

Clinical Laboratory Partners Conference Combined Calls Summary

September 10, 2009 at 11 A.M. and September 14, 2009 at 2 P.M.

Sponsored by MDCH Bureau of Laboratories

- I. Attendance Confirmation – Attendees were asked to email ClarkP@michigan.gov to confirm attendance:
 - Sept 10: 67 people from 33 institutions
 - Sept 14: 65 from 36 institutionsDr Frances Downes, MDCH BOL lab director, and Dr. Trish Somsel, Infectious Diseases Division director, thanked and urged all to
 - Please stay healthy – eat well, sleep well, exercise, wash hands
 - Get all flu shots
 - Stay home when you are sick, keep your children home when they are sick
 - Make plans now: what will you do when you have sick family members, or your children’s schools close?

- II. Highlights of Fall 2009 Flu Documents: MDCH has developed several tools, available on our lab novel H1N1 (swine) influenza page at http://www.michigan.gov/mdch/0,1607,7-132-2945_5103-213906--,00.html
See Number VII below.
 - Quick guides – how to:
 - Fill out test requisitions
 - Make your own collection kits
 - Package and ship specimens
 - Downloadable, on-line fillable shipping labels for UN3373 category B substances
 - MDCH Testing protocol algorithms
 - Clinician guidance
 - Link to biosafety guidelines
 - Preparation checklist for labs
 - Rapid testing information

- III. MDCH Collection Kits Contain Pre-Paid Shipping Labels For these specimens, we will pay for mailing by Express Mail (overnight). To order kits – see item X below. Collection procedure was briefly reviewed: http://www.michigan.gov/documents/DCH-0772_7497_7.pdf
See Number VIII below.

- IV. Test Codes – Because the testing changed so quickly, we had two different test number codes last spring. To minimize the confusion, you do not need to write in a test number on the requisition. Simply write “Novel Influenza A” in the space for “other.”

- V. Required Items on Test Request Form – See “quick guide to filling out MDCH test req” for all required fields. Patient city of residence is needed -- we report our results to their local health department. Very important: you must indicate a reason for testing (i.e., which of the targeted groups the patient is in – ICU, pregnant and severely ill, etc.) If any required info is missing, we will freeze the

specimen and return the requisition form to you by fax for response. If there is no response within 30 days the specimen will be reported out as “Not tested.”

VI. Interpretation of Results (Seasonal H1 vs. Novel H1) – The possible report results were reviewed and explained. A written guide to interpretation will be written and distributed via normal channels.

VII. Public Health vs Diagnostic Testing

Due to limited amount of reagents available to us from CDC, MDCH BOL is limiting testing to certain groups targeted by CDC because they are at higher risk for severe disease (ICU hospitalizations, severely ill pregnant women, patients with unusual and severe presentations, influenza related deaths), to congregate setting outbreak/cluster investigations initiated by public health, and to samples submitted by our network of sentinel physicians and sentinel labs to monitor for shifts/drifts in the virus. We understand that this will make your jobs more difficult and wish we could test all the samples your physicians will want tested. However, this will not be possible. Our primary responsibility in utilizing these reagents provided by CDC is to public health directed case investigation and surveillance. Our turn around time will not meet that of private sector labs nor will it meet the demand of your physicians in terms of volume. Again, we will NOT be doing diagnostic testing. Remember, CDC suggests influenza diagnosis based on presentation only is usually adequate to drive treatment decisions. But, because your physicians will demand testing, we suggest you line up alternate sites where diagnostic testing is available. The MDCH lab is validating Novel H1 tests for MI clinical labs through a specimen exchange. This testing can be done in any lab with advanced molecular capabilities. If your lab has this expertise and you would like help validating your novel H1 PCR, contact Patty Clark at the email address on your agenda and we will be glad to assist. The MDCH lab will also be posting a list of MI labs where novel H1 PCR diagnostic testing has been validated and is available. Additionally, there are national laboratories where PCR testing for novel H1 is available. Check the MDCH BOL web page (address at the bottom of the agenda) for a listing of these labs.

If we are to provide the surveillance in the targeted groups that might detect a change in the virulence or resistance of this virus, we will need to receive specimens from these patients. Due to our turn-around-time, the clinician may choose to have the specimen sent to a private laboratory for testing. In that case, we would ask you consider splitting the aliquot and sending a portion to us, or collecting two specimens (if on a swab). Alternatively, you could request the testing laboratory, if in MI, to send positives on to us for further testing.

Another item we should address is the use of rapid testing. Rapid tests may have only a 40% PPV with 2009 novel H1N1, as opposed to 60-80% in seasonal flu. Health care providers who diagnose and treat influenza patients must be cognizant of the fact that a negative rapid test result does NOT rule out influenza infection with the 2009 novel H1N1 virus and is not a good screening test for this virus. There has been at least one published account of the death of a patient at risk for severe disease whose inappropriate treatment was based upon false negative rapid tests. Furthermore, rapid tests do not differentiate between subtypes of influenza A and some types do not detect influenza B

virus. Also it is important to remember that the performance of any influenza test is dependent upon the quality of the specimen. CDC has a lot of great information regarding rapid testing on their novel H1N1 page at http://www.cdc.gov/h1n1flu/guidance/rapid_testing.htm

VIII. Where To Find Things on the BOL Web Page <http://www.michigan.gov/mdchlab>
Follow link to Laboratory Novel H1N1 (Swine) Influenza Page

IX. Minimum Packaging & Shipping Requirements – a quick guide for review will be prepared and posted. These are “Category B” infectious substances, and some regulations apply even to specimens transported by courier. Please do not use wet ice – if specimen tubes get wet, we will assume that it is due to specimen leakage, and they will not be tested.

X. Specimen Collection Kit Distribution – We are pre-deploying collection kits (including the paid postage labels) around the state in each local health department jurisdiction, and have placed about 1400 kits already. We are also prepared to stock each hospital lab with 10 collection kits, which can be replenished as they are used. (E.g., please do not request 10 kits on Monday, 10 kits on Tuesday, etc.). These kits are to be used only for the MDCH surveillance and targeted testing, not for routine diagnostic testing of patients outside the targeted groups. Order kits by sending an email to Dr. Massey at MasseyJ@michigan.gov or by telephone at 517-335-8074.

XI. MALPH web site (www.malph.org) or MIHAN Directory for public health contacts – If we have to go to a pre-approval process as we did in spring, you may need to contact your local health department. We suggest you find out now who will be the best person to contact. Michigan Association of Local Public Health maintains a directory on their webpage. You may also search the directory in the MIHAN.

XII. Q & A

Q. Is it true that no pre-approval is required now? **A.** Yes, but you must indicate the reason for testing – patient’s diagnosis or risk group, which targeted testing group, etc.

Q. Can we order collection kits now? **A.** Yes. See X above.

Comment – the labs that are validating the PCR assay may not be prepared to accept samples from other labs. Strongly suggested you make prior arrangements.

Q. Can you give us an example of what you mean by “unusual presentation?” **A.** Yes. Consider presentations such as Guillain Barré syndrome, ARDS, cardiac or neurologic complications, especially those that could be an indication this virus is changing.

Q. What is the minimum specimen volume, in case we must “split” a sample? **A.** Our viral transport medium (VTM) contains 3 ml, other manufacturers provide 2 ml. We would like at least 2 ml.

Q. Are you accepting viral cultures? **A.** Yes, from Sentinel lab sites only.

Q. What do we do if we had a patient tested in a reference lab but MDCH needs a sample? **A.** Please consider collecting a second sample or save an aliquot from the original.

Comment: Nasal aspirate is an approved specimen type. Send 2-3 ml.

Clarification: Please express all the liquid from the swab against the inside of the tube and discard the swab from the before sending to us.

Q. What do we do if our local health department is not involved in the pre-approval process? **A.** We recognize this was a problem in the spring and this is being addressed. The approval process will include some accommodation for these situations.

Suggestions from Attendees:

1. Create a Quick Guide for Interpretation of Results
2. Utilize the conference call more frequently during the second wave
3. Requests to be on email listing
4. Requests for the link to the CDC rapid flu testing web page
5. Requests for the link to MMWR article on rapid flu testing
6. Requests for collection kits
7. Request for a review of the STEC guidelines via similar conference call