimen types have not been cleared by FDA for use with NAATs, laboratories must establish performance specifications when using these specimens to meet Clinical Laboratory Improvement Amendments (CLIA) regulatory requirements and local or state regulations as applicable prior

continued on page 2

to reporting results for patient management. *Because Marshfield Labs receives so few of these specimens we have not been able to validate these sample types. Specimens submitted for non-FDA sample types will be sent for testing to a reference laboratory which has validated these sample types.*

- Routine repeat testing of NAAT-positive genital tract specimens is not recommended because the practice does not improve the positive predictive value of the test.
- Laboratory interpretation of test results should be consistent with product inserts for FDA-cleared tests or have met all federal and state regulations for a modified procedure if the laboratory has changed the cutoff values or testing algorithm. This approach provides the most appropriate information to the clinician, who is ultimately responsible for assessing test results to guide patient and partner management.
- *N. gonorrhoeae* culture is still needed for evaluating suspected cases of treatment failure and monitoring antimicrobial susceptibility.
- *C. trachomatis* and *N. gonorrhoeae* culture might still be needed in instances of child sexual assault in boys and extragenital infections in girls.

Guidelines specific to men include:

- A first catch urine is the recommended sample type and is equivalent to a urethral swab in detecting infection.
- A urethral swab specimen for *N. gonorrhoeae* culture should be obtained and evaluated for antibiotic susceptibility in patients who have received a CDC-recommended antimicrobial regimen as treatment, and subsequently had a positive *N. gonorrhoeae* test result (positive NAAT ≥7 days after treatment), and did not engage in sexual activity after treatment.

Guidelines specific to women include:

- A self- or clinician-collected vaginal swab is the recommended sample type. Self-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. Self-collected samples are FDA approved only if collected in a providers office.
- An endocervical swab is acceptable when a pelvic examination is indicated.
- A first catch urine specimen is acceptable but might detect up to 10% fewer infections when compared with vaginal and endocervical swab samples.
- An endocervical swab specimen for *N. gonorrhoeae* culture should be obtained and evaluated for antibiotic susceptibility in patients who have received a CDC-recommended antimicrobial regimen as treatment, and subsequently had a positive *N. gonorrhoeae* test result (positive NAAT ≥7 days after treatment), and did not engage in sexual activity after treatment.

Sample Types:

Of particular note in the above guidelines is the new recommendation of vaginal samples being preferred over other sample types. There are no stated performance differences between vaginal and cervical specimens; however, the guidance document states that detection in urine specimens can be less sensitive than these sample types. As a reference, Table 1 below includes the published sensitivity and specificity characteristics for the Aptima Combo 2® method used by Marshfield Labs for different specimen types[2].

continued on page 3

Table 1

Aptima Combo 2® Method				
	C. trachomatis		*N. gonorrhoeae*	
	Sensitivity	Specificity	Sensitivity	Specificity
Endocervical Swab	94.2%	97.6%	99.2%	98.7%
Female Urine	94.7%	98.9%	91.3%	99.3%
ThinPrep Liquid Pap	96.7%	99.2%	92.3%	99.8%
Clinician Collected Vaginal Swab	96.6%	96.8%	96.0%	99.2%
Patient Collected Vaginal Swab	96.6%	97.4%	100%	99.4%
Male Urethral Swab	95.9%	97.5%	99.1%	97.8%
Male Urine	97.9%	99.2%	92.3%	99.8%

For providers who wish to submit self- or clinician-collected vaginal specimens, vaginal specimen collections devices can be ordered by requesting the Aptima Vaginal Swab Specimen Collection Kit (Lawson # 220016). The collection kit packaging for the Aptima Unisex and Vaginal Specimen Collection kits looks very similar. However, the Vaginal Collection Kit contains a single pink swab while the Aptima Unisex Collection Kit contains a white swab (to remove mucus from the cervix) and a blue swab (for sample collection).

Providers must be aware that vaginal specimens collected using a blue Aptima Unisex swab or cervical/urethral specimens collected using the pink Aptima Vaginal Collection swab will be rejected on the basis that an inappropriate collection device was used to obtain the specimen. The performance of this test using inappropriate swabs has not been approved by the FDA or validated by our laboratory.

The table above reflects data collected in controlled clinical studies with rigorous patient education procedures to ensure proper sample collection. Patient instructions and adherence to proper specimen collection procedures must be maintained to obtain valid samples for clinical testing.

For urine samples, there are three critical factors necessary for optimal specimen collection:

1. The patient should not have voided within the past hour.
2. Only the first portion of the urine stream should be collected.
3. No more than 20-30 ml of urine should be collected. Since patients may have a difficult time estimating this volume, a line should be drawn on the sage cup to instruct the patient of the proper volume to collect. The patient **must not** fill the cup and then pour off excess to bring the urine volume to the designated line.

PDFs outlining proper urine, cervical, urethral and vaginal sample collection instructions are available at: Physician Collected Vaginal Swab, Patient Collected Vaginal Swab, Unisex Swab Collection, and Urine Collection.

continued on page 4

Cases of Sexual Abuse:
In addition, there is a section in the document regarding testing for victims of sexual abuse. *"NAATs for C. trachomatis and N. gonorrhoeae are preferred for the diagnostic evaluation of adult sexual assault victims, from any sites of penetration or attempted penetration (97,98). Data on use of NAATs for detection of N. gonorrhoeae in children are limited. Consultation with an expert is necessary before use of NAATs for this indication in children to minimize the possibility of positive reactions with nongonococcal Neisseria species and other commensals. NAATs can be used as an alternative to culture with vaginal specimens or urine specimens from girls. Culture remains the preferred method for urethral specimens from boys and extragenital specimens (pharynx and rectum) in boys and girls."*

According to established Clinic policy (STD PCR Sexual Abuse Lab Evaluation Document ID: 62U3QES2XUJM-3-1995), Marshfield Labs will not perform testing for *C. trachomatis* or *N. gonorrhoeae* in prepubescent patients except in the cases of Clinic providers ordering in consultation with the Pediatric Abuse/Neglect Clinic or Child Advocacy Center. https://www.marshfieldclinic.org/Doctors/Search?k=pediatrics%20child%20abuse

REFERENCES:

1. *Centers for Disease Control and Prevention: Recommendations for the laboratory-based detection of Chlamydia trachomatis and Neisseria gonorrhoeae—2014., in MMWR Recomm Rep.* p. (RR-2) 1-19.
2. Handsfield, H., *Control of sexually transmitted chlamydial infections.* JAMA, 1987. **257**(15): p. 2073-2074.

LABORATORY UPDATE: EXPANDED LIST OF ACCEPTABLE SOURCES FOR THE RESPIRATORY PANEL BY PCR (TEST CODE FARP)

Thomas Novicki, PhD, DABMM, Clinical Microbiologist
Mary Stemper, MT(ASCP), MS, Technical Director

SUMMARY

Effective October 1, 2014, two changes will be made to the Respiratory Panel by PCR test (test code FARP):

- Bronchial wash and bronchoalveolar lavage specimens will now be accepted for this test.
- The name will change to Respiratory Panel by PCR to better reflect its bacterial as well as viral targets. All other aspects of this test, except the addition of bronchoscopy specimens, will remain unchanged, including its availability for patients in hospital only.

As a reminder, the target pathogens of this test are listed in the Table 2.

continued on page 5

Table 2 - Target Pathogens

Viruses	
Adenovirus	Coronavirus 229E
Coronavirus HKU1	Coronavirus NL63
Coronavirus OC43	Enterovirus/Rhinovirus
Human Metapneumovirus	Influenza A H1
Influenza A H1-2009	Influenza A H3
Influenza B	Parainfluenza 1
Parainfluenza 2	Parainfluenza 3
Parainfluenza 4	Respiratory Syncytial Virus
Bacteria	
Bordetella pertussis	*Mycoplasma pneumoniae*
Chlamydia pneumoniae	

ORDERING INFORMATION

Table 3

Test	Keywords	Lab Test Code	Clinic (COM)	Hospital (Centricity)
Respiratory Panel by PCR	Respiratory Virus, Virus Culture, Flu, RSV, Adeno, Entero, Rhino, Virus	FARP	Not Available	Respiratory Panel by PCR

Downtime: Write-In (Form 1)

Acceptable Specimens

- Nasopharyngeal swab in M6 or other viral transport medium
- Bronchoalveolar lavage fluid
- Bronchial wash

Test Schedule

Daily, 1 day's time to result report

PERFORMING LAB

Marshfield Center

CPT

87633 x1

CONTACTS

Interpretive: Dr. Thomas Novicki, Dr. Thomas Fritsche (ext. 1-6300)
Technical: Microbiology Lab (ext. 1-6141)
(Or call 800-222-5835)

See the Marshfield Labs Test Reference Manual for full details as of October 1, 2014.