Virologic Surveillance for Influenza

I. Rationale

a. Monitor the local spread of the disease and gauge the effectiveness of interventions.
b. Enhance the opportunity in New Jersey to identify earliest case involving a novel or pandemic strain of influenza
c. Refer isolates to CDC in order to monitor antiviral resistance and other characteristics of circulating strains
d. Provide physicians and hospitals with assistance in the form of laboratory testing assistance to aid them in rendering a diagnosis.

II. Current New Jersey Department of Health and Senior Services Division of Public Health and Environmental Laboratories (PHEL) Testing Capabilities

- PHEL is prepared to isolate/grow on tissue culture and identify by type and subtype human influenza strains that may be or are currently circulating in North America, including A/H1, A/H3, A/H5 and B.
- PHEL BSL2 laboratory will inoculate patient sample material onto tubes seeded with RhMK, observe cultures over a 10 day period for CPE and, as warranted, perform DFA/IFA to identify pathogen for flu type/subtype.
- PHEL will concurrently perform real time PCR assay (APHL protocol) for same
- PHEL, as warranted, will perform a Rapid Antigen Assay on patient samples to determine flu type. This assay type is a useful tool when a timely result is deemed a necessity since turn around time for test results is less than an hour. The caveats with assays are well documented particularly regarding sensitivity and positive/negative predictive value.
- Determine presence of A/H7 in the event that routine subtyping does not yield a definitive diagnosis. Inform DHSS's Communicable Disease Service (CDS) and CDC if H7 is identified in patient clinical sample.

III. PHEL Laboratory Testing Methods

a. <u>Isolation</u>: Growing the viral strain in cell culture is the "gold standard" for influenza diagnostics because it confirms that the virus is viable. Virus isolation followed by antigenic and genetic (sequencing) analysis is used to characterize influenza isolates, as well as to monitor virus for novel strains. As a collaborating laboratory in the WHO Global Influenza Surveillance Network, PHEL's Virology Program uses virus isolation followed by DFA, IFA staining, or RT-PCR to monitor circulating seasonal strains of influenza.

b. **<u>Real-time PCR</u>:** Influenza specimens can be typed and subtyped using RT-PCR, which does not require *in vitro* growth or isolation of the virus. Protocols/reagents, provided through the Laboratory Response Network (LRN) for confirmatory level laboratories, will be used by PHEL for the identification of this pathogen in a clinical sample.

c. **Rapid Antigen Testing:** Several rapid diagnostic test kits based on antigen detection are commercially available for influenza. The specificity and, in particular, the sensitivity of rapid tests are lower than for viral culture and vary by test and specimen tested. The majority of rapid tests are >70% sensitive and >90% specific. Thus, as many as 30% of samples that would be positive for influenza by viral culture may give a negative rapid test result with these assays. The PHEL uses a rapid diagnostic kit that detects both influenza A and B viruses from a variety of specimen types. Like RT-PCR, rapid diagnostic tests do not require *in vitro* growth or isolation of virus.