Physician Signatures—Still Confusing

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For some time, laboratories have been trying to make sense out of conflicting directives and communications from Medicare/Medicaid and other billing regulatory agencies about whether or not the laboratory can process laboratory tests without a physician’s signature on the test requisition.

Many labs, MDL included, have struggled with how to handle test requisitions that come to the lab unsigned. Should the lab hold the test results until it receives a signed requisition from the physician? Or should the lab release the test results and request that the physician send a signed requisition to the lab later?

Historically, the Centers for Medicare & Medicaid Services (“CMS”) have stated that test requisitions do not need to be signed by the physician as long as the physician clearly documents in the patient’s medical record his or her intent that the test be performed. In August 2008, CMS confirmed this position.

However, CMS recently requested comments on a proposed rule to operate indirectly “clarify” its policy on physician signatures. The proposed rulemaking restates CMS’s position that test requisitions do not need to be signed by the physician as long as the physician clearly documents in the patient’s medical record his or her intent that the test be performed. In August 2008, CMS confirmed this position.

Because for many labs, the test requisition serves as the test order, we do not believe that the new rule will change CMS’s historical position that requisitions sent to the lab do not need to be signed. However, this latest word from CMS seems to emphasize that the physician has an independent duty to order laboratory tests and to indicate whether or not the laboratory can process laboratory tests without a physician’s signature on the test requisition.

Moreover, physicians should take note of the fact that the laboratory tests they perform are required to be documented and included in the patient’s medical record.

Some experts say that just because CMS may not require a signature on the physician order for laboratory tests does not mean that laboratories should not obtain physician signatures on the laboratory requisition. For example, some state Medicaid plans, including New Jersey and other payors require physician signatures for patients covered under such plans or policies.

Therefore, MDL will continue to encourage its physician clients to sign all test requisitions, in addition to including signed orders in the patient’s medical record on a signed order attached to the medical record.

Group B Streptococcus (Streptococcus agalactiae, GBS) is a gram-positive, β-hemolytic bacterium that is the most common cause of neonatal blood infections and meningitis, and a frequent cause of pneumonia. Under the 2002 Centers by Disease Control (CDC) guidelines, pregnant women are screened for GBS at 35-37 weeks of gestation. Treatment recommendations for women who test positive for GBS are β-lactam antibiotics such as penicillin G, given at 4-6 hours prior to delivery. Following the implementation of the CDC GBS screening guidelines, neonatal GBS disease declined from 1.7 per 1,000 live births in 1993 to 0.6 per 1,000 live births in 2005. Despite a dramatic drop in the incidence of infection in the United States, GBS remains a leading cause of neonatal morbidity and mortality, resulting in an estimated 1,425 early neonatal deaths annually.

To date, no case of penicillin resistance have been reported in GBS in the scientific literature. Our laboratory, however, has identified a phenotype of penicillin tolerance in which the microorganism is inhibited for growth in the presence of the drug, but remains viable for an extended period of time as compared to susceptible strains. These strains can then start propagating once the drug concentration decreases below the effective levels. This proposed bacteriostatic mechanism of penicillin on GBS and other gram-positive bacteria is inhibited by the inhibition of penicillin-binding proteins (PBPs). PBPs are enzymes that synthesize the bacterial peptidoglycan cell wall. The inhibition of the PBPs by penicillin triggers the re-activation and overproduction of large amounts of bacterial autolysins, resulting in cell wall degradation and cell death. Our hypothesis is that penicillin tolerant (PT) strains are more resistant to autolysin digestion due to differences in the construction of the cell wall or differences in the level of secreted autolysins. This phenomenon has been identified and reported in a number of other organisms, including Streptococcus pneumoniae, Streptococcus pneumoniae, Streptococcus pyogenes, Enterococcus faecale and Mycobacterium tuberculosis.

We examined clinical isolates of GBS, which initially 15.7% were found to be tolerant to penicillin and other β-lactam antibiotics such as ampicillin and oxacillin. Whereas, non-β-lactams, such as erythromycin, clindamycin or vancomycin were still effective. We have identified two novel amino-acids polymorphisms in a FBP found within approximately 50% of the penicillin tolerant GBS strains and are virtually absent in the penicillin susceptible strains. These GBS tolerant strains and have been found to have evidence of structural changes in the peptidoglycan cell wall. This supports our hypothesis that penicillin tolerant strains are more resistant to autolysin digestion due to differences in the construction of the cell wall.

These data have been submitted to a peer-reviewed journal for publication.

Currently, the mechanism(s) of the other 50% of the PT strains are under investigation. However, tolerance may be due to differences in cell wall synthesis rates, cell wall thickness, autolysin activity, or mutations in the penicillin-induced autolysin upregulation via a signal transduction mechanism. Additionally investigating the incidence of PT (FBP) resistance by collecting clinical isolates from mothers and their infected neonates is underway. Although increasing the duration of penicillin treatment will eventually kill PT GBS strains, this is not a practical option when dealing with labor and delivery. However, we hypothesize that by alerting physicians to the phenomena of penicillin tolerance we can directly affect patient care by prompting the prescription of alternative non-β-lactam antibiotics, such as erythromycin, clindamycin, or vancomycin, and further decrease the incidence of illnesses and deaths associated with neonatal infections with GBS.

PENICILLIN TOLERANCE IN GROUP B STREPTOCOCCUS

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UPCOMING EVENTS

3/11-3 ACOG: Annual District Meeting (District V) Indianapolis, IN

3/11-4 ACOG: Annual District Meeting (District VII and IX) Naples, CA

3/15-18 ACOG: Annual District Meeting (Districts I & III) Orlando, FL

3/15-18 ACOG: Annual District Meeting (District IV) Ashville, NC
were also processed for identification of prospectively obtained in the third trimester (35 to less than 37 weeks of gestation) and Test 1125: 2009 H1N1 influenza virus (Swine Flu) with Factor V Leiden and Factor II Prothrombin by resistant strains. Maternal colonization by MRSA was linked to a computerized This study attempted to estimate the frequency of genital tract colonization by in pregnant women.


Enomoto M, Morigi K, Morishita T, Katakura K, Nakamura M. 2009. Novel Diagnostic Tool for Detecting Neonatal Infections Using Multiplex Polymerase Chain Reaction. susceptibility testing and Ancient surveillance was conducted in selected counties in ten US states. A case was defined as isolation of GBS from a normally sterile site in a nonpregnant resident of a case patients. A total of 19,512 GBS cases were identified in nonpregnant adults defined as isolation of GBS from a normally sterile site in a nonpregnant resident of a defined as isolation of GBS from a normally sterile site in a nonpregnant resident of a case patients. A total of 19,512 GBS cases were identified in nonpregnant adults defined as isolation of GBS from a normally sterile site in a nonpregnant resident of a case patients. A total of 19,512 GBS cases were identified in nonpregnant adults defined as isolation of GBS from a normally sterile site in a nonpregnant resident of a case patients. 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Medical Diagnostic Laboratories, L.L.C.

A. We do not accept standing orders. In an effort to ensure that tests ordered on a given date of service are medically necessary for the diagnosis and treatment of that specific patient, we require requested tests to be clearly marked on each test requisition form submitted. If the tests are not marked on the requisition form or are marked in such a way that we feel some degree of ambiguity in your request, we will contact your office for clarification of the orders to ensure that we are only performing the tests the physician has deemed appropriate for that patient on that date of service.

Q: If you have a question you would like addressed in future issues, please email your question(s) to Q&A@mdlab.com

Current Publications

HUMGEN, L.L.C.

Abstracts


Peer-Reviewed Papers


For results to the electronic Epidemiology Quiz, please visit www.mdlab.com and click on the e-Quiz link.

1. Group B streptococcus (GBS) infections in the newborn can manifest as:
   a. Septis b. Meningitis c. Pneumonia d. All of the above

2. True or false. If a newborn does not develop symptoms of GBS infection within one week of birth, they will not develop it at all.

3. True or false. The incidence of group B streptococcal disease in babies less than a week old declined by over 70% in the 1990s, coinciding with increased use of intrapartum antibiotic prophylaxis
   a. HLA-A b. HLA-DR c. HLA-C d. HLA-G

4. The Centers for Disease Control and Prevention (CDC) recommends universal prenatal screening for vaginal and rectal group B strep colonization of all pregnant women at each prenatal visit.

5. In the United States, GBS remains a leading cause of newborn morbidity and mortality, resulting in an estimated 1,425 early onset cases and ___ deaths annually.
   a. 7 b. 27 c. 63 d. 93