

Laboratory Diagnostics - Appendix 7

Surge Capacity Plan for Eliminating Non-Essential Lab Services

VIROLOGY PROGRAM

Note: Regardless of whether or not a lab or a particular test is deemed essential, samples in all areas listed below can be frozen and then tested at a later time. Hence, the only thing affected would be turn-around-time. As evidence below we describe samples coming from clinics. Activity at these clinics may be curtailed or temporarily suspended during a flu pandemic. If the later is the case, the need to determine whether a lab is essential or not may be made for us.

List of Prioritized Virology Laboratory Services:

1. Molecular Virology
2. Rabies
3. HIV
4. Viral Isolation
5. Viral Serology

1. Molecular Virology: This laboratory would be the **primary testing lab** during a flu pandemic, as real time PCR testing is the current assay of choice for identification of influenza types/subtypes.

This laboratory services state mosquito agencies during the summer/fall months providing surveillance data on arboviral pathogens, particularly West Nile virus and Eastern Equine Encephalitis virus. This data in turn is used to direct mosquito abatement in order to prevent human exposure to these mosquito borne viral pathogens. If a pandemic were occurring during mosquito transmission season a decision would have to be made regarding this testing.

2. Rabies: Testing of potentially rabid animals involved in human exposures would need to be continued regardless of the circumstances. When or if testing is not possible the recommendation would be to proceed with rabies prophylaxis for those individuals involved. Further, elimination of submission of no bite, no exposure animals and surveillance specimens could be warranted at this time.
3. HIV Testing: Specimens are submitted through the HIV Counseling and Testing Site Network. In a pandemic these clinics may not be open to see patients. If the clinics are still operating as usual, and timely testing of those samples was impossible, then samples should be frozen until normal laboratory activity could recommence.
4. Viral Isolation: May take part in sample testing for a novel strain of influenza. Samples submitted for other pathogen identification could be frozen and assayed at a later time.
5. Viral Serology: Archive samples at -20°C until normal activity is restored. Any outbreak events would be supported with timely testing.

Curtailling lab activity as outlined above for the Virology Program would free 6-10 Virology staff to perform tasks related to pan flu. The current assay of choice is real time PCR at the present time. An assay has been authored by LRN staff to identify the H5N1 virus. Available staff would perform the following tasks:

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Sample Processing

This involves transferring the sample from its shipping container into a 2-dram vial. This must be done aseptically in a biosafety cabinet, and in a manner preventing the creation of aerosols. Gloves should be changed after handling each specimen to avoid contaminating the next sample. Samples will be sorted into batches for PCR testing. Three workstations on the laboratory's 5th floor will be used for this purpose. Staff will be assigned to this task depending on incoming sample volume.

Nucleic Acid Extraction

Batched samples will be processed manually if sample volume allows. Two work stations exist in L230 for this purpose. If sample volume dictates two 9604 BioRobots will be employed to perform viral nucleic acid extraction. One technician would be required to run the Robots.

Master Mix Preparation

This could be accomplished at a single workstation or expanded as necessary.

Plate Preparation for PCR Testing

This task could be done manually, but only if the number of incoming samples is low. For higher sample thru-put the 9604 BioRobots will be employed to load PCR plates with sample and master mix.

PCR Amplification/Detection

PHEL has five ABI 7000 Sequence Detection Systems. Two are located in the MDS Lab and three are located in the modular laboratory. These instruments operate in a 96-well format and can test 24 samples in one run. If higher thru-put is required virology has two ABI 7900 Sequence detection System which work on a 384-well platform. On this instrument 96 samples could be run at one time. All these instruments are walk-away requiring no technician intervention during operation.