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**Rapid Influenza Diagnostic Testing Practices in Laboratories**

***The following questions are about rapid influenza diagnostic testing (RIDT) practices and procedures in your laboratory. These questions should be completed by the Laboratory Director or Laboratory Supervisor.***

**Section A: Background and Demographic Information**

1. Which of the following best describes your title?

❒a. Laboratory medical director

❒b. Laboratory director

❒c. Laboratory manager - administrative

❒d. Technical consultant

❒e. General supervisor

❒f. Specialty supervisor

❒g. Non-supervisory testing personnel

❒h. Other (Specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1a. Which of the following best describes your laboratory?

❒a. Independent

❒b. Reference laboratory

❒c. Laboratory inside a hospital

❒d. Other (Specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1b. Which of the following best describes the facility in which you work? (Please select one.)

❒a. Community (City or County) non-profit hospital

❒b. Community for-profit hospital

❒c. Laboratory for a hospital and/or clinic (i.e. centralized laboratory) network

❒d. University/Medical school/Teaching Hospital

❒e. Veterans Administration Hospital

❒f. Commercial/Independent laboratory, Single location

❒g. Commercial/Independent laboratory, Multiple locations

❒h. Outpatient clinic

❒i. Other (Specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1c. If you answered “hospital” above, what is the size of your hospital?

       ❒a. Greater than 500 beds

       ❒b. 200-499 beds

       ❒c. 100- 199 beds

 ❒d. Less than 100 beds

1d.What type(s) of Clinical Laboratory Improvement Amendment (CLIA) certificate(s) does your laboratory hold? *(Select all that apply)*

 ❒a. Certificate of Waiver

 ❒b. Certificate for Provider-Performed Microscopy Procedures (PPMP)

 ❒c. Certificate of Registration

 ❒d. Certificate of Compliance

 ❒e. Certificate of Accreditation

1e. What are the qualifications of your microbiology laboratory director?

❒ a. Clinical microbiologist PhD

❒b. Clinical microbiologist and Pathologist MD

❒c. Clinical microbiologist MD

❒d. Pathologist director (AP only)

❒e. Pathologist director (AP/CP)

❒f. Physician director, type\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ g. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1f. Does your microbiology laboratory director have any of the following certifications?

❒ a. American Board of Medical Microbiology (ABMM)

❒ b. American Board of Pathology, Medical Microbiology

❒ c. Neither of the above

❒ d. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section B: Testing Practices**

2. Have RIDTs ever been performed in your laboratory?

 ❒ a. Yes 🡪 **Continue with Question 2a**

 ❒ b. No 🡪 **Explain below and then Skip to Question 28-28d and then end survey)**

 **If No,** why are rapid influenza diagnostic tests **not** performed in your laboratory?*(Select all that apply)*

 ❒ 1. Rapid test kits are too costly

 ❒ 2. Tests are not sensitive enough to detect influenza

 ❒ 3. Tests are not specific enough to detect influenza

 ❒ 4. Diagnosis of influenza is based on clinical judgment of a practitioner, not a rapid test result

 ❒ 5. Treatment is the same regardless of rapid test result

 ❒ 6. We perform rapid test method(s) other than RIDTs Enzyme Immuno Assay (EIA) method

 Please check if applicable:

❒ Direct Fluorescent Antibody (DFA)

❒ Nucleic acid amplification/RT-PCR

 ❒ 7. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2a. In which of the following time frames have RIDTs been performed in your laboratory?

*(Select all that apply)*

❒ a. Prior to April 15, 2009 (before the emergence of H1N1)

❒ b. After April 15, 2009 (since the emergence of HIN1)

❒ c. RIDTs are currently performed

**NOTE: If RIDTs are not currently performed in your laboratory, please answer the following questions according to procedures followed when they were in use.**

|  |  |  |
| --- | --- | --- |
|  |  |  |

3. When is RIDT available? *(****Select only one****)*

❒a. Throughout the year for all patients

❒b. Throughout the year for select patients

❒c. Only during influenza season for all patients

❒d. Only during influenza season for select patients

❒e. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3a. When RIDTs are available, please indicate your laboratories testing frequency.

❒a. One shift a day

❒b. Two shifts a day

❒c. All three shifts a day

❒d. Other

4. Approximately how many rapid influenza tests were performed in your laboratory between?

August 1, 2009 and July 31, 2010? \_\_\_\_\_\_\_\_\_

August 1, 2010 and July 31, 2011? \_\_\_\_\_\_\_\_\_

5. Since the emergence of 2009 H1N1 (after April 15, 2009), have rapid influenza diagnostic testing practices in your laboratory changed?

❒a. No

❒b. Yes (Please explain): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6. Who provides technical oversight of influenza testing in your laboratory?

       ❒a. Doctoral specialist **on site**

       ❒b. Doctoral specialist **off site**

       ❒c. Non-doctoral specialist **on site**

       ❒d. Non-doctoral specialist **off site**

6a. What kind of procedures/instructions are provided to clinicians ordering RIDTs by the laboratory?) (*Select all that apply*)

❒a. No specified procedures exist? **🡪 Skip to Question 7**

❒b. Written procedures for contacting laboratory when ordering RIDTs

❒c. Written procedures for when it is appropriate to order a RIDT (for example, not in summer, not on an asymptomatic person etc.)

❒ d. Written instructions explaining how well the test works to diagnose influenza disease (sensitivity, specificity, in what population, etc.)

❒e. Contract or memo

 ❒f. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6b. Who approved the procedures/instructions that are provided to the clinicians ordering RIDT?

❒ a. Lab Director

❒ b. Emergency Department Director

❒ c. Infection Control Director or staff

❒ d. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ g. Do not know

6c. Does the procedure of ordering RIDTs vary by shift (e.g. day, evening, night shift)?

 ❒a. No

 ❒b. Yes (Explain) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

7. Does your lab consider the impact of currently circulating influenza subtypes on the performance of the RIDT?

❒ a. Yes ❒ b. No

8. What is the initial screening test for influenza in your facility?

❒ a. RIDT

❒ b. Direct Fluorescent Antibody DFA

❒ c. Viral Culture

❒ d. Nucleic acid amplification/RT-PCR

❒ e. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8a. In addition to RIDT, what other tests are used to diagnose influenza in your laboratory?

❒ a. Viral culture

❒ b. Immunofluorescence [Direct Fluorescent Antibody (DFA)]

❒ c. Nucleic acid amplification/ RT-PCR

❒ d. Serology

❒ e. None

❒ f. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section B1: Pre-Analytic Phase**

9. What is the source of RIDT specimens received by your laboratory? (*Select all that apply*)

❒a. Inpatients within our hospital/facility

❒b. Inpatients from other hospital/facility

❒b. Hospital based ambulatory patients

❒c. Doctor’s office patients

❒d. Emergency Department patients within our hospital(s)

❒e. Emergency Department patients for other hospitals

❒f. Patients from long term care facilities

❒g. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10. How are the RIDT specimens transported to your laboratory? (*Select all that apply*)

       ❒a. Hand delivered

       ❒b. Translogic tubing system

       ❒c. Local courier

       ❒d. Air Mail

       ❒e. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10a. Is the respiratory specimen transported in any of the following media? (*Select all that apply*)

❒ a. Phosphate buffered saline

❒ b. M4RT viral transport media

❒ c. Hanks Balanced Salt solution

❒ d. UTM viral transport media

❒ e. Normal Saline

❒ f. No transport media is used

❒ g. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

11. What type of specimen do you **most often receive** for rapid influenza testing? (*Select only one)*

❒ a. Throat swab

❒ b. Nasopharyngeal wash

❒ c. Nasophayngeal aspirate

❒ d. Nasophayngeal swab

❒ e. Nasal wash

❒ f. Midturbinate swab

❒ g. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

11a. What other type(s) of specimen(s) do you accept? (*Select all that apply*)

❒ a. Throat swab

❒ b. Nasopharyngeal wash

❒ c. Nasophayngeal aspirate

❒ d. Nasophayngeal swab

❒ e. Nasal wash

❒ f. Midturbinate swab

❒ g. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 11b. Do you accept specimens other than the type specified by the test manufacturer?

❒ a. Yes ❒ b. No

12. Who collects the RIDT specimens in your facility (*Select all that apply*)?

❒ a. Laboratory Staff

❒ b Emergency Department Staff

❒ c. Respiratory therapist

❒ d. Physicians/Residents

❒ e. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

12a. Does the staff collecting specimens change due to…. (*Select all that apply*)

❒ a. Shift

❒ b. Holidays or weekends

❒ c. Patient volume

❒ d. Available staff

❒ e. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

13. Is there an algorithm or triage system in place for collecting and testing specimens from critical or high risk patients?

❒a. Yes ❒b. No ❒c. Don’t know

13a. Is there an algorithm or triage system in place for collecting and testing specimens from high volume outpatient areas such as Emergency Department?

❒a. Yes ❒b. No ❒c. Don’t know

14. Did your laboratory perform a validation/verification study on the sensitivity and specificity of the RIDT used most frequently in your laboratory?

❒a. Yes, 🡪 **Continue**

❒b. No, 🡪 **Skip to Question 15**

❒c. Don’t know, 🡪 **Skip to Question 15**

14a. What specimens were used to perform the validation/verification study? *(Select all that apply)*

❒ a. Split fresh patient specimens

❒ b. Split stocked frozen patient samples

❒ c. Frozen stock influenza virus

❒ d. Company provided panels

❒ e. Public Health lab provided panels

❒ f. Sample exchange or donation from outside laboratory

❒ g. Purchased panels

❒ h. Multiple specimen sources

❒ i. Don’t know

❒ j. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

14b. Where was the comparison (“gold standard” ) testing for the RIDT validation/verification performed?

❒ a. In-house

❒ b. A reference laboratory (could be a clinical, commercial or public health laboratory)

14c. What was the comparison (“gold standard”) method used for the RIDT validation/verification study?

❒ a. Virus culture

❒ b. RT-PCR

❒ c. DFA

❒ d. Another RIDT

❒ e. Other

❒ f. Don’t know

14d. How often does your lab perform verification studies to select a RIDT?

❒ a. Every season

❒ b. Once in every two-three years

❒ c. Have not changed the kit in last 3 years

❒ d. Not applicable

**Section B2: Analytic Phase**

15. Please indicate which RIDT is currently used most frequently in your laboratory. (*Select only one)*

❒ a. 3M™ Rapid Detection Flu ❒ f. (Quidel) – Moderate Complexity

A+B Test (3M) ❒ g. QuickVue® Influenza A+B Test (Quidel)

❒ b. Directigen™ EZ Flu ❒ h.TRU FLU® (Bioscience)

A+B (Becton-Dickinson) ❒ i. XPECT™ Flu A&B (Remel/Thermofisher)

❒ c. BinaxNOW® Influenza ❒ j. Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A&B (Alere) - CLIA Waived \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ d. BinaxNOW® Influenza

A&B (Alere) - Moderate Complexity

❒ e. Clearview Exact® II Influenza A &B

❒ f. QuickVue® Influenza Test

15a. Why was this RIDT selected? *(Select all that apply)*

❒ a. Low cost

❒ b. Ease of use

❒ c. Turn-around time

❒ d. Type of specimen required

❒ e. Perceived sensitivity (the test correctly identifies patients with influenza)

❒ f. Perceived specificity (the test correctly identifies patients without influenza)

❒ g. Sales representative gave them to us to try

❒ h. Clinical Laboratory Improvement Amendment (CLIA) waived status

❒ j. In -house verification studies

❒ k. Published findings

❒ l. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ m. Don’t know

15b. What is the estimated sensitivity (ability to identify patients with influenza) of the RIDT

that is most frequently used in your laboratory? \_\_\_\_\_\_\_\_\_\_\_\_%

 15c. From what source did you learn about the estimated sensitivity of this RIDT test?

 ❒ a. Package insert

 ❒ b. Ongoing monitoring/Pre-implementation verification study

 ❒ d. Published studies

 ❒ e. Physician input

 ❒ f. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

16. Are you planning to change methodologies from RIDT to one of the newer rapid technologies?

❒ a. No

❒ b. Yes, we have decided to change to a rapid molecular method , FDA Approved (Cepheid Xpert® Flu)

❒ c. Yes, we have decided to change to a new film array technology, FDA Approved (Idaho Technology Film Array RP System®/Film Array Respiratory Panel®)

❒ d. We are considering changing to a rapid molecular technology, FDA Approved (Cepheid Xpert® Flu)

❒ e. We are considering changing to a film array technology, FDA Approved (Idaho Technology Film Array RP System®/Film Array Respiratory Panel®)

❒ f. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

17. Who tests the RIDT specimens in your facility? (Select all that apply)

❒ a. Laboratory Staff

❒ b. Emergency Department/Medical Staff

❒ c. Respiratory therapist

❒ d. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section B3: Post-Analytic Phase**

18. What is the average turn-around time to report results of an RIDT specimen once it is received in your laboratory for the day, evening, and night shift?

|  |  |
| --- | --- |
|  | **Average Turn-Around Time – Receipt to Reporting** |
| **Shift** | **Less than 30 minutes** | **30 minutes to less than one hour** | **1-2 hours** | **greater than 2 hours** | **Not Available during shift** |
| 1. **Day Shift**

 **(*Select one*)** 🡪 | ❒ | ❒ | ❒ | ❒ | ❒ |
| 1. **Evening Shift**

 **(*Select one*)** 🡪 | ❒ | ❒ | ❒ | ❒ | ❒ |
| 1. **Night Shift**

 **(*Select one*)** 🡪 | ❒ | ❒ | ❒ | ❒ | ❒ |

18a. Are there special procedures for faster turn-around time for handling RIDT specimens from critical or high risk patients

❒a. Yes ❒b. No ❒c. Don’t know

19. **Who** usually communicates the RIDT results from your laboratory? (*Select only one)*

❒a. Laboratory Director

❒b. Laboratory Supervisor

❒c. Laboratory Technician who performed the test

❒d. It varies, there isn’t one specific person who is responsible for conveying the results

❒e. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

19a. **How** are RIDT results most often communicated? (*Select only one)*

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **For Routine Patients****(Select Only One)** | **For High Risk/Critical Patients** **(Select Only One)** |
| **a.** | **By phone** | **❒** | **❒** |
| **b.** | **Computer/electronic** | **❒** | **❒** |
| **c.** | **Fax** | **❒** | **❒** |
| **d.** | **Paper record** | **❒** | **❒** |
| **e.** | **By smartphone** | **❒** | **❒** |
| **f.** | **Other (Please describe)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **❒** | **❒** |

19b. **To whom** are the RIDT results from your laboratory most often communicated? ((*Select only one)*

❒a. The ordering provider

❒b. The nurse

❒c. The clerk on the floor

❒d. It varies, there isn’t one specific person who results are typically communicated to

❒e. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

19c. Does your RIDT report include any disclaimer on the impact of test performance due to influenza prevalence?

❒a. Yes ❒b. No ❒c. Don’t know

20. To which of the following did your facility report positive influenza test results? *(Select all that apply)*

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Prior to H1N1 emergence (before April 15, 2009) | Since H1N1 emergence (after April 15, 2009) |
| a. | The local health department | ❒ | ❒ |
| b. | The state health department | ❒ | ❒ |
| c. | Other organization/agency | ❒ | ❒ |
|  |  Specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| d. | None – We do not report influenza results | ❒ | ❒ |
| e. | Don’t know | ❒ | ❒ |

20a. Which department within your facility reports positive influenza test results to health departments? *(Select all that apply)*

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Prior to H1N1 emergence (before April 15, 2009)** | **Since H1N1 emergence** **(after April 15, 2009)** |
| **a.** | **The emergency department** | **❒** | **❒** |
| **b.** | **Laboratory** | **❒** | **❒** |
| **c.** | **Infection control** | **❒** | **❒** |
| **d.** | **Other entity within the hospital (specify** | **❒** | **❒** |
|  | **Specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |  |  |
| **e.** | **The doctor’s office** | **❒** | **❒** |
| **f.** | **None** | **❒** | **❒** |
| **g.** | **Don’t know** | **❒** | **❒** |

21. Does your laboratory conduct confirmatory testing of RIDT results **internally**? *(Select all that apply)*

❒ a. Yes, on specimens from patients who tested positive for influenza

❒ b. Yes, on specimens from patients who tested negative for influenza

❒ c. Yes, on specimens from patients in outbreak settings (e.g. congregate facilities and schools)

❒ d. No 🡪 **Skip to Question 21c**

21a. On which types of specimen(s) is confirmatory testing performed **internally**? *(Select all that apply)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **Beginning of the influenza season** | **Middle of the influenza season** | **End of the influenza season** | **Off season** |
| **a.** | **Positive RIDT specimens**  | **❒** | **❒** | **❒** | **❒** |
| **b.** | **Negative RIDT specimens**  | **❒** | **❒** | **❒** | **❒** |

21b. What type of confirmatory testing is done **internally**? *(Select all that apply)*

❒ a. Culture

❒ b. RT-PCR/ Nucleic acid amplification (FDA approved)

❒ c. RT-PCR/ Nucleic acid amplification (In-house developed)

❒ d. DFA

❒ e. Repeat RIDT, same type

❒ f. Another RIDT, different type

❒ g. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ h. None

21c. Does your laboratory **send specimens out** for confirmatory testing of rapid influenza diagnostic test results?

*(Select all that apply)*

❒ a. Yes, we send specimens from patients who tested positive for influenza

❒ b. Yes, we send specimens from patients who tested negative for influenza

❒ c. Yes, we send specimens from patients in outbreak settings (e.g. congregate facilities and schools)

❒ d. No -> **Skip to Question 22**

21d. Which type of specimen(s) does your laboratory **send out** for confirmatory testing? *(Select all that apply)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **Beginning of the influenza season** | **Middle of the influenza season** | **End of the influenza season** | **Off season** |
| **a.** | **Positive RIDT specimens**  | **❒** | **❒** | **❒** | **❒** |
| **b** | **Negative RIDT specimens**  | **❒** | **❒** | **❒** | **❒** |

21e. What type of confirmatory testing is done **externally**? *(Select all that apply)*

❒ a. Culture

❒ b. RT-PCR/ Nucleic acid amplification (FDA approved)

❒ c. RT-PCR/ Nucleic acid amplification (In-house developed)

❒ d. DFA

❒ e. Repeat RIDT, same type

❒ f. Another RIDT, different type

❒ g. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ h. None

**Section C: Quality Assurance**

22. What is done to ensure good laboratory practices are followed in performing RIDTs **within** the laboratory?

 *(Select all that apply by completing the following sentence)* **Our laboratory . . .**

❒ a. Has no formal processes

❒ b. Has a written procedures manual

❒ c. Has standard operating procedures for performing RIDTs

❒ d. Has a system in place for monitoring and evaluating the procedures for Patient Test Management

❒ e. Ensures those who perform RIDTs follow the manufacturer’s instruction/package inserts or our written procedures that include the manufacturer’s instructions.

❒ f. Has knowledgeable personnel who teach/mentor new staff

❒ g. Evaluates the competency/performance of staff periodically

❒ h. Participates in a proficiency testing program

❒ i. Documents problems arising in using RIDTs and takes corrective action

❒ j. Evaluates the effectiveness of corrective actions taken in regard to the quality issues related to RIDT

❒ k. Ensures CDC guidelines are followed

❒ l. Ensures other external guidelines are followed

22a. If you have a system in place for monitoring and evaluating the procedures for Patient Test Management **within the laboratory**, please specify what it includes below. (*Select all that apply*)

❒ a. Specimen collection

❒ b. Specimen labeling

❒ c. Preservation and transportation

❒ d. Test requisition completeness

❒ e. Test report completeness

❒ f. Timely reporting of results

❒ g. Accuracy and reliability of test reporting systems

❒ h. Storage and retrieval of results

❒ i. No system in place

❒ j. Other (Specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ k. Not applicable

23. What is done to ensure that RIDT guidelines and good laboratory practices are followed **outside of the laboratory**? *(Select all that apply by completing the following sentence)* **Our laboratory . . .**

 ❒ a. Does not evaluate quality assurance practices for other areas performing RIDTs

 ❒ b.Designates someone responsible for overseeing testing quality assurance outside of the laboratory

 ❒ c. Reviews or participates in updating a written procedures manual

 ❒ d. Reviews or participates in updating standard operating procedures for performing RIDTs

 ❒ e. Reviews or participates in evaluating procedures for patient test management

 ❒ f. Ensures those who perform RIDTs follow the manufacturer’s instructions/package inserts or our written procedures that include the manufacturer’s instructions

 ❒ g. Has knowledgeable personnel who teach/mentor new staff outside of the laboratory.

 ❒ h. Evaluates the competency/performance of staff periodically outside of the laboratory

 ❒ i. Ensures those who perform RIDTs follow CDC guidelines

 ❒ j. Ensures those who perform RIDTs follow other external guidelines

 ❒ k. Provides or participates in a proficiency testing program for testing performed externally

 ❒ l. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

23a.If you have a system in place for monitoring and evaluating the procedures for Patient Test Management that occur **outside** the laboratory, please specify what it includes below. (Select all that apply)

❒ a. Specimen collection

❒ b. Specimen labeling

❒ c. Preservation and transportation

❒ d. Test requisition completeness

❒ e. Test report completeness

❒ f. Timely reporting of results

❒ g. Accuracy and reliability of test reporting systems

❒ h. Storage and retrieval of results

❒ i. No system in place

❒ j. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ k. Not applicable

24. Does your laboratory have a mechanism to monitor ongoing RIDT performance?

❒ a. Yes (Briefly describe)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ b. No

25. What quality controls samples are used for the RIDT?

❒ a. Positive and negative control from the kit

❒ b. Previously positive and negative patient specimens

❒ c. Both of the above

❒ d. None of the above

❒ e. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

25a. How often are the quality control samples run?

❒ a. Every time a new box of RIDT is opened

❒ b. Once with every new lot or shipment

❒ c. Performed every 30 days

❒ d. Performed on weekly basis

❒ e. No quality control samples are run

26. What bio-safety procedures are in place for RIDT testing?

 ❒ a. Routine BSL-2 protective equipment (e.g. gloves, lab coat, eye protection)is employed

 ❒ b. Testing is performed in a Class II bio-safety cabinet

 ❒ c. Testing is performed behind a bench shield

 ❒ d. Additional Personal Protective Equipment (e.g. mask, N-95 respirator, etc.)is employed

 ❒ e. RIDT testing is performed in a isolated/sequestered area

 ❒ f. RIDT testing is performed on an open bench area

 ❒ g. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section D: Training**

27. How is staff trained to do RIDT testing? *(Select all that apply)*

❒ a. Informal on-the-job training

❒ b. Formal in-service education

❒ c. Provided with manual/directions to read and review

❒ d. Rely on educational program skills obtained prior to employment

❒ e. Other (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ f. Don’t know

27a. Who is responsible for training staff to collect RIDT specimens?

❒ a. Laboratory

❒ b. Respiratory Therapy Staff

❒ c. Emergency Department Staff

❒ d. Nursing Staff

❒ e. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

27b. What types of educational information is provided by laboratories to those ordering RIDTs?

❒ a. Educational comments on lab reports regarding sensitivity and specificity of tests

❒ b. Educational comments on test interpretation

❒ c. Educational information regarding specimen collection

❒ d. Educational memos or posters

❒ e. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

27c. What is the frequency of training of laboratory testing personnel?

❒ a. Initial training only

❒ b. Annual Training

 ❒ c. Only when test kit is changed

❒ d. No training is conducted

27d. What is the frequency of training of clinicians for respiratory specimen collection?

❒ a. Initial training only

❒ b. Annual training

❒ c. No training

❒ d. Don’t Know

**Section E: Influenza Information and Resources**

28. How do you obtain information regarding influenza activity in your area? *(Select all that apply)*

❒ a. Media

❒ b. Journal publications

❒ c. Local Health Department

❒ d. State Health Department

❒ e. Local hospitals

 ❒ f. CDC guidance at [www.CDC.gov](http://www.CDC.gov)

 or [www.cdc.gov/flu](http://www.cdc.gov/flu)

❒ g. Guidance at [www.WHO.int](http://www.WHO.int)

❒ h. Our hospital infection control staff or infections disease consult service

❒ i. Professional Organizations (e.g. Websites, newsletters)

❒ j. Other internet sites (Specify)

❒ k. Other (Specify)

28a. How do you prefer to receive influenza-related information? *(Select* ***up to two*** *responses)*

❒ a. Direct email (e.g. GovDelivery, CDC newsletter/update)

 (Please specify type of email communication you prefer) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 ❒ b. CDC social media (e.g. Twitter, RSS Feed, Facebook)

 ❒ c. CDC publications and articles (e.g. MMWR, EID)

 ❒ d. Audio/visual broadcasts (e.g. podcasts, Webinars, conference calls)

 ❒ e. Clinician Outreach and Communication Activities (COCA)

 ❒ f. Professional organization resources (e.g. newsletters, announcements)

 ❒ g. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 28b. Did your state or local public health system provide information related to influenza testing?

❒ a. Yes ❒ b. No ❒ c. Don’t know

28c. What kind of information did your state and local public health systems provide regarding influenza?

 *(Select all that apply under each time period)*

Prior to H1N1 emergence Since H1N1 emergence

 (before April 15, 2009) (after April 15, 2009)

a. Recommendations for rapid influenza

 diagnostic test use ❒ ❒

b. Guidelines for interpretation of rapid influenza

 diagnostic test results………………………………. ❒ ❒

c. Guidelines for diagnosing influenza ❒ ❒

d. Treatment guidelines ❒ ❒

e. Surveillance data (prevalence and

 location of confirmed cases) ❒ ❒

f. Training resources ❒ ❒

g. Unaware of the information provided by

 my state and local public health systems ❒ ❒

h. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ❒ ❒

28d. Do state and local public health systems provide influenza information in a timely manner?

❒ a. Yes

❒ b. No

❒ c. Information not provided

❒ d. Don’t know

**Section F: Advantages and Disadvantages**

29. What are the top three problems that your laboratory has encountered with RIDTs or the testing process? *(Select* ***up to three*** *responses)*

❒ a. Differing opinions on which RIDT kit the laboratory should use

❒ b. Shortage of RIDT kits

❒ c. Rapid tests are not very good at correctly identifying those with influenza (poor sensitivity)

❒ d. Rapid tests are not very good at correctly identifying those without influenza (poor specificity)

❒ e. Poor performance with certain circulating influenza subtypes

❒ f. Difficulty interpreting test results/ambiguous test results

❒ g. Expense of RIDT kits

❒ h. Staff availability

❒ i. Inadequate/improperly collected specimen

❒ j. Other (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❒ k. None (have not experienced any problems with RIDT)

29a. What do you perceive are the advantages of RIDT to your **laboratory**? (*Select all that apply)*

❒ a. Inexpensive

❒ b. Rapid

❒ c. Useful for “stat” testing

❒ d. Useful for third shift

❒ e. None

❒ f. Other: (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

29b. What do you perceive are the advantages of RIDT to your **facility**? (*Select all that apply)*

❒ a. Don’t know

❒ b. It enhances the ability to make

 accurate diagnoses

❒ c. It reduces unnecessary antibiotic prescriptions

❒ d. It helps inform decision about antiviral prescriptions

❒ e. It is useful during an influenza outbreak

❒ f. It helps physicians decide if a patient can return to work or school

❒ g. None

29c. What do you perceive are the disadvantages of RIDT? (*Select all that apply)*

❒ a. Lacks specificity

❒ b. Lacks sensitivity

❒ c. Too costly

❒ d. Not very useful during periods of low influenza activity

 because there is a higher probability of false positives

❒ e. During peak influenza activity, clinical judgment is more predictive

 of influenza than rapid influenza diagnostic test results

❒ f. Tests are difficult to perform

❒ g. Results are difficult to interpret

❒ h. For patients with flu-like symptoms, treatment (with antiviral medication) is the same regardless of

 the rapid influenza diagnostic test result

❒ i. None

❒ j. Other (Specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_