Laboratory Medicine Update

December 12, 2018

Change to threshold for protection – Hepatitis B Surface Antibody

To reflect changes by the vendor and revised WHO recommendations, all results for Hepatitis B Surface Antibody testing will now indicate that "values ≥**12** mIU/L are considered protective." This is a change from a level of 10 mIU/L. Values between 8.00 and 12.00 mIU/L are considered borderline have the comment "Borderline immune status, suggest further assessment and retest if clinically indicated" attached.

In-house PF4 Antibody Testing

The Core Laboratory is excited to announce that we will now be performing the platelet factor 4 (PF4) antibody testing in the Special Coagulation Laboratory.

The details of this testing are below:

- This test is a purely qualitative test with a positive/negative result. This test is not the same as the previous ELISA methodology, and an OD is unavailable.
- A light blue top tube (3.2% Sodium Citrate) is required.
- All positive results will automatically reflex to the serotonin release assay (SRA). This will require a separate red top tube and it will automatically populate the nurse's worklist to draw this tube.
- If received in the lab before 12:00 pm on a weekday, same day turn-around time can be expected.
- On weekends, results can be expected within 24 hours.

This test performed exceptionally well when compared to the current test, PF4 ELISA, and to the SRA. For further information, please see the paper (our test is referred to as CLIA):
Warkentin, TE, et al. High sensitivity and specificity of an automated IgG-specific chemiluminescence immunoassay for diagnosis of HIT. Blood. 2018;132(12):1345-1349.

New Code for Capillary Whole Blood Lead Analysis

Analysis of capillary whole blood for lead is now orderable in Epic as LAB6171: Lead, Blood w/ demographics, capillary. The required sample is 0.4 mL blood in a lavender microtainer tube. Careful cleaning of the finger prior to collection is mandatory to prevent spuriously high levels. LAB 6126, a venous sample, remains the preferred sample and test.

Please be aware that any measurable lead in a patient less than 15 years old is reported to Virginia Department of Health.

Think your patient has *Mycoplasma pneumoniae*? Current recommendations for laboratory diagnosis of *M. pneumoniae* infection include a combination of serology and direct detection by molecular methods.

Order LAB6116 *Mycoplasma pneumoniae* Antibody, IgG/IgM. This test is an orderable send-out to Mayo Medical laboratories with about a 1 day turn-around time Monday through Friday.

In addition if you suspect an acute or current infection with *M. pneumoniae* you may also order a real-time PCR for detection of DNA from clinical specimens (e.g respiratory). This test is also available as a send-out by contacting the Micro resident on call (1852) or Micro director on call (1221), and has a comparable turn-around time to antibody testing.

Development of IgM antibodies takes approximately 1 week and the IgM response in adults may be variable or decreased in immunosuppressed individuals. Serologic evaluation of IgM and IgG antibodies can be used in combination with PCR for the most sensitive and specific method of detecting current infections with *M. pneumoniae*.

Do not order cold agglutinin testing. Due to a recent increase in the frequency of orders for cold agglutinin testing to evaluate for *Mycoplasma pneumoniae* infection, a literature review was performed to determine what, if any, diagnostic utility there is for cold agglutinin testing in this setting, now that improved diagnostic testing options are available. The literature concludes that cold agglutinin testing has a sensitivity of only 20% and a specificity of 81.7% for *M. pneumoniae* infection. This means that due to the relatively low prevalence of *M. pneumoniae* as the etiologic organism for community acquired pneumonia, there is only a miniscule increase in the post-test probability of *M. pneumoniae* infection with a positive cold agglutinin test. In addition, positive cold agglutinin test can be seen with multiple other infections, including infectious mononucleosis, Cytomegalovirus, *Legionella sp*, *Citrobacter sp*, Influenza, and Varicella. One further consideration is the utility of cold agglutinin testing in the setting of a negative direct antiglobulin test (DAT). A 2017 study by Wilen et al, concluded that 98% of patients with a negative DAT (specifically negative for C3) had a negative cold agglutinin titer (<64). This would essentially eliminate the need to perform cold agglutinin testing in patients with a previously negative DAT. Furthermore, the cold agglutinin studies performed in the UVA Blood Bank and Transfusion Medicine Services do not include a titer, rather this is a screen for patient reactivity at 37°C and room temperatures.

References:

Daxboeck F, Krause R, Wenisch C. Laboratory diagnosis of *Mycoplasma pneumoniae* infection. *Clin Microbiol Infect*. 2003. doi:10.1046/j.1469-0691.2003.00590.x

Fischer BG, Baduashvili A, Evans AT. Cold Agglutinins in *Mycoplasma* Infection—Reply. *JAMA*. 2018;320(10):1039. doi:10.1001/jama.2018.9253

Stein B, DeCredico N, Hillman L. Evaluation of the direct antiglobulin test (DAT) in the setting of *Mycoplasma pneumoniae* infection. *JAMA*. 2018. doi:10.1001/jama.2018.1969

Wilen CB, Booth GS, Grossman BJ, Lane WJ, Szklarski PC, Jackups R. Using direct antiglobulin test results to reduce unnecessary cold agglutinin testing. *Transfusion*. 2017. doi:10.1111/trf.14059

***Chlamydia trachomatis* and *Neisseria gonorrhoeae*:**

Addition of anal and oral samples to testing available in the UVA Medical Laboratories

The UVa Clinical Microbiology and Molecular Diagnostics laboratory is pleased to announce the addition of anal and oral swab samples to our current testing platform for detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG). Please review the guidelines for considerations in specific populations at risk at https://www.cdc.gov/std/tg2015/default.htm. **Specimens must be collected using the *m*ulti-Collect Specimen Collection Kit, in order to be tested by the UVA Medical Laboratories.** These are the same collection devices currently used for urogenital samples from both males and females. Please order GC/CHLAMYDIA SCREEN, PCR, SWAB ONLY [LAB3688], and select the appropriate sample type. Samples submitted to the laboratory using the previous Aptima collection devices will continue to be tested by our reference laboratory. Culture for *N. gonorrhoeae* remains orderable and is performed by the UVA Clinical Microbiology Laboratory. *C. trachomatis* culture remains available as a referral test with approval from the Clinical Microbiology director on call (PIC 1221).

The Abbott CT/NG assay is approved for detection of CT and NG from the vagina and male urethra, or male and female urine. While there are no commercially available, FDA-approved tests for detection of CT and NG from anal and oral samples, the UVA laboratories has validated the analytical performance characteristics of the Abbott CT/NG test with these sample types. Inhibition was seen in anal samples with visible quantities of stool covering the swab. Please insert the swab no more than 1 inch beyond the anus for best test performance.

The CT test will detect all serovars of *C. trachomatis* containing the cryptic plasmid and the NG test will detect all strains of *N. gonorrhoeae*. Neither assay cross-reacts with other strains of *Chlamydia* or non-STD *Neisseria*. Nevertheless, in low prevalence populations as seen at UVa, positive predictive values may be reduced. As a reminder:

- Use only the orange shaft swab provided in the *m*ulti-Collect Specimen Collection Kit for collection. The swab must remain in the Transport Tube with the buffer intact after specimen collection. Do not place multiple swabs or a combination of swab and urine in the Transport Tube. A new specimen will be requested if a swab specimen is received without transport buffer, without a swab, or with multiple swabs.
- For urine specimens, the liquid level in the specimen transport tube must fall within the fill window on the tube label, or a new specimen must be collected. Urine specimens arriving in the laboratory in a urine specimen collection cup will be transferred by laboratory personnel, but **must arrive within 24hr of collection**.
- Once placed in *m*ulti-Collect Specimen Collection Kit, specimens may be stored and transported at 2°C to 30°C for up to 14 days.
- Do not use the *m*ulti-Collect Specimen Collection Kit beyond its expiration date. Do not use the *m*ulti-Collect Specimen Collection Kit if the packaging is damaged, the seal is broken, or if buffer has leaked from the tube.
- The presence of blood, mucus, some spermicidal agents, feminine powder sprays, and treatments for vaginal conditions such as yeast infection may interfere with nucleic acid test based assays.