

Lab Meeting Minutes (June 6, 2011)

Participants

Gary Budnick (CT)  
Arthur Kazianis (MA)  
Tracy Stiles (MA)  
Jemelie Bessette (ME)  
Carol Loring (NH)  
Bob Ireland (RI)  
Sherry French (VT)  
John Papp (CDC) – by phone  
Rick Steece (CDC) – by phone  
Jaya Mathur (JSI)

- A. National Lab Update (John Papp and Rick Steece)
- a. Gail Bolan is the new division director
  - b. Dr. Bolan has requested that the new lab guidelines include more information on GC
  - c. John Papp will now add more information on GC culture and susceptibility testing, and will then send the revised guidelines to the committee for one last look
  - d. Highlights
    - i. Recommendations on rectal and pharyngeal testing
    - ii. More information on culture as we face antimicrobial resistance
    - iii. Recommendation for no repeat testing
    - iv. Recommendation on lab protocol in cases of sexual assault/abuse (which is fairly consistent with the treatment guidelines)
  - e. Should the guidelines be a web document or a report/recommendations document on MMWR?
    - i. All lab members like the idea of a web document
  - f. How many labs are doing culture and susceptibility testing for GC?
    - i. All states are, but the volume is not very high
    - ii. VT has only a couple cultures
    - iii. Conn does about 1,200 or 1,300 cultures, but they are just oral/pharyngeal (OP) and rectal
      1. Conn does not do susceptibility testing, just ID
      2. The positivity is not very high (i.e. only a couple of positives per month)
      3. Conn has frozen isolates
    - iv. Could labs send their culture data to CDC?
      1. With GISP, all data is male urethral specimens
    - v. NH does about 500 GC cultures a year, and has 10-12 positives a year; it also may do susceptibility testing
    - vi. MA does about 2,000 cultures a year and has 1 or 2 positives a month; it also does susceptibility testing
  - g. The next lab subcommittee meeting will be in September and John Papp will join that discussion and likely have more information on the lab guidelines
  - h. Dr. Bolan would like to have rectal and pharyngeal specimens for NAATs verifications
    - i. This is one of the top priorities
    - ii. It is up to state labs to follow through
    - iii. BD verification

1. One site has almost completed an in-house verification study, which it will then be able to share with others
  - i. Question to John and Rick: If running BD, will there still be language in the guidelines to support off-label testing of other sample types?
    - i. Labs would need to consult the product insert
    - ii. CDC will leave the language ambiguous
    - iii. There is not a lot of cross-reaction in clinical studies
    - iv. Played around with LCX in the lab
  - j. MA doesn't perform repeat testing for CT or GC by NAAT, but reports indicate that there may be cross-reactivity with other non-pathogenic species of Neisseria
  - k. Validation
    - i. ME is doing validation and possibly has specimens to share
    - ii. NH previously validated rectal assay for CT only using the BD Probe Tech
      1. NH has saved all rectal specimens but almost all are negative
      2. The NH state legislature is likely cutting funding so it is unclear how much longer NH will be running validation tests
  - l. Question to John and Rick: When will the new lab guidelines be released?
    - i. The new guidelines will hopefully go out to the committee at the end of June, then will hopefully get clearance at the beginning of August so that they can be released in October/November
  - m. Question to John and Rick: Will there be funding to maintain testing of rectal and pharyngeal specimens?
    - i. This might cost an additional \$20,000-30,000
    - ii. It is a good question that lab members could raise to Dr. Bolan via the Infrastructure
    - iii. John Papp and Rick Steece will bring this up on the next Coordinators call
    - iv. Lab will then discuss the issue again on the September subcommittee call
- B. Off-label validation
- a. Massachusetts
    - i. MA has nearly completed its QX validation
    - ii. The MA validation protocols were reviewed by Charlie Reynolds
    - iii. MA hasn't done pharyngeal validation yet, only rectal validation
  - b. Connecticut
    - i. Conn could get some OP and rectal swabs and then send swabs to MA
    - ii. Conn could also send swabs to NH, because they have the same equipment (except NH is manual and Conn is automated)
    - iii. Conn would like to validate extraction technology
  - c. New Hampshire
    - i. Charlie Reynolds told NH that he wants labs' performance targets before validation begins, so that they can compare the target to actual results
  - d. Maine
    - i. The ME validation protocols were also reviewed by Charlie Reynolds
  - e. The vast majority of states use Aptima
  - f. Labs may want to do seeded samples and test cross-reaction (just 10 or 15 samples)
  - g. Charlie Reynolds also wants to see inter-assay reproducibility
  - h. It does not make sense to do an oral CT test, because supposedly it does not take; but Connecticut has a dual test
  - i. Documents on how to run a validation recommend using 100 samples

- j. If Lab A is using the same criteria/kit/machines as Lab B and Lab B has already conducted reproducibility testing, then Lab A does not need to conduct an additional full-featured validation
- k. Labs should be saving all their specimens
- l. Charlie Reynolds does not want all validation data, just a summary
  - i. The Wadsworth lab in NY has a good sample validation on their website
- C. Introduction of Tracy Stiles
  - a. Tracy Stiles is the new Microbiology Division Director for the MA State Lab
- D. Budgets
  - a. Connecticut
    - i. Conn ran short of money, but might get \$30,000 to \$500,000 of leftover fiscal year money
    - ii. Conn was saved by language in statutes saying that non-profits/colleges/universities can purchase tests kits for the state lab; as a result , the state lab saved about \$35,000
    - iii. Conn is building a new lab, with an expected completion date of spring 2012
  - b. New Hampshire
    - i. NH does not know what the future holds given that the state legislature will likely slash funding
    - ii. NH used this year's funds to buy extra test kits to last through December
  - c. Vermont
    - i. VT has not heard any rumors about the budget
    - ii. The VT sample load is depressing at this point (after a higher-up decided that the state lab should charge more per test to make more money and, as a result, customers have gone elsewhere)
      - 1. The VT state lab went from a specimen value of 16,000 to 5,000 in about 6 months
    - iii. VT might get a new lab in two years
  - d. Maine
    - i. ME has to order kits weekly because it does not know the future of funding
  - e. Massachusetts
    - i. MA is getting a new air conditioning system, which will help with testing efficiency