**Appendix A: Customizable Tables**

**Response Plan Checklist**

The checklist, Table A (below), reflects the steps that are required in a complete investigation, though additional steps may be performed.

* Check “In-house” for any steps that your lab currently performs.
* Check “Referral” for any steps that you would need to refer to another laboratory.

Specific *Legionella* tests performed by your laboratory are recorded in Table D.

**Table A: Checklist**

|  |  |  |  |
| --- | --- | --- | --- |
| **Laboratory Response Step** | **In-house** | **Referral** | **Notes** |
| *Legionella* Isolation | | | |
| Clinical Specimens |  |  |  |
| Environmental Samples |  |  |  |
| Isolate Characterization (e.g., qPCR/MALDI-TOF/Antibody-based) | | | |
| Species |  |  |  |
| *L. pneumophila* Serogroup |  |  |  |
| Molecular Typing (e.g., PFGE/SBT/WGS) | | | |
| *Legionella* Isolate Comparison |  |  |  |

**Response Team Plan**

Identify and record contact information for primary responders within your public health department who would be involved in a Legionnaires’ disease investigation in Table B (below).This team should include representatives from your laboratory and the state or local public health department’s epidemiology, environmental health, and communications divisions with whom you will coordinate activities in the event of a response. Response Team information should be reviewed and updated annually or with any staff changes to ensure accuracy.

**Table B: Response Team Contact Information**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | **Name** | **Email Address** | **Office Phone Number** | **Mobile Phone Number** |
| **Laboratory** | Primary Contact |  |  |  |  |
| Secondary Contact |  |  |  |  |
|  |  | | | | |
| **Epidemiology** | Primary Contact |  |  |  |  |
| Secondary Contact |  |  |  |  |
|  |  | | | | |
| **Environmental Health** | Primary Contact |  |  |  |  |
| Secondary Contact |  |  |  |  |
|  |  | | | | |
| **Communications** | Primary Contact |  |  |  |  |
| Secondary Contact |  |  |  |  |
|  |  | | | | |

**Response Team Plan**

Complete the plan in Table C (below) in coordination with Response Team representatives. This plan allows the team to establish a framework for key activities that will be coordinated across health department epidemiology, laboratory, environmental health, and communications staff in the event of a response. In addition, the completed LDLRP can be shared with the Response Team to inform expectations of laboratory requirements, processes, and turn-around times. The end of this section provides signature lines for documentation of Response Plan agreement.

**Table C: Response Team Plan**

|  |  |
| --- | --- |
| **Response Communications** | |
| Who will contact the laboratory in the event of an investigation? |  |
| Which laboratorian should be contacted first? |  |
| Which laboratorian will report results? |  |
| Who should receive laboratory reports? |  |
| How will laboratory results be reported? |  |
| **Environmental Samples Handling** | |
| What types of environmental samples (e.g., potable water, swabs, cooling tower water) might be collected in an investigation? |  |
| Who will collect environmental samples?  *Note: Include the lead person responsible, a back-up, and all of their contact information.* |  |
| What protocols will be followed for environmental sample collection?  *See the resources section of this toolkit for links to instructional videos and detailed information regarding environmental sample collection for* Legionella *investigations.* |  |
| Who will provide environmental sample collection materials (e.g., sterile watertight containers, swabs)?  *See the resources section of this toolkit for links to instructional videos and detailed information regarding environmental sample collection for* Legionella *investigations.* |  |
| What are acceptable methods of environmental sample delivery and storage?  *See sample requirements in* Table F*.* |  |
| **Clinical Specimens Handling** | |
| What sources (e.g., hospital laboratories) might send clinical specimens (e.g., sputum, lung tissue, bronchoalveolar lavage fluid)? |  |
| Do sources know to collect respiratory specimens during a Legionnaires’ disease response?  **If not,** how will sources be made aware? |  |
| Do you have specimen collection requirements and shipping instructions that can be shared with labs/providers that are shipping you samples?  *See specimen requirements in* Table F *and example shipping requirements in the resources section of this toolkit.* |  |

**Response Team Signatures**

Use Table D (below) to document the LDLRP agreement among your health department’s Legionnaires’ disease Response Team members.

**Table D: LDLRP Team Signatures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title** | **Name** | **Signature** | **Date** |
| Laboratory Primary Contact |  |  |  |
| Epidemiology Primary Contact |  |  |  |
| Environmental Health Primary Contact |  |  |  |
| Communications Primary Contact |  |  |  |

**In-house Testing Plan**

The In-house Testing Plan outlines your laboratory’s Legionnaires’ disease response workflow. Establishing the processes and tests to be performed, who will be performing them, and when to expect results will increase your laboratory’s efficiency and manage expectations for obtaining results during a response.

Use Table E (below) to designate test protocols that will be performed in-house, who is trained and responsible for performing these tests, what results will be generated, and the turn-around time for results. Non-culture methods of *Legionella* detection directly from specimens or samples have also been included below. However, this step is not required for a complete *Legionella* investigation. The In-house Testing Plan should be reviewed and updated annually or with any staff changes to ensure accuracy.

**Table E: In-house Testing Responsibilities**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **In-house Process Step** | **In-house Protocol Name(s)** | **Staff Member Responsible** (multiple names may be listed) | **Results Reported** (genus, spp, serogroup, etc.) | **Turn-around Time** |
| *Legionella* Detection (e.g., qPCR/DFA/UAT) | | | | |
| Clinical Specimens |  |  |  |  |
| Environmental Samples |  |  |  |  |
| *Legionella* Isolation | | | | |
| Clinical Specimens |  |  |  |  |
| Environmental Samples |  |  |  |  |
| Isolate Characterization (e.g., qPCR/MALDI-TOF/DFA/latex agglutination) | | | | |
| Species |  |  |  |  |
| *L. pneumophila* Serogroup |  |  |  |  |
| Molecular Typing (e.g., PFGE/SBT/WGS) | | | | |
| *Legionella* Isolate Comparison |  |  |  |  |

**Specimen and Sample Requirements and Storage Policies**

Table F (below) provides a space to document the minimum requirements or acceptance criteria for:

* Clinical specimens or environmental samples that may be processed during a response
* Short- and long-term storage conditions
* Locations for each material
* How long each material will be retained by your laboratory

Examples are listed.

**Note:** Distribute information recorded in the table below related to acceptance criteria, pre-shipment storage instructions, and shipping requirements to entities that may send clinical specimens or environmental samples to your laboratory for processing. Having a pre-made document helps ensure the integrity of specimens and samples received and reduce shipping delays. An example shipping document is available in the resources section of this toolkit.

**Table F: Specimen and Sample Requirements and Storage Policies**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Accepted  Specimens/ Samples** | **Specimen/ Sample Minimum Requirements** (volume, other specifications, etc.) | **Storage Before Shipment** (temperature, duration, etc.) | **Shipping Conditions** (temperature, cold packs, dry ice, etc.) | **Length of Retention After Testing** |
| Clinical Specimens | | | | |
| Urine |  |  |  |  |
| Sputum |  |  |  |  |
| Tissue |  |  |  |  |
| Bronchoalveolar Lavage |  |  |  |  |
| Other |  |  |  |  |
| Environmental Samples | | | | |
| Potable Water |  |  |  |  |
| Cooling Tower Water |  |  |  |  |
| Swabs |  |  |  |  |
| Filters |  |  |  |  |
| Others |  |  |  |  |
| *Legionella* Isolates |  |  |  |  |

**In-house Testing Plan**

Table G (below) contains additional questions to consider regarding in-house testing. Space is provided for responses or notes related to each question.

**Table G: In-house Testing Plan**

|  |  |
| --- | --- |
| **Documentation** | |
| Which documents will be used to record the chain of custody of clinical specimens or environmental samples? |  |
| Which documents will be used to record results from each in-house laboratory process or test that will be performed on clinical specimens or environmental samples? |  |
| Which documents will be used for reporting results from clinical specimens or environmental samples? |  |
| How will you use your document management system to help prepare for information requests related to a potential legal investigation? |  |
| **Clinical Specimens** | |
| Most legionellosis cases are identified by UAT, but respiratory specimens are important for linking clinical isolates to environmental sources. How will clinicians be asked to obtain respiratory samples? |  |
| Do you have a document with shipping instructions for labs/providers? |  |
| Have you successfully completed proficiency testing or an alternative assessment for each of your tests? |  |
| **Environmental Samples** | |
| Do you plan to screen environmental samples for the presence of *Legionella* DNA with qPCR?  **If yes,** does this qPCR include an inhibition control?  *This control is required due to the composition of environmental water samples.*  **If yes,** does your laboratory retain qPCR-negative environmental samples to attempt isolation if needed?  **If yes,** have your tests been validated within your laboratory?  *If qPCR is used with environmental samples, CDC recommends that it be implemented primarily to screen and prioritize processing of large numbers of samples for culture.* |  |
| Have you successfully completed proficiency testing or an alternative assessment for each of your tests?  *Information related to the Environmental* Legionella *Isolation Techniques Evaluation (ELITE) alternative assessment program can be found here:* [*http://www.cdc.gov/legionella/elite.html*](http://www.cdc.gov/legionella/elite.html) |  |
| **Workforce Capacity** | |
| What is the maximum test volume that may be processed by your laboratory using currently trained and competent staff? |  |
| List additional staff that can be trained if a large scale outbreak occurs. |  |
| List any laboratory activities or testing that may be affected by redirecting staff. |  |
| Are staff available to work weekend or holiday hours in the event of a high-priority response?  *If staff are not available to work extended hours during an investigation, the Response Team should be informed at the onset and expectations about the timeline for results adjusted accordingly.* |  |
| **Culture** | |
| Will your laboratory make or order BCYE agar plates?  *BCYE agar is a specialized media specific for* Legionella *growth. This media has an extensive ingredient list and can be challenging to make correctly. BCYE agar is available commercially, but can be expensive and is often back-ordered in the summer months, the most common time of year for Legionnaires’ disease outbreaks. See the resources section of this toolkit for links to detailed protocols.* |  |
| How many BCYE plates does your laboratory normally keep in supply?  *While actual plate requirements will vary by investigation and laboratory protocols, a mid-size investigation with 25 environmental samples and 2 clinical specimens, for example, could require 250 or more BCYE agar plates total. See the* Example Laboratory Response Scenario *for more details.* |  |
| What types of selective BCYE agar will you use?  *CDC recommends the use of selective BCYE agar plates containing the following types of selection:*   1. *Polymyxin, vancomycin, and cyclohexamide* 2. *Polymyxin, vancomycin, cyclohexamide, and glycine*   ***Note:*** *Other antibiotics may be substituted. See the resources section of this toolkit for links to detailed protocols.* |  |
| ***Legionella* Identification** | |
| How many colonies do you pick per plate from original specimen/sample plates to screen for cysteine auxotrophy?  *This informs the number of downstream isolates to be processed and BCYE agar plates used. Weigh increased workload vs. sensitivity of detection.* |  |

|  |  |
| --- | --- |
| **Storage** | |
| Do you have overflow storage space at required temperatures to accommodate environmental samples and related culture plates that can be used during a response?  **If yes,** what is the maximum capacity? |  |
| **Referral Laboratory** | |
| How many environmental samples can your lab handle before surge assistance is required? |  |
| What other factors will determine if you need support from a referral laboratory?  *(i.e., type of isolates recovered, need for molecular typing)* |  |
| **Administration** | |
| What are the funding mechanisms for a Legionnaires’ disease response?  *A Legionnaires’ disease response often requires increased use of lab supplies, test reagents, and personnel overtime.* |  |
| **Post-response Activities** | |
| Will clinical specimens be retained?  **If yes,** for how long? |  |
| Will environmental samples be retained?  **If yes,** for how long? |  |
| Will any *Legionella* isolates from clinical specimens or environmental samples be stored?  **If yes,** for how long? |  |
| If indicated, will there be remediation sampling and in-house laboratory testing? |  |

**Related Documents**

List any laboratory documents (policies, processes, technical procedures, or protocols) related to the In-house Testing Plan in Table H (below).

**Table H: Related Documents**

|  |  |
| --- | --- |
| **Document Title** | **Document Number/Location** |
|  |  |
|  |  |
|  |  |
|  |  |

**In-house Testing Plan Notes**

Record any additional information or notes related to your In-house Testing Plan in the space below.

|  |
| --- |
|  |

**Referral Laboratory Contact Information**

List the contact information for the referral laboratories you have established in Table I (below).

**Table I: Referral Laboratory Contact Information**

|  |  |  |
| --- | --- | --- |
|  | **Primary Referral Laboratory** | **Secondary Referral Laboratory** |
| **Referral Laboratory Name** |  |  |
| **Tests Requested** |  |  |
| **Primary Point of Contact** | | |
| Name |  |  |
| Phone Number |  |  |
| Email |  |  |
| **Secondary Point of Contact** | | |
| Name |  |  |
| Phone Number |  |  |
| Email |  |  |
| **Who is responsible for contacting the referral laboratory?** |  |  |
| **At what point in response should the referral laboratory be contacted?** |  |  |
| **Additional Notes** |  |  |

**Referral Laboratory Plan Overview**

Document expectations of the referral laboratory in advance of a response in Table J (below).Record each type of specimen or sample, requested tests, anticipated cost, resulting information, and expected turn-around time. In the case of more than one referral laboratory, adding a “Referral Laboratory Name” column may be helpful.

**Table J: Referral Laboratory Plan**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Referral Laboratory Process Step** | **Materials to Be Shipped** (specimen/ sample/ isolate) | **Tests Requested** | **Cost** (per specimen, sample, or isolate) | **Results Reported** (genus, spp, serogroup, molecular typing) | **Turn-Around Time** |
| *Legionella* Isolation | | | | | |
| Clinical Specimens |  |  |  |  |  |
| Environmental Samples |  |  |  |  |  |
| Isolate Characterization (e.g., qPCR/MALDI-TOF/Antibody-based) | | | | | |
| Species |  |  |  |  |  |
| *L. pneumophila* Serogroup |  |  |  |  |  |
| Molecular Typing (e.g., PFGE/SBT/WGS) | | | | | |
| *Legionella* Isolate Comparison |  |  |  |  |  |

**Referral Laboratory Storage and Shipping Requirements**

Complete Table K (below) by contacting the referral laboratory to determine specific requirements for storing and shipping specimens or samples. This information is essential for ensuring materials being shipped will meet the referral laboratory’s acceptance criteria and that the integrity of the materials remain uncompromised. Example specimen and sample types are listed.

**Table K: Referral Laboratory Storage and Shipping Requirements**

|  |  |  |  |
| --- | --- | --- | --- |
| **Referred Specimens/Samples** | **Referral Lab Minimum Requirements** (volume, other specifications) | **Referral Lab Requirements Before Shipment** (temperature, duration) | **Referral Lab Shipping Specifications** (temperature, packaging, delivery service, acceptable dates) |
| Clinical Specimens | | | |
| Sputum |  |  |  |
| Respiratory Tissue |  |  |  |
| Bronchoalveolar Lavage (BAL) |  |  |  |
| Other |  |  |  |
| Environmental Samples | | | |
| Potable Water |  |  |  |
| Cooling Tower Water |  |  |  |
| Swabs |  |  |  |
| Filters |  |  |  |
| Other |  |  |  |
| *Legionella* Isolates |  |  |  |

**Referral Laboratory Plan Notes**

Record any additional information or notes related to your Referral Laboratory Plan in the space below.

|  |
| --- |
|  |