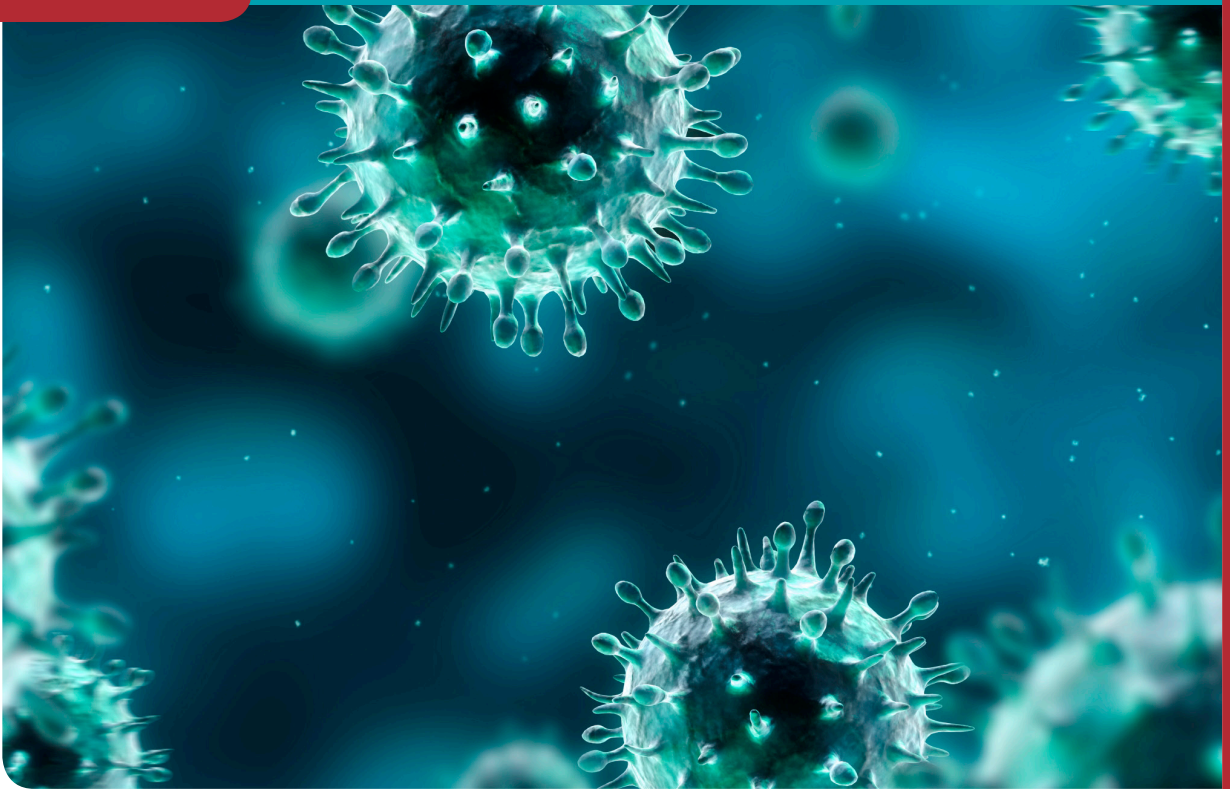


Influenza Virologic Surveillance Right Size Roadmap

Implementation Checklists

June 2014



Right Size Roadmap Implementation Checklists Instructions for Use

The Roadmap Implementation Checklist has been developed to help public health laboratories and health departments assess their influenza surveillance program, identify areas for potential improvements and prioritize changes in relation to the requirements put forth in the *Influenza Virologic Surveillance Right Size Roadmap*. **These checklist worksheets are for your jurisdiction's internal use only.**

As outlined in the Roadmap, a successful virologic surveillance program requires collaboration and coordination between public health laboratory and health department personnel. When using the Roadmap Implementation Checklist, it is strongly encouraged that your jurisdiction identifies one public health laboratory staff member and one epidemiologist or influenza coordinator to facilitate use of the Roadmap checklist by a workgroup. Facilitators should be familiar with the Roadmap and have extensive knowledge of your jurisdiction's influenza virologic surveillance program. When forming a workgroup(s) to address the Roadmap and this checklist, consider all stakeholders and select appropriate participants as it pertains to each section. Personnel to consider include, but are not limited to: influenza testing staff, virology supervisors, laboratory directors, state epidemiologists, infectious disease epidemiologists, influenza coordinators, informatics/information technology staff, clinicians and training coordinators.

Laboratory Right Size Implementation Lead: _____

Phone: _____ Email: _____

Epidemiology/Influenza Right Size Implementation Lead: _____

Phone: _____ Email: _____

Instructions for Use:

- The checklist is divided into separate worksheets for each of the Roadmap requirement areas.
- On each worksheet you will find a list of the requirements in that area followed by related questions for consideration.
- Two worksheet formats, with identical content, are provided to help best suit different needs and approaches to completing the worksheet.

- 1. Printable PDF:** For each question and/or requirement, describe your current activities and procedures and refer to written protocols, if available. Select the most closely related status in the checkboxes below each question (or create your own status checklist). For items that will be implemented in the near future or need improvement, it is suggested that the workgroup list appropriate action items, assign a responsible person(s) and select a target completion/milestone date.
- 2. Excel Spreadsheet:** This version was developed to allow more space for capturing written notes and comments. It also provides more flexibility if you want to add different implementation status checkbox options or other fields. The same information as described above for the PDF is included in this version. Rather than checkboxes, a drop-down menu is available for status implementation; additional status implementation options can be added by just typing into this field so they can be tailored to your jurisdiction.

Questions to consider are provided in the worksheet to guide, not limit, discussions; some questions may not be applicable to all jurisdictions. Each jurisdiction is encouraged to review the Roadmap and determine additional questions and areas for further discussion.

It is widely recognized that there is no universal solution for virologic surveillance and as such your workgroup and jurisdiction will need to define your own criteria and definitions for success for some of the checklist items. You are encouraged to keep quality monitoring, improvement and evaluation metrics in mind while working through the questions and to establish a quality management system as appropriate for requirements that you select.

Helpful Resources

- 1. Influenza Virologic Surveillance Right Size Roadmap:** <http://www.aphl.org/aphlprograms/infectious/influenza/Pages/Influenza-Virologic-Surveillance-Right-Size-Roadmap.aspx>
- 2. Influenza Virologic Surveillance Right Size Sample Size Calculators:** <http://www.aphl.org/aphlprograms/infectious/influenza/Pages/Influenza-Virologic-Right-Size-Sample-Size-Calculators.aspx>
- 3. Questions or feedback?** Contact fluquestions@aphl.org.

Select questions may be used in future APHL surveys to gauge Right Size implementation.

SAMPLING

(Roadmap 1st Ed., Pg. 22)

Sampling Requirements: Provide year-round access to clinical specimens from ILINet providers and/or other primary care providers and clinical laboratories.

Sampling Requirement 1: Establish a system that ensures efficient collection and timely flow of high quality specimens from the patient management tier of influenza surveillance to the CDC tier throughout the year.

1. Are criteria established for recruiting specimen providers (e.g., ILINet providers) that are representative of the population as a whole or of specific target populations as needed to meet surveillance objectives?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Do other providers (e.g. hospital laboratories, commercial laboratories) routinely submit specimens? Are these samples representative of the whole population?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Do you have a source of influenza specimens from a variety of patient types and outcomes (e.g. hospitalized, non-hospitalized, fatalities)? Do you currently collect or at least have the ability to alter the system to collect specimens year round?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Sampling Requirement 1 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Sampling Requirement 2: Establish a representative network of specimen submitters using ILINet providers and/or other clinical primary care sources. Also, collect specimens from hospital/clinical laboratories to ensure that a subset of specimens represents hospitalized patients. Capture unsubtypable¹ influenza positives from clinical and commercial laboratories performing PCR methods that subtype currently circulating viruses.

1. Are ILINet providers and other clinical primary care sources recruited and trained prior to the start of influenza season?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Is a point of contact identified at each sentinel provider or hospital laboratory?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Does your laboratory have appropriate procedures in place to assure quality and timeliness of specimens received?

- **For example, consider the following questions: How are specimens transported to the laboratory? What is the typical transit time? Do specimen collection kits include freezer packs if transportation time makes it necessary? Do specimen collection kits include up to date instructions?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Are you aware of the subtyping capabilities of clinical laboratories in your jurisdiction? (Also see Partnerships and Communications: Page 21, Q6)

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Sampling Requirement 2 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

¹ Any influenza positive specimen that cannot be definitively typed and subtyped as a circulating seasonal influenza virus and/or influenza positive specimens producing non-standard or inconclusive results as defined in the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel Instructions for Use package insert.

Sampling Requirement 3: Utilize a statistical, systematic approach to collect an appropriate, adequate number of specimens for testing that will provide reliable data with acceptable confidence limits to meet surveillance objectives and recommended thresholds of detection, including timely detection of rare/novel influenza events. The sampling methodology should limit sampling bias where possible.

1. Have you used the Right Size sample size calculator or other internal assessment/tool to evaluate your program’s sample numbers?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Have you needed (or plan to) to adjust your recruitment and training for specimen providers to meet the target sample sizes for novel event detection and situational awareness?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Does your network of submitters (ILINet, clinical partners, clinical laboratories, etc.) also include providers that submit representative specimens that are not pre-screened positive specimens? If so, what percentage of your total specimens do you receive that are unscreened for influenza test status prior to submission? (Note: See Roadmap 1st Ed, page 66 for screened vs unscreened definitions)

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Do clinical laboratories submit specimens that are both screened and unscreened in accordance with your jurisdiction’s sampling and sample size criteria?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Sampling Requirement 3 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Sampling Requirement 4: Utilize sampling approaches that ensure specimens submitted throughout the entire surveillance specimen submission and testing process are representative of: virus types and subtypes, the entire year, geographic diversity of the population, age of influenza-like illness (ILI) patients, disease severity, and targeted populations when necessary for specific investigations.

1. Are there communications to providers and/or laboratories to submit specimens for influenza testing year round? (Also see Sampling: Page 4 Q3 and Page 7 Q5)

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Have you evaluated your previous year's sampling for geographic and age distribution? Is it representative of your overall population?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Is disease severity or hospitalization status captured on your specimen requisition? Do you monitor for this? If so, how and by whom is this additional information monitored? Note: In this context, disease severity indicators could include clinical, epidemiologic (demographics, residence) and outcomes (died, hospitalized, ICU) related information.

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Do you have the ability to quickly modify specimen sources and patient types (e.g., if H3N2v were identified in children at fairs, could you quickly modify your surveillance systems to capture your target population)?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

5. Are the target numbers of specimens submitted year-round? Is there a way to increase off-season submissions, if needed?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

6. Does your network of selected providers include members representative of each geographic region in your state?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

7. Do you have providers that are representative of different healthcare settings (acute care, outpatient) and which collect samples across different targeted demographic populations (children, adults, elderly)?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Sampling Requirement 4 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Sampling Requirement 5: Send representative clinical specimens and/or virus isolates to CDC or a CDC-designated laboratory for national surveillance purposes, including annual vaccine virus selection, based on annual CDC criteria and guidance.

1. Are CDC specimen submission instructions and other documents maintained in an organized manner and accessible location? Is a system in place for selecting specimens to submit to CDC?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Have you evaluated the representativeness (e.g., age, geography, severity of illness, influenza type/subtype) of specimens submitted to CDC or a CDC-designated laboratory in the previous season?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Sampling Requirement 5 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

LABORATORY TESTING

(Roadmap 1st Ed., Pg. 27)

Laboratory Testing Goals: *Ensure capability to detect type, subtype and characterize influenza viruses from clinical specimens in a timely manner using reliable laboratory methods.*

Testing Requirement 1: Utilize molecular detection, typing and subtyping methods (e.g., rRT-PCR) for influenza virologic surveillance.

1. Does your laboratory use the CDC Flu rRT-PCR Dx Panel for typing and subtyping influenza viruses? If you are not using the CDC assay, have you discussed the rationale for not doing so?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Testing Requirement 1 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Testing Requirement 2: Maintain instrumentation, personnel, expertise and adequate capacity to test the volume of specimens needed to achieve surveillance objectives.

1. Who in your laboratory is responsible for ensuring influenza testing equipment is maintained appropriately?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Is maintenance being performed according to manufacturers' recommendations and regulatory requirements?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Are service contracts in place to enable routine or emergency repairs?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Do you have adequate staffing levels to perform influenza surveillance testing?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

5. Does staff have adequate education and training to maintain the necessary expertise to perform molecular testing?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

6. Have you reviewed your job descriptions and minimum education/experience levels to ensure they are appropriate for staff performing molecular detection methods?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

7. Has staff met the training requirements of your organization?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Testing Requirement 2 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Testing Requirement 3: Ensure that staff members are knowledgeable in general principles of virology, molecular biology and surveillance, as well as appropriate specimen collection, handling and transport methods.

1. Do you evaluate staff knowledge in principles of virology, molecular biology and surveillance either at hire or on-the-job?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Are continuing education opportunities for expanding the knowledge of virology, molecular biology and surveillance offered to staff?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Are the following reviewed and updated, as needed, at minimum annually: 1) package inserts for commercially obtained kits and 2) all standard operating procedures, worksheets and policy documents (e.g., specimen collection, handling and transport procedures)?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Testing Requirement 3 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Testing Requirement 4: Notify CDC immediately and ship unsubtypeable influenza A viruses to CDC within 24 hours of detection to rule-out novel viruses.

1. Is there a documented procedure for immediate notification and shipment to the CDC, in the event of detection of an unsubtypeable influenza A virus? Does everyone who performs influenza testing know the procedure? Are after-hours phone numbers for laboratory staff, supervisors and the laboratory director available to all staff?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Are staff adequately trained on how and to whom to send unsubtypeable specimens, including being currently certified for training in packaging and shipping of specimens?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Testing Requirement 4 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Testing Requirement 5: Routinely refer a representative subset of specimens (and viruses) to CDC or a CDC-designated laboratory for genetic and antigenic characterization.

- 1. Who in your laboratory is responsible for selecting specimens to refer to CDC or designated laboratories for further characterization? Do they have training in packaging and shipping, and are they aware of the most current CDC influenza specimen submission criteria?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

- 2. Do the staff who are selecting specimens to send to CDC attend the CDC/APHL national informational calls at the start of, and during, influenza season?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

- 3. In the last influenza season, did your laboratory routinely submit the requested number of influenza viruses in the specified time frame to CDC or CDC-designated public health laboratory?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

- 4. Have epidemiology and laboratory staff discussed how the subset of specimens are selected to send to CDC or the CDC designated public health laboratory? Does the laboratory communicate CDC surveillance testing results on these specimens back to epidemiology staff?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Testing Requirement 5 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Testing Requirement 6: Maintain capability to rapidly adopt new molecular test methods or test modifications if a new influenza virus with pandemic potential emerges or when new technology provides improvements to virologic surveillance.

1. Does your laboratory maintain situational awareness for disease outbreaks and emerging influenza viruses (e.g., monitoring CDC FluView, WHO website and maintaining communications with epidemiologists)?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Is the appropriate laboratory staff receiving email announcements from CDC and/or APHL?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Do you have assay validation templates, training checklists and SOP templates available?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Do you have adequate staff to validate new tests and/or train on new tests while continuing routine testing?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Testing Requirement 6 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Testing Requirement 7: Maintain additional influenza testing capabilities (as defined in the Roadmap) as appropriate for the jurisdiction or utilize shared testing services models to ensure access to testing.

1. Do you have resources to purchase influenza testing reagents outside of those supplied by the IRR?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Have you discussed what additional testing methods are priorities for your jurisdiction to perform in-house? For those tests that are not a priority have you identified, if needed, alternate methods to obtain this data such as submitting specimens to national reference centers?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Are you aware of the influenza testing capabilities of your neighboring states, your state’s hospital laboratories, clinical laboratories and national reference centers?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Are any formal or informal agreements in place for assistance with testing, if needed?

Note: Some examples, if needed, can be found on the [APHL Members Resource Center](#), using keywords *Policy Guide*.

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Testing Requirement 7 Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

DATA MANAGEMENT

(Roadmap 1st Ed., Pg. 30)

Data Management Requirements: Report results to providers, epidemiologists and CDC.

Data Management Requirement 1: Use electronic data systems that provide data in real time and utilize national standards (HL7, SNOMED, LOINC).

1. Do you have the capability to transmit laboratory test results using data transmission standards (HL7, SNOMED, LOINC)?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Is the transmission of laboratory test results real time? Does it meet the needs of your jurisdiction?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Do you have the ability to communicate laboratory results electronically to providers? To epidemiology staff?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Do you routinely assess your electronic data systems to ensure data is being transmitted and received correctly?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Data Management Action 1 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Data Management Requirement 2: All data submitted should provide: Specimen identifier and unique patient identifier, the state where specimen was collected, date of birth of patient and/or age with unit (years, weeks, months, days), specimen collection date, specimen received date, test method performed, test result.

1. Are these data elements being captured on your laboratory requisition form and within your LIMS?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Are data elements electronically transmitted by your LIMS?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Is data complete? Do you monitor data for completeness and accuracy?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Data Management Action 2 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Data Management Requirement 3: Laboratories that have established PHLIP capability should also provide the following data elements, if available: submitter information, provider identifier for the CDC Program (i.e., ILINet provider, EIP, other), current influenza vaccination status, antiviral treatment, travel information, patient death information, additional geographic information (e.g., county, city, zip), patient location at time of testing (inpatient, outpatient, long-term care facility), whether specimen was related to an outbreak, whether specimen was sent to CDC and if so, include specimen identifier, date of illness onset.

1. Are you currently utilizing PHLIP to report influenza virologic surveillance to CDC?

- If not, have you contacted APHL or CDC to start the process?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Is the auxiliary data described above being collected on your laboratory requisition form and in your LIMS?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. PHLIP participants: Do you have the ability to send any of the extra fields requested?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Data Management Action 3 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Data Management Requirement 4: States should consider incorporating data from rapid test sites and/or clinical laboratories to supplement influenza surveillance state data.

- 1. Does your influenza surveillance system incorporate virologic data from other sources (healthcare providers, clinical/commercial laboratories, NREVSS)? (Also see: Partnerships and Communication, Page 21, Q6)**
- **If yes, is this data from rapid test, PCR or culture? Are both the number positive and the total number tested collected? Are the data case-based or aggregate? Is the data received consistent and reliable? How often is data from alternate sources received (e.g., clinical, commercial, physician office laboratories)? How are these data presented and to whom? Have you discussed with CDC if you should include these data or not in your reports to CDC?**
 - **If no alternate data is collected and incorporated into your surveillance data, have you considered collecting the data in the future? If you do not have enough specimens to meet Right Size calculator targets, would you consider using alternate data? What are the challenges to collecting alternate data?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Do you have a mechanism for receiving and processing virologic data from other sources?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Do you have a method for integrating, or not, these data with PHL data?

- **How do you use alternative data in regards to sample-size calculators?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Data Management Action 4 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

PARTNERSHIPS AND COMMUNICATION:

(Roadmap 1st Ed., Pg. 34)

Partnerships and Communication Requirement: Establish and maintain partnerships and networks enabling communications that support routine surveillance and emergency preparedness and response, data sharing and specimen sharing. Several interrelated partnerships are needed among the public health and healthcare communities for routine surveillance including:

CDC:

- 1. Do you have a current list of CDC influenza contacts (e.g., virus surveillance, Diagnostic Team Lead, Molecular Epidemiology)? Do others in your laboratory know how to access this information?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

- 2. Does everyone know the situations in which CDC should be contacted and with what urgency?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

CDC-Related Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Epidemiologist/Surveillance Coordinator:

- 1. Do PHL staff and epidemiology/influenza coordinators have regular meetings?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

- 2. Are the roles and responsibilities for each party clearly defined for both regular surveillance and in the case of a novel event investigation?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Are there protocols and/or methods in place for data sharing of laboratory results?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Are there effective and timely practices in place to maintain situational awareness between and among PHL staff and epidemiologists/influenza coordinators? Is information shared between groups and distributed to all relevant staff?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

5. If an unsubtypable or novel influenza is identified in your laboratory, are there guidelines for who should be notified (e.g., epidemiologists, supervisors, CDC, local health departments, state health officials or submitting agency) and when?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Epidemiologist/Surveillance Coordinator-Related Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

PHL, Clinical, Commercial Laboratories, Rapid Influenza Diagnostic Testing (RIDT) Sites:

1. Does your laboratory maintain a database of current contact information and influenza testing capabilities for identified laboratories within your jurisdiction?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Do you routinely and collaboratively review the list of contacts to ensure that all key partners are included (e.g., identify new partners, update for staffing changes, etc.)?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Do you have multiple mechanisms for communicating with these groups (e.g., state medical association or Laboratory Response Network meetings, electronic messages, website, fax)?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Do you provide timely communication to all participants and stakeholders?

Examples include: relaying the importance of receiving specimens for confirmatory testing, subtyping and identifying unsubtypable¹ specimens for your clinical partners especially when the threat of a novel virus is high (e.g., H3N2v, H7N9), informing partners of commercial kit shortages, educating partners on the limitations of RIDT, circulating viruses and other surveillance data and reports.

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

5. Do you collaborate to collect influenza testing data and/or specimens from clinical laboratories/testing sites? Is there a mechanism to collect testing data from clinical and commercial laboratories? If so, is this data shared with program and laboratory staff?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

6. Do other laboratories in your jurisdiction perform subtyping? If yes, do they understand the difference in terminology between unsubtypable and not subtyped? Do they report unsubtypable specimens detected at those laboratories to your PHL and know how to forward the specimen? Do they subtype for all circulating strains?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

¹ Any influenza positive specimen that cannot be definitively typed and subtyped as a circulating seasonal influenza virus and/or influenza positive specimens producing non-standard or inconclusive results as defined in the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel Instructions for Use package insert.

7. Are influenza test results reportable to your state? If yes, what influenza data is reportable? How do you communicate what is reportable to laboratories in your state?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Laboratory/Testing Site-Related Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Clinicians:

1. Do you provide reports on the current status of circulating influenza types and subtypes, other respiratory viruses and antiviral resistance, if available, via website, newsletter or other means?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Do you provide education and training to these partners? If yes, what type of training is offered, who delivers it and how?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Do you provide feedback to providers who submit poor quality or improperly packaged specimens?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Clinician-Related Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

QUALITY MANAGEMENT SYSTEMS

(Roadmap 1st Ed., Pg. 37)

Quality Management Systems Requirement: *Establish performance metrics, monitor performance and make improvements as needed to ensure national and state surveillance requirements are being met in an effective and efficient manner.*

Quality Management Systems Requirement: **Establish performance metrics, monitor performance and make improvements as needed to ensure national and state surveillance requirements are being met in an effective and efficient manner.**

1. Have performance metrics for virologic surveillance been identified? Is there a mechanism in place to monitor identified metrics and how often are those metrics re-evaluated?

Describe Current Activities, Procedures and Notes: _____

No Plans to Implement Plan to Implement in Near Future Needs Improvement

Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Do virologic surveillance metrics align with grant/cooperative agreement milestones/deliverables? For example do you track the systematic submission of representative influenza positive clinical materials to CDC according to submission guidance and submit the requested percentage of influenza test results from the PHL to CDC within two weeks of test date?

Describe Current Activities, Procedures and Notes: _____

No Plans to Implement Plan to Implement in Near Future Needs Improvement

Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Do the metrics address other aspects of virologic surveillance (e.g., representativeness, sample size considerations, various surveillance objectives, quality of samples received from submitters)?

Describe Current Activities, Procedures and Notes: _____

No Plans to Implement Plan to Implement in Near Future Needs Improvement

Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Is there a process to address areas needing improvement?

Describe Current Activities, Procedures and Notes: _____

No Plans to Implement Plan to Implement in Near Future Needs Improvement

Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Quality Management Systems Action Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

SURGE CAPACITY

(Roadmap 1st Ed., Pg. 38)

Surge Capacity Requirement 1: Maintain a year-round virologic surveillance system that is flexible and scalable for rapid, effective response to support diagnostic needs and case counts in rare/novel influenza event investigations, enhance surveillance for outbreak and pandemic scenarios and has criteria to determine when to scale up and ramp down.

1. Are staff cross-trained to enable an effective response in a pandemic (including pre-analytical, laboratory testing, post-analytical and quality assurance activities)? Is there a “just in time” training plan to train more staff in testing activities?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Does your laboratory have a high-throughput nucleic acid extraction platform that can be utilized for influenza specimens? Is there other equipment available (e.g., thermocyclers) that can be used for testing additional influenza specimens?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Do both laboratory and epidemiology know where they can locate your state influenza Pandemic Response Plan? Have you read your Pandemic Response Plan this season?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Does epidemiology make laboratory staff aware of, or involve them in the investigations of, respiratory disease outbreaks in your jurisdiction?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

5. Do you have a plan for changing specimen submission requirements during a pandemic or outbreak?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Surge Capacity Action 1 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Surge Capacity Requirement 2: Incorporate the role and resource needs of the PHL in the state pandemic plan. PHL representatives should be part of state pandemic planning processes.

1. Is the PHL involved in the pandemic planning process?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Have you reviewed your 2009 Influenza Pandemic after-action report? Has your pandemic response plan been updated to reflect recommendations in the report?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Surge Capacity Action 2 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Surge Capacity Requirement 3: Develop and maintain a laboratory pandemic surge plan that addresses criteria for specimen triage, algorithm changes to improve throughput, and resource needs (e.g., staff, equipment, space, IT, reagents and supplies).

1. Does your laboratory have a pandemic surge plan? Is it reviewed once a year?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Does your laboratory review and update, as needed, your Continuity of Operations Plan (COOP) and Incident Command structure?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
- Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. Does your pandemic response plan address specimen triage, algorithm changes and resource needs? Do you have a list of vendors where you get your supplies, and do you have agreements to get additional supplies quickly as needed?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Does your pandemic response plan contain the use of right size sample size calculators? Do changes in algorithms and specimen triage align with the sample sizes needed under the evolving surveillance objectives during a pandemic?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

5. Have laboratory and epidemiology staff met to develop a plan about how and when specimen submissions should increase or decrease throughout a pandemic? How would changes in specimen triage or algorithms be communicated with epidemiology staff and/or external partners?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

6. Are agreements established with any other laboratories (clinical, commercial, or other PHLs) to assist with processing specimens during a surge?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

7. Do you have an up-to-date list of other laboratory resources that may be able to assist in processing specimens (e.g. clinical, commercial, university laboratories)? Do you periodically communicate about your potential surge capacity needs with these laboratories?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Surge Capacity Action 3 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

FINANCIAL RESOURCES

(Roadmap 1st Ed., Pg. 41)

Financial Resources Requirement 1: State influenza surveillance programs and PHLs should have adequate funding to support virologic surveillance requirements.

1. Have you identified/estimated the full costs of the current influenza surveillance and laboratory program to your jurisdiction, including personnel, materials & supplies, equipment and overhead/miscellaneous?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

2. Which aspects of your entire virologic surveillance system lack adequate funding?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

3. How are those costs allocated across available funding sources? Do you anticipate any of the sources ones that you anticipate will no longer be available or expect there to be cuts to in the near future?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

4. Have you considered other funding sources (e.g. fee for service, state funds)?

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Financial Resources Action 1 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Financial Resources Requirement 2: State influenza surveillance programs and PHLs should coordinate planning and allocation of available funds (Epidemiology and Laboratory Capacity [ELC], Public Health Emergency Preparedness [PHEP], EIP, state) to program and laboratory elements (staff, information technology, all supplies, reagents and equipment maintenance).

- 1. Is there a process for deciding how to equitably allocate or prioritize available funds across programs to achieve the objectives of flu surveillance, meet any benchmarks required by each funding source and in accordance with the stipulations on the funds? Does the PHL have adequate funding? Does the program have adequate funding?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

- 2. Is there a process for addressing real or anticipated funding and/or resource reductions that will minimize the impact to the jurisdiction’s flu surveillance? (Example: Does your PHL have an estimated cost for reagents in the event that the IRR would not be able to supply reagents?)**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Financial Resources Action 2 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Financial Resources Requirement 3: National, state and local programs and PHLs should have effective cost accounting practices to justify resource needs and efficiently allocate available funds.

- 1. Is there a cost accounting system and process in place that allows you to identify and monitor the true cost of virologic surveillance?**

Describe Current Activities, Procedures and Notes: _____

- No Plans to Implement Plan to Implement in Near Future Needs Improvement
 Currently Implementing/Improving Implementation Complete/Ongoing Maintenance and Monitoring

Financial Resources Action 3 Item(s) and Target Completion Dates: _____

Responsible Person(s): _____

Influenza Virologic Surveillance Important Contacts

NAME	POSITION	PHONE	EMAIL	AFTER HOURS
Public Health Laboratory				
Epidemiology/Influenza Coordinator				
Centers for Disease Control and Prevention				
Other				

Abbreviations

EIP	CDC's Emerging Infections Program
ELC	Epidemiology and Laboratory Capacity for Infectious Diseases cooperative agreement
ICU	Intensive Care Unit
ILI	Influenza-like illness
ILINet	US Outpatient Influenza-like Illness Surveillance Network
IRR	Influenza Reagent Resource
LIMS	Laboratory Information Management System
NRVESS	National Respiratory and Enteric Virus Surveillance System
PHEP	Public Health Emergency Preparedness cooperative agreement
PHL	Public health laboratory
PHLIP	APHL-CDC Public Health Laboratory Interoperability Project
RIDT	Rapid influenza diagnostic test
rRT-PCR	Real-time reverse transcriptase polymerase chain reaction