COVID-19 Onsite Business Testing: Quidel QuickVue Testing Playbook

Last updated 12/17/2021

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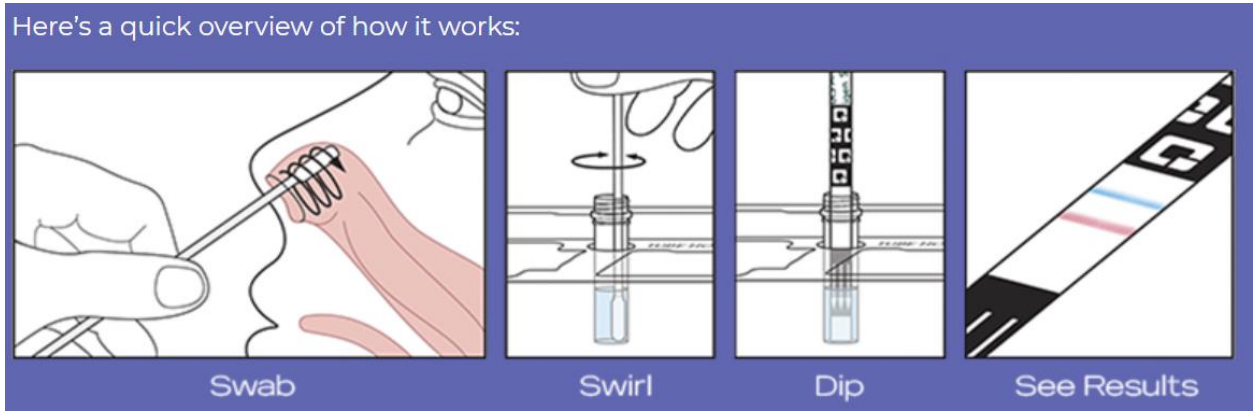
What is a Quidel QuickVue test?

The Quidel QuickVue COVID-19 test uses a gentle self-collected anterior nasal (nares) swab sample to determine a positive or negative COVID-19 result. The swab is swirled in a tube of reagent solution, then removed, before a test strip is inserted. After ten minutes, you can take the strip out of the tube and see your results.

- Self-collected: individuals swab themselves (4-5 circles in each nostril)
- The Quidel QuickVue test kit contains a tube holder, tube(s), swab(s), and test strip(s) along with an instruction manual. It contains all necessary items to collect and process a sample.
- Rapid test: After 10 minutes, a result will appear on the test strip. Note: results should be read and recorded within 5 minutes after completion of the test to ensure accuracy.
- Antigen-based test: detects the virus in the early part of the disease when people are most infectious.

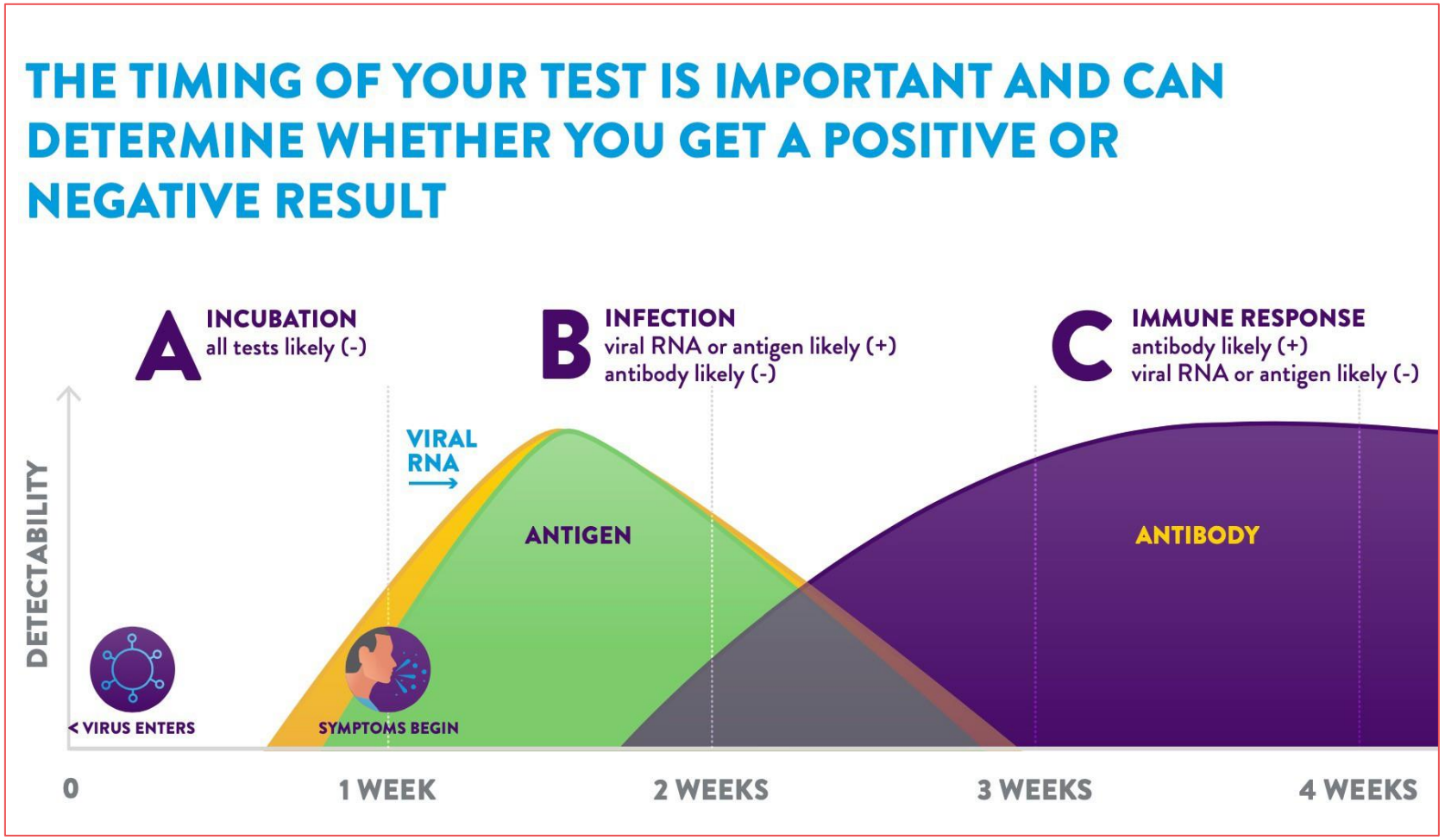


Overview: Antigen Test vs PCR Test

Antigen Tests: detect COVID-19 antigens which appear in the early part of the disease when people are most infectious. (Levels of antigens shown in green to the left)

PCR Tests: Polymerase chain reaction (PCR) tests detect the presence of the COVID-19 virus itself (and not the antigen response). PCR tests must be sent to a laboratory for analysis. (Levels of viral RNA shown in yellow and green to the left)

Key difference: PCR tests can detect infections earlier and later than antigen tests. Antigen tests are good at identifying positive cases when they are infectious and likely to spread the virus.



How does the process work?

Any Rhode Island employer can sign up to participate. Here is an outline of the process:

A: Onboarding Paperwork

- Submit signed MOU (must be the version released in Aug 2021)
- Set up Reporting Account

If CLIA is Required:

- Submit CLIA Waiver Form & non-refundable $180 processing fee.

B: Training and Logistics

- Establish testing plans and practices within your facility
- Communicate with employees.
- Train staff to supervise tests and report results

C: Get Started

- Pick up Quidel QuickVue tests
- Begin testing and reporting results
- Schedule waste pickup with RIDOH point of contact

This process typically takes about 5-7 business days to complete.

Onboarding Paperwork

To enroll in the program, there are several instructional and informational documents that require your attention. Be sure to sign and return specified documents in a timely fashion.

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The CLIA Waiver: Do I require one?

What is a CLIA waiver?

Clinical Laboratory Improvement Amendments Application for Certification - A Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver is a certification that allows a facility, primarily laboratories, to legally examine a person through waived tests in order to assess health, diagnose, and determine treatment.

Do I require a CLIA Waiver?

Please determine the need for a CLIA Waiver based on the criteria listed in the document titled CLIA COVID-19 WORKPLACE FACT SHEET: https://www.cms.gov/files/document/clia-covid-fact-sheet.pdf

If required based on the Criteria above:

1. During onboarding your POC will provide you with the CLIA form and an example of how the form should be completed. Sample filled-out CLIA forms and a short tutorial video is also available upon request.
2. ***Please complete CLIA waiver form and send to*** DOH.OFR@health.ri.gov with your RIDOH Business Testing representative on cc'd.

IF additional assistance is required, please email RIDOH.COVID19BizTesting@health.ri.gov

A: Onboarding Paperwork

To participate, the employer must complete the following steps before testing begins:

1. **MOU:** Outlines the expectations and qualified immunity for the business that is conducting on-site testing. Sign your MOU and submit it to the Business Testing Contact Center. Note: MOU must be the version released in August 2021 to be valid.

2. **CLIA Waiver:** Please refer to https://www.cms.gov/files/document/clia-covid-fact-sheet.pdf

   If you are required to have an active CLIA waiver, complete the CLIA Waiver form and send it to DOH.OFR@health.ri.gov with your RIDOH Business Testing representative CC'd. Once approved, you will receive a CLIA identification number and a fee coupon will be mailed to your business' address, at which time a one-time non-refundable $180 fee must be paid.

3. **Reporting account:** Once your MOU and (if required) CLIA Waiver are approved, RIDOH will create an account for your facility in the results portal. This is where you will report all test results conducted at your business. When your account is created, you will receive an email from RIDOH with a link and prompt to finish creating your account. Note: you will have 24 hours to complete the account setup before the link expires.

Training and Logistics

FOR FACILITIES THAT DO NOT REQUIRE CLIA WAIVER (See SLIDES 10-17)

Its time to design your testing plan and coordinate the training and logistics for your team.

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B: Training and Logistics - Results Reporting

One of the most important pieces to this program is the reporting of your test results to RIDOH after each testing event, using the results portal (account should have been setup as part of the onboarding process).

Reporting all results ensures that you are working jointly with RIDOH to appropriately address public health considerations, as well as ensuring results and documentation thereof are accessible for your employees.

- You must report all aggregate results received during any given testing event as follows:
  - Date of tests, aggregate number tests performed, aggregate number of positive tests, and aggregate number of negative tests.
  - Negative **and** Positive results: Both require the number of negative results in total, number of positive results in total.

  The aggregate reporting option will not generate a confirmatory document with result status. Should an employee require a document with result status from RIDOH, please advise them to schedule a test at a local pharmacy such as CVS or Walgreens, a primary care physician or at a local state run testing facility using www.portal.ri.gov

B: Training and Logistics - Training

Training your staff:

- All staff who will be involved in the testing plan must watch the training videos prior to picking up the tests.
  - Video 1: Quidel QuickVue Test Kit Training Video
- Facilities reporting aggregate results must watch this training video:
  - This Video reviews the reporting and data entry process for aggregate reporting..
- In-Person training can be facilitated by RIDOH, if needed. This should be coordinated with your RIDOH business testing representative. on Training

B: Training and Logistics- Overview

Building a testing plan means identifying all the key factors that will make your plan successful.

The below process outlines the major considerations for facilities that DO NOT require a CLIA Waiver:

- ☐ Build your schedule. Decide how often your employees will test themselves.
- ☐ Secure initial test kits: Log initial test kit needs with RIDOH point of contact. RIDOH point of contact places your initial order and arranges pick-up date/time.
- ☐ Prepare staff to self swab: Instruct each staff member to view all training materials before testing. Collect Quidel QuickVue tests at the RIEMA Warehouse.
- ☐ Communicate: Share your testing plan, and its importance to protecting your workforce, with your employees to encourage their participation and acceptance.
- ☐ Plan for Safety: Secure adequate PPE for self swabbers (masks & disposable gloves at a minimum).

Get Started

It’s time to start testing!

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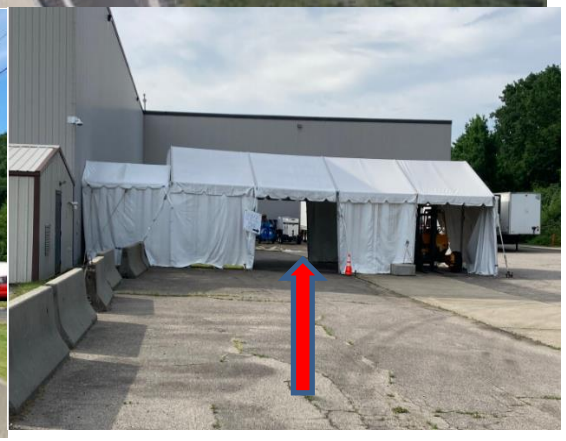
C: Get Started- Procure Tests

Once you have completed the onboarding and training processes, your RIDOH point of contact will schedule your pickup.

- Please be sure to schedule your pick up with your Business Testing representative. If you are unable to make your pick up date, please be sure to alert us of the scheduling change.
- Test Kits & biohazard waste bags must be picked up at the REIMA Warehouse (address: 2700 Plainfield Pike, Cranston, RI 02921)
- Quidel QuickVue may come in 25-packs or 2-packs and can be broken apart to test multiple employees (As long as the tests are taken within 24-36 hours apart it's not required to use the same test kit)
- Businesses can order replacement tests once their stock runs low (<25% remaining) via their RIDOH point of contact
- Be prepared to verify the organization's request and provide the point of contact's name and quantity scheduled for pick up.

Directions: Turn right just after the guard shack . Follow the road around. Notes: Off 295, take Plainfield Pike Westbound



Tips & Tricks To Be Successful

MAXIMIZE PARTICIPATION

Educate staff about the importance of this surveillance testing

- Distribute video of test, internal communications, etc.

Be proactive with employee messaging

- Share information about testing and why it is important with your staff on a regular basis.

PREPARE

Educate multiple staff members on process

- What if a team member is out/unavailable on testing day?

Walk through process with all involved staff prior to testing day.

- Check PPE, Materials. Does everyone understand protocols?

Time Management Plan

- Rehearse some contingencies- late arrivals, technical challenges, PPE changes
- Tools to mark, time tests

TESTING DAY

Ensure all regular active screening is occurring daily to ALL employees (especially if only a % of employees are tested on any given day)

Improvise as problems arise

- Did we miss the window of time to read an accurate result?

Designate staff member responsible for results monitoring in real time, and reporting to RIDOH

- Report to RIDOH
- Monitor results for accurate reporting

Collection Workflow Process

Step-by-Step User Instructions can be found at the following links:

- English version
- Spanish version

* NOTE: Under the CLIA and MOU, specimen collection does not require a health care professional. Employees may self swab with a trained observer.

Required Materials for Onsite Testing

- Test Kits & biohazard bags:
  - Provided by RIDOH, business must pick up at RIEMA Warehouse.
  - Note: Each biohazard bag can hold approximately 50lbs. *It is recommended to coordinate for pick up when your bag reaches just under 50lbs.*
- Businesses can coordinate waste pick up directly by contacting the vendor at: **Joanne Spaziante, at js@approvedmedwaste.com or 914-664-4791 (main line), 914-652-4726 (cell).**
- Appropriate PPE for staff running test operations:
  - All staff should, at a minimum, be wearing appropriate face masks and disposable gloves. Additional PPE such as face shields, Plexiglas dividers, etc. are also useful risk mitigation steps.
- Cleaning materials:
  - Anti-viral disinfectant wipes/cleanser to clean the space pre and post testing events

Training and Logistics

FOR FACILITIES THAT REQUIRE CLIA WAIVER (See SLIDES 19-27)

Its time to design your testing plan and coordinate the training and logistics for your team.

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B: Training and Logistics - Results Reporting

One of the most important pieces to this program is the reporting of your test results to RIDOH after each testing event, using the results portal (account should have been setup as part of the onboarding process).

Reporting all results ensures that you are working jointly with RIDOH to appropriately address public health considerations, as well as ensuring results and documentation thereof are accessible for your employees.

- **If CLIA is Required:** You must report all (line level) data (including employee demographics) received during any given testing event as follows:
  - Negative **and** Positive results: Both require detailed information including address, birthdate, primary language and symptom information.

  The line level reporting option will generate a confirmatory result status document from RIDOH.

B: Training and Logistics - Training

Training your staff:

- ☐ All staff who will be involved in the testing plan must watch the training videos prior to picking up the tests.
  - ☐ Video 1: Quidel QuickVue Test Kit Training Video
- ☐ Staff who will be responsible for reporting under CLIA guidelines must watch this training video:
  - ☐ This video reviews the reporting and data entry process for line level reporting.
- ☐ In-Person training can be facilitated by RIDOH, if needed. This should be coordinated with your RIDOH business testing representative. on Training

B: Training and Logistics- Overview

Building a testing plan means identifying all the key factors that will make your plan successful. The below process outlines the major considerations for facilities that require a CLIA Waiver:

- ☐ Form your testing team:
  - (1) Testing Manager
  - (2) Testing Coordinator(s) to manage testing event and reporting
  - (3) Testing Administrator(s) to observe swabbing and results reporting
- ☐ Build your schedule. Decide if you will test weekly or bi-weekly.
- ☐ Identify your collection site: Identify a large space for testing (gym, cafeteria, conference room) and set-up space to meet health and safety guidance.
- ☐ Secure initial test kits: Log initial test kit needs with RIDOH point of contact. RIDOH point of contact places your initial order and arranges pick-up date/time.
- ☐ Prepare staff to test: Train testing team (onsite testing available by RIDOH if needed) and collect Quidel QuickVue tests at the RIEMA Warehouse.
- ☐ Communicate: Share your testing plan, and its importance to protecting your workforce, with your employees to encourage their participation and acceptance.
- ☐ Plan for Safety: Secure adequate PPE for swabbers (masks & disposable gloves at a minimum).

Get Started

It’s time to start testing!

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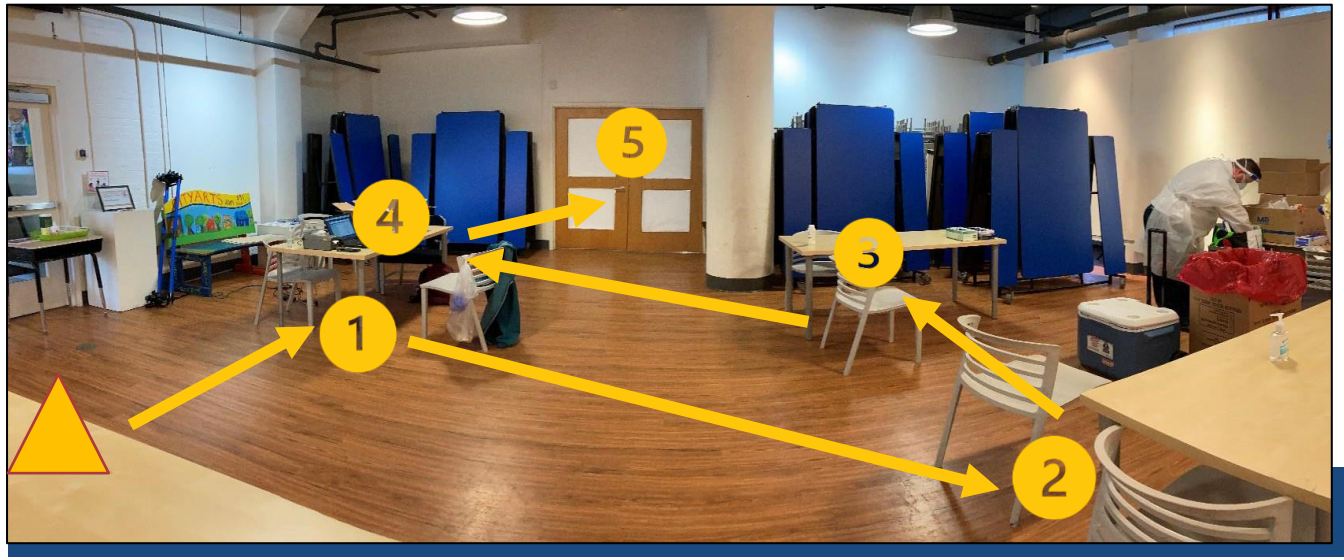
C: Get Started: Set Up Your Test Site/Flow

Conference room setup:

Note: proper PPE on testing staff, Plexiglas divider between employee & staff, conduct swabbing, timed results

Multipurpose Room setup:



1. Employee check-in & test distribution
2. Swab station (monitored by observer)
3. Swab dropped off & inserted into test tube with reagent
4. Results reported to testing team
5. Employee Exit

C: Get Started: Testing Day Management

Run of Show for Testing Event Days

- ☐ Check: Conduct second walkthrough of testing space and meeting with testing team to finalize logistics, roles, and responsibilities.
- ☐ Protect: Ensure proper PPE & safety precautions for staff handling testing materials.
  Antigen test materials are disposed of in biohazard waste bags.
- ☐ Track all positive and negative test results throughout the testing process as part of the workflow.
  A reminder that test results are valid only if read during the 5-minute window post-test.
- ☐ Respond to any positive tests following your organizations established response protocols.
- ☐ Report testing results to RIDOH using the resulting portal (total tests, total positive, total negative).
  If businesses experience issues with the antigen tests, please report the issue to your RIDOH point of contact. Include the following information in that report: test lot number, nature of the problem (failed control, broken swab, faulty test card, etc.), photographs of test kit materials, amplifying details such as time, circumstances, procedure followed before/during/after fault discovered. Save & return any faulty test kits to the RIEMA Warehouse.
- ☐ Clean: Deep clean testing space.
- ☐ Secure: Securely store unused tests and biohazard waste bags.

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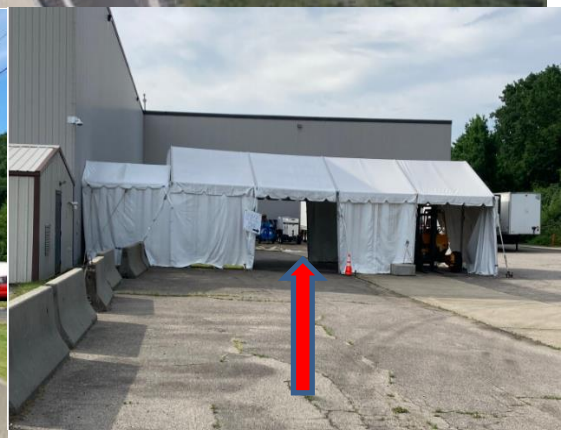

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Additional Resources

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Glossary

Term	Definition
Close contact	Being within six feet of an infected person (with or without a face mask) for at least 15 minutes, or having unprotected direct contact with secretions or excretions of a person with confirmed COVID-19 during the infectious period
Community Transmission	Occurs when individuals acquire COVID-19 through contact with someone in their local community, rather than through travel to an affected location.
Confirmed Case	A person who has tested positive for SARS-CoV-2 infection (the virus that causes COVID-19)
Contact Tracing	Process of identifying individuals who have had close contact (see definition above) with someone infected with COVID-19
Incubation	The time between getting the virus and when you first show symptoms is called the incubation period. When you first get infected with COVID-19, the virus enters your body. During the following week, you may start to show symptoms.
Infectious Period	Two days prior to testing (the date of the swabbing was conducted) until CDC criteria to discontinue isolation are met
Surveillance Testing	Refers to regular testing for individuals who are not experiencing any COVID-19 symptoms

Glossary

Term	Definition
Isolation	Process of separating individuals who are infected with COVID-19 from others. Isolation lasts a minimum of 10 days from symptom onset if symptomatic. If a person infected with COVID-19 has no symptoms, isolation lasts a minimum of seven-10 days from the date of test specimen collection (test). For individuals with severely immunocompromising conditions, isolation is at least 20 days.
Protocol	Recommended actions to follow in the event of a probable or confirmed case of COVID-19 occurs
Probable Case	Individual who has at least one of the following symptoms: cough, shortness of breath, or difficulty breathing, new loss of smell or new loss of taste, or at least two of the following symptoms: fever (measured > 100.4 degrees Fahrenheit or subjective), chills (rigors), body aches (myalgia), headache, sore throat, nausea or vomiting, diarrhea, fatigue, or congestion or runny nose
Quarantine	Process of separating and restricting the movement of individuals who were in close contact with someone who tested positive or had symptoms of COVID-19. Anyone who has been in close contact with someone who has COVID-19 must stay home for a minimum of 14 days since the last day of contact with the person with COVID-19 and watch for symptoms of COVID-19. Persons in quarantine should self-monitor for symptoms and seek medical advice and test if recommended by RIDOH or healthcare provider.

Glossary

Term	Definition
Testing	Three types of tests are available for COVID-19: viral tests, antigen tests, and antibody tests. • Viral tests and antigen tests indicate if you have a current infection • Antibody tests indicate a previous infection. For viral tests there are two types: molecular tests, often referred to as PCR tests, and antigen tests ❖ QuickVue is an antigen test.
Sentinel Testing	Sentinel surveillance – or testing randomly in the community/group can identify infection among symptomatic and asymptomatic carriers. This is different from screening testing or symptomatic testing. Screening testing often seeks a more comprehensive sample and symptomatic or diagnostic tests seek to confirm infection in individuals exhibiting symptoms.
Swabbing	Swabbing refers to the process of collecting a specimen from the throat or nose. This is usually done with a "swab" or stick designed to collect a specimen or sample for testing.