Peterson's Press

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UP FRONT

Recent Changes to Syphilis Screening Algorithms

Suzanne Tucker, MD, and Josh A. Hanson, MD

A growing number of laboratories in the United States have reversed the long-established, traditional algorithm for laboratory diagnosis of a syphilis infection. Instead of screening with a non-treponemal test, such as the rapid plasma reagin (RPR) and confirming reactive results with a direct treponemal test, such as the fluorescent treponemal antibody absorption (FTA-ABS), these laboratories screen with an automated direct treponemal test and confirm with a non-treponemal test, often the RPR. This reversal of traditional syphilis testing was primarily initiated by the decreased cost, improved sensitivity and specificity, and improved efficiency of automated treponemal testing.

The adoption of the new algorithm has resulted in cases of discordant laboratory results (a reactive treponemal test and negative RPR) that would not otherwise have been identified in the traditional method. In a study performed by the Centers for Disease Control and Prevention (CDC), 3,664 (3%) of 116, 822 total specimens or 56% of total initial reactive specimens had a reactive treponemal test and negative RPR. From a laboratory standpoint, a reactive direct treponemal test indicates only that a treponemal infection has occurred sometime in a patient's lifetime, regardless of whether the patient has been adequately treated in the past. This is a common occurrence, as antibodies often persist in patients long after the infectious agent has been eliminated; and therefore a positive treponemal test may not indicate an active infection, but only a previous exposure. The RPR, however, usually becomes non-reactive following successful treatment, thus a negative RPR in this setting often indicates previous treatment. Unfortunately, there are no standardized algorithms on how these results should be interpreted or how these patients should be managed.

If the patient knows his or her treatment history and there are no clinical symptoms of a recurrent or inadequately treated initial syphilis infection, a positive direct treponemal test and negative RPR results are often attributed to previous treatment. However, if the patient has no recollection of previous treatment, the patient can be tested with a second, different treponemal test, such as the FTA-ABS or the TP-PA. If that result is also negative, clinical suspicion must be assessed to decide whether treatment is indicated or if a third treponemal test should be used to resolve the discrepancy between the two treponemal test results. A thorough history and physical exam are necessary to determine the clinical suspicion of a syphilis infection in cases of discrepant results.

Despite these new clinical dilemmas, the sensitivity and specificity of the automated direct treponemal tests are improved over the RPR. For instance, the laboratory at Fletcher Allen Health Care at the University of Vermont recently began using an automated antigen-based chemiluminescence immunoassay, which has a sensitivity of 99.2% for the detection of syphilis. This is an improvement over the RPR, which has an overall sensitivity of 96.3% for the detection of non-treated syphilis. RPR sensitivity drops significantly to 6.5% in cases of previously treated, latent syphilis, limiting its use as a diagnostic test for an inadequately treated syphilis infection. In addition, the RPR suffers from poor specificity as it can be reactive in patients with common diseases such as infectious mononucleosis, *Streptococcus pyogenes* infection, viral infections, and autoimmune diseases.

In conclusion, automated direct treponemal testing has an improved sensitivity and specificity compared to the RPR in the detection of primary, secondary and latent syphilis. These automated tests are less expensive to perform than the RPR and remove operator bias since many treponemal tests are objective rather than subjective. However, they often result in discordant results when used with a confirmatory non-treponemal test, such as the RPR. Standardized follow-up algorithms have not yet been established to guide clinicians when the direct treponemal test and RPR disagree. Understanding the clinical situations in which these tests were performed is essential for the correct interpretation of the results.

NEWS AND NOTES

Reach Us Through Secure Clinical Messaging

As physicians ourselves, we understand your hectic schedule. Questions you may have about a patient result are often phoned-in between patient visits. If one of the two pathologists who read the patient's case is not immediately available, a message is left for them to return your call. When the call is returned, you may then be with a patient.

While you are invited to phone the pathologists with your inquiries as always, you may also reach us through secure email as an alternative communication method if you use KS Health Information Network (KHIN) Secure Clinical Messaging. In addition to our pathologists, key management staff can also be reached.

The cost to participate is very reasonable. For more information, call (877) 520-5446 or go to http://www.khinonline.org.

Computer Assisted Pap Screening Coming Onboard

Peterson Laboratory will add computer-assisted cervical cytology screening this Spring.

The resulting "dual review" of cytologist read liquid-based pap testing combined with computer assisted screening offer two unique components for comprehensive and accurate cervical cancer testing.

There is simply no room for error in case diagnosis. Adding computer assisted cytology review complements our long-standing 100% quality assurance review (double over-read) performed on all surgical specimens.

Using dual review screening, slides are analyzed by the imaging system and screened by a skilled cytotechnologist. Cells of interest are highlighted for cytotechnologists' review, helping them to better focus their interpretive skills where it counts most. The addition of computer assisted screening results in improved disease detection as well as a decrease in unsatisfactory and ASCUS rates compared to manually reviewed slides.

2012 KSCLS/Wheatlands CLMA Annual Conference

"Destination-Knowledge" will be held Wednesday-Friday, May 2-4, 2012 at the Marriot Hotel and Conference Center in Wichita. There are 46 different presentation sessions within the areas of management, coagulation, chemistry and microbiology. Almost all sessions carry 1 CEU.

New this year will be the ability to register and pay online. Institutional passes are available. The hotel lodging rate is $93 per night. If you do not receive your conference announcement via email or postal service by April 1, please call or email Maureen, 785-565-8738, "mjensen@petersonlab.com.

At What Age Should Pap Screening Cease?

The American College of Obstetricians and Gynecologists (ACOG) recommends that women with at least 3 consecutive documented satisfactory normal Pap tests within the last 10 years can cease cervical cancer screening between the ages of 65-70, while the American Cancer Society recommends these same women may cease cervical cancer screening at age 70. The United States Preventative Services Task force (USPSTF) recommends that women with adequate normal screening in the last 10 years can cease Pap testing at age 65.

Should screening cease following hysterectomy?

All three organizations state that screening should cease following a total hysterectomy if there was no CIN2, 3 or cancer at the time of the hysterectomy. HPV screening is also no longer necessary.

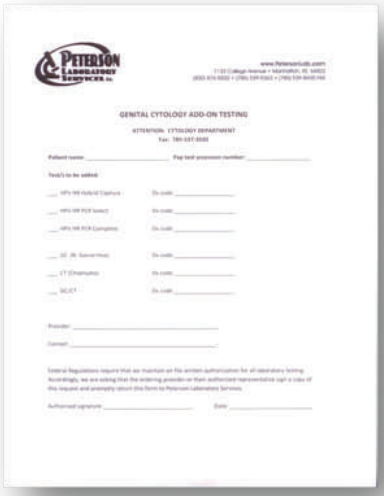
Same Sample HPV PCR Select and Complete Tests

As announced in November, PCR Select is the new default HPV test. If no other method is selected, PCR Select will be ordered. PCR Select will yield a positive/negative result for genotype 16, positive/negative result for genotype 18 and a positive/negative result for the remaining group of 13 HR genotypes.

PCR Complete (reports a positive/negative result individually for 15 HR genotypes) may be ordered using the same specimen up to one year later.

Gyn-Cytology Add-On Form

Do you have a copy of our most recent Genital Cytology Add-On Testing form?



Several changes have been made to the genital cytology testing menu in the last 18 months. If you would like to add additional tests to a Pap order (HPV or GC/Chlamydia), please fax a copy of the current add-on testing form within 3 weeks (21 days) of the date of pap collection. A copy of the form is attached to this newsletter. You may also download the form at www.petersonlabcom.

Regulations require laboratories to have written documentation for every test performed.

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