

Quidel COVID-19 Rapid Antigen Testing

Standard Operating Procedure

Please note, this guidance is specific to the **Quidel COVID-19 Rapid Antigen Test kits**. If you are using testing material from any other manufacturer, please refer to the guidance for the use of that product. **ONLY facilities CURRENTLY in possession of a Quidel Sofia or Sofia2 analyzer are eligible to receive these test kits. Use of this test requires a CLIA Certificate of Waiver.**

Date: 8/1/2020

Revision:

Amendments: MOU

Purpose

This Standard Operating Procedure (SOP) will guide you in the process of requesting and utilizing **Quidel COVID-19 Rapid Antigen Test** kits that have been provided to you by the State of Tennessee.

Responsibilities

It is the responsibility of the receiving agency to properly store the test kits that have been provided. These kits do not require refrigeration but should be protected from extreme temperatures. These kits are to be used for the diagnosis of COVID-19. There is no age restriction for the use of this testing platform. Nasal swabs may be used for nasopharyngeal or nasal specimen collection. It is the responsibility of the receiving agency to ensure that procedures are followed according to the guidance laid out in this document and provided in the Quidel Sofia2 FDA Emergency Use Authorization <https://www.fda.gov/media/137886/download> and instructions for use <https://www.fda.gov/media/137885/download>.

Procedures

Complete the Memorandum of Understanding (MOU)

- 1) Your organization must complete and return the attached Memorandum of Understanding, in which the organization agrees to abide by the policies and procedures, as described
- 2) Return the signed MOU to COVID19.testing@tn.gov

Request Testing Supplies

- 1) Qualifying organizations may request test kits by completing the survey found here: <https://arcg.is/1GPI0a>. If the survey will not load, use an alternate internet browser (internet explorer does not support this application)
- 2) Enter the facility type and county location of the facility
- 3) Choose from the dropdown list of qualifying entities. If your organization is not listed, email COVID19.testing@tn.gov to request approval. Your facility will need a unique User ID and password in order to order patient testing. If you have not yet been provided with one, email COVID19.testing@tn.gov

- 4) Provide point of contact name, phone number, and email. The shipping address is pre-populated and should reflect the address to which the kits should be shipped. If the address needs to be changed, email COVID19.testing@tn.gov
- 5) Select “Quidel Rapid Antigen Test Kit” and the quantity requesting (tests come in boxes of 25). **ONLY facilities CURRENTLY in possession of a Quidel Sofia or Sofia2 analyzer are eligible to receive these test kits.** Provide the intended use for the test kits
- 6) Forecast the number of tests you anticipate will be used in the next 30 days
- 7) Provide the number of Quidel tests currently in stock
- 8) Provide any additional information you feel we should have in order to complete this request (e.g., if you have 200 kits on hand but have a testing event planned for 300 people, explain that you need an additional 100 kits to meet that capacity)
- 9) Click submit
- 10) The email provided will receive a confirmation of the placement of the request
Note: Requests placed prior to 5pm CST Wednesday will be shipped on Thursday. Expect to receive kits within five business days. Requests placed after 5pm CST Wednesday will ship the FOLLOWING Thursday. If test kits are needed urgently, email COVID19.testing@tn.gov for assistance

Receiving Testing Supplies

- 1) Test kits will be shipped to the address provided in the online request form
- 2) Test kits must be protected from extreme temperatures
- 3) **Respond to the verification email received after the online Survey123 request for kits and verify the quantity received. Failure to verify receipt may result in delay of future shipments**

Testing

- 1) Identify patient for testing. Quidel Rapid Antigen Tests should be used for diagnostic testing of symptomatic patients.
- 2) Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- 3) Negative results from asymptomatic patients or patients with symptom onset more than five days prior to testing should be treated as presumptive and **confirmation with a molecular assay (PCR) should be performed**. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19
- 4) Collecting the Specimen
 - a. Nasal mid-turbinate (NMT) swab, also called Deep Nasal Swab
 - 1) Use a flocked tapered swab

- 2) Tilt patient's head back 70 degrees
- 3) While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at turbinates)
- 4) Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.

b. Nasalpharyngeal Swab

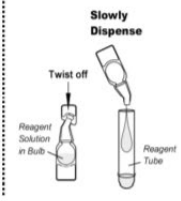
- 1) Insert minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
- 2) Swab should reach depth equal to distance from nostrils to outer opening of the ear.
- 3) Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.
- 4) Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection.
- 5) If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

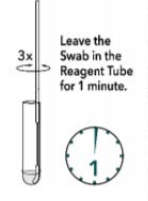
5) Handling the Specimen

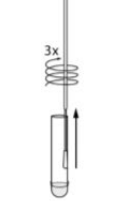
- a. To obtain the most sensitive results, directly test patient specimens without transport media
- b. When collecting a nasal swab sample, use the Nasal Swab supplied in the kit. When collecting a nasopharyngeal swab sample, use a nylon flocked nasopharyngeal swab.
- c. Use the appropriate Fixed Volume Pipette in accordance with test procedures.
- d. Do not pour sample from the Reagent Tube into the Test Cassette sample well. Use the provided Small, Clear 120 μ L Fixed Volume Pipette when adding the sample to the Test Cassette.
- e. To obtain accurate results, do not use visually bloody or overly viscous samples.
- f. Do not write on the barcode of the Test Cassette. This is used by Sofia and Sofia 2 to identify the type of test being run and to identify the individual Test Cassette so as to prevent a second read of the Test Cassette by the same Sofia or Sofia 2.
- g. As the detection reagent is a fluorescent compound, no visible results will form on the test strip. Sofia or Sofia 2 must be used for result interpretation.
- h. To obtain accurate results, an opened and exposed Test Cassette should not be used inside a laminar flow hood or in a heavily ventilated area.
- i. Testing should be performed in an area with adequate ventilation.
- j. Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements.
- k. Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- l. Wash hands thoroughly after handling.

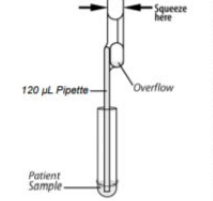
Swab Test Procedure (Nasal/Nasopharyngeal Swab)

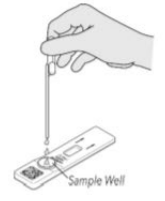
- 1** Verify that Sofia or Sofia 2 is set to the desired Mode: **WALK AWAY** or **READ NOW**. See the "Using Sofia and Sofia 2" section for more information.
- 2** Dispense all of the Reagent Solution into the Reagent Tube. **Swirl the Reagent Tube to dissolve its contents.**


- 3** Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube. Leave the swab in the Reagent Tube for 1 minute.


- 4** Roll the Swab head against the inside of the Reagent Tube as you remove it. Dispose of the used Swab in your biohazard waste.


- 5** Fill the provided Small, Clear 120 µL Fixed Volume Pipette with patient sample from the Reagent Tube. To fill the Fixed Volume Pipette with the patient sample:

 - a) FIRMLY squeeze the top bulb.
 - b) Still squeezing, place the Pipette tip into the sample.
 - c) With the Pipette tip still in the sample, release pressure on bulb to fill the Pipette.
- 6** Firmly squeeze the top bulb to empty the contents of the Small, Clear 120 µL Fixed Volume Pipette into the Test Cassette sample well. Extra liquid in the overflow bulb is OK. **NOTE:** The Fixed Volume Pipette is designed to collect and dispense the correct amount of patient sample. Discard the Pipette in your biohazard waste. **NOTE:** Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 µL Fixed Volume Pipette.


- 7** Proceed to the "Using Sofia and Sofia 2" section to complete the test.

- 6) Processing the Specimen (Nasal/Nasopharyngeal)
 - a. Verify that Sofia or Sofia 2 is set to the desired mode: WALK AWAY or READ NOW.
 - b. Dispense all of the Reagent Solution into the Reagent Tube. Swirl the Reagent Tube to dissolve its contents.
 - c. Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube. Leave the swab in the Reagent Tube for 1 minute.
 - d. Roll the swab head against the inside of the Reagent Tube as you remove it. Dispose of the used swab in your biohazard waste.
 - e. Fill the provided Small, Clear 120 µL Fixed Volume Pipette with the patient sample from the Reagent Tube. To fill the Fixed Volume Pipette with the patient sample:
 - 1) FIRMLY squeeze the top bulb.
 - 2) Still squeezing, place the Pipette tip into the patient sample.
 - 3) With the Pipette tip still in the patient sample, slowly release pressure on bulb to fill the Pipette.
 - 4) Firmly squeeze the top bulb to empty the contents of the Small, Clear 120 µL Fixed Volume Pipette into the Test Cassette sample well. Extra liquid left over in the overflow bulb should be left behind.
 - a. **NOTE:** The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample. Discard the pipette in your biohazard waste.
 - b. **NOTE:** Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 µL Fixed Volume Pipette.
- 7) Using SOFIA and SOFIA2 Walk Away/Read Now
 - a. Sofia and Sofia 2 may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.
 - 1) In WALK AWAY Mode, the user immediately inserts the Test Cassette into Sofia or Sofia 2. Sofia and Sofia 2 scans the Test Cassette periodically during the test development time. Positive and negative test results will be displayed in 15 minutes.

- a. Critically important: Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia or Sofia 2.
 - b. The user must first place the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia 2) and manually time this development step.
 - c. Then, the user inserts the Test Cassette into Sofia or Sofia 2.
 - 2) In READ NOW Mode, Sofia and Sofia 2 will scan and display the test result within 1 minute
 - a. Warning: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia or Sofia 2 past this time may result in false results.
- b. Tips for Batch Testing
 - 1) Depending on the workload, several options exist to make batch testing easier.
 - a. The user can add the Reagent Solution to one or more Reagent Tubes, recap them, and store them on the bench at room temperature (RT) for up to 12 hours without loss of activity before adding the sample(s).
 - b. Critically important: The user should never open the foil pouch exposing the Test Cassette to ambient environment until ready for immediate use.
- c. Run Test with Sofia
 - 1) Input the User ID using the barcode scanner or manually enter the data using the keypad.
 - a. NOTE: If you mistakenly scan the incorrect barcode, use the Arrow Buttons on the Sofia keypad to re-highlight the field. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.
 - 2) Input the Patient ID or Order # using the barcode scanner or manually enter the data using the keypad.
 - 3) Press Start Test and the Sofia drawer will automatically open.
 - 4) Verify that the correct development mode, WALK AWAY or READ NOW, has been selected. Insert the prepared patient Test Cassette into the drawer of Sofia and close the drawer.
 - 5) Sofia will start automatically and display the progress, as shown in the example below.
 - a. In WALK AWAY Mode, the test results will be displayed on the screen in approximately 15 minutes.
 - b. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Interpretation of Results section.
- d. Interpretation of Results Using Sofia
 - 1) When the test is complete, the results will be displayed on the Sofia screen.
 - 2) The results can be automatically printed on the integrated printer if this option is selected.
 - 3) Test Lines, which are fluorescent, cannot be seen with the naked eye.

- a. The Sofia screen will display results for the procedural control as being “valid or invalid,” and will individually provide a positive or negative result for SARS.
- b. If the procedural control is “invalid,” retest with a new patient sample and a new Test Cassette
- c. Negative results from patients with symptom onset beyond five days should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
- d. Invalid Results: If the test is invalid, a new test should be performed with a new patient sample and a new Test Cassette.
- e. Limitations
 - 1) Use of viral transport media may result in decreased test sensitivity, and directly testing specimens is recommended
 - 2) NOTE: Negative results from patients with symptom onset beyond five days should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed

Results Notification

- 1) The facility performing the test is responsible for informing the patient of their test result, the limitations of this test, and requirements for isolation and quarantine of close contacts, if applicable
- 2) The facility performing the test is responsible for report all test results to the Tennessee Department of Health (TDH) within 24 hours of receiving notification of results and reporting all positive test results to the local health department immediately upon notification of those results. Fax PH1600 form to 615-741-3857 <https://www.tn.gov/content/dam/tn/health/documents/reportable-diseases/PH-1600.pdf>
- 3) The facility performing the test should record the individual’s testing information in an office log that includes the date of testing, the date of the result notification, the result of the test, the source of specimen collection (nasopharyngeal, nasal, saliva, oropharyngeal), the method of specimen collection (health care provider collection, observed self-collection, self-collection), if the individual had known exposure to COVID-19, if the individual was symptomatic at the time of testing, date of onset of symptoms, the date of notification to Tennessee Department of Health (TDH), the date of notification to the local health department if the result was positive, and the date the individual was notified of test results.
- 4) Must report the number of tests conducted each week and the numbers of positive and negative results (aggregate, de-identified data) to COVID19.Testing@tn.gov
- 5) Must provide the individual with a written record of their test result and date of testing unless the patient has access to their results via an online portal.

Billing and Payment

- 1) Quidel COVID-19 Rapid Antigen Test kits are provided at no charge by the state of Tennessee and funded by federal COVID-19 relief funding
- 2) Facilities are not to bill patients for the cost of these tests

COVID-19 Testing Supplies Memorandum of Understanding (MOU)

INSTRUCTIONS

Complete this form in its entirety and return via email at COVID19.Testing@tn.gov.
If an organization has multiple locations that are to be supplied with COVID-19 testing supplies covered by this MOU, please list the facility name, address, and primary point of contact for each location on the additional page provided.
All fields are required.

ORGANIZATION

Name of Organization, Facility, or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

Check here if multiple locations from one organization are to be supplied with COVID-19 testing supplies covered by this MOU. If so, please list the facility name, address, and primary point of contact for each location on the additional page provided.

_____ Number of associated locations that are to be supplied with COVID-19 testing supplies covered by this MOU.

MEDICAL DIRECTOR

Medical Director (or equivalent) of organization, facility, or practice must have an active and unencumbered TN medical license. Write N/A if this organization does not have a medical director)

Name

Credentials

Title

TN Medical License Number

National Provider Identifier (NPI)

E-mail

POINT OF CONTACT (POC)

Point of Contact (POC) is the person completing this MOU on behalf of the organization, facility, or practice.

Name

Credentials

Title

(_____) -
Phone

(_____) -
Fax

E-mail

AGREEMENT OF UNDERSTANDING

The State of Tennessee, through federal COVID-19 relief funding, has procured COVID-19 testing supplies to provide to certain Tennessee agencies for the purpose of performing testing on symptomatic individuals and for limited surveillance testing. In accepting the statements below, this organization (and associated facilities) agrees to abide by the following guidelines in exchange for being provided these testing supplies.

Please indicate your agreement to each of the conditions by checking "Accept" beside each statement.

The requesting organization and associated facilities agrees to:

- Accept 1. Provide COVID-19 testing to individuals who report symptoms consistent with COVID-19, who have exposure to someone who has been diagnosed with COVID-19, or who are tested as part of the organization's COVID-19 surveillance testing strategy.
- Accept 2. Store and handle the testing supplies in accordance with the package insert provided with the testing supplies.
- Accept 3. Report all test results to the Tennessee Department of Health (TDH) within 24 hours of receiving notification of results (unless a commercial laboratory is used that reports automatically to the State) and report all positive test results to the local health department immediately upon notification of those results. Fax PH1600 form to 615-741-3857. <https://www.tn.gov/content/dam/tn/health/documents/reportable-diseases/PH-1600.pdf>
- Accept 4. Record the individual's testing information in an office log that includes the date of testing, the date of the result notification, the result of the test, the source of specimen collection (nasopharyngeal, nasal, saliva, oropharyngeal), the method of specimen collection (health care provider collection, observed self-collection, self-collection), if the individual had known exposure to COVID-19, if the individual was symptomatic at the time of testing, date of onset of symptoms, the date of notification to Tennessee Department of Health (TDH), the date of notification to the local health department if the result was positive, and the date the individual was notified of test results.

AGREEMENT OF UNDERSTANDING (cont'd.)

In addition, the requesting organization:

- Accept 5. Shall not charge individuals, health insurance plans, or other third-party payers for the test or any testing supplies provided at no cost to the organization.
- Accept 6. Must report the number of tests conducted each week and the numbers of positive and negative results (aggregate, de-identified data) to COVID19.Testing@tn.gov.
- Accept 7. Must provide the individual with a written record of their test result and date of testing unless the patient has access to their results via an online portal.
- Accept 8. Shall assure that all persons participating in the COVID-19 testing program at this organization are made aware of their obligations under the terms of this agreement.
- Accept 9. Shall not refuse to provide testing to an eligible individual until notified by the State of Tennessee that the testing initiative has been suspended or discontinued.
- Accept 10. Acknowledges that negative results obtained through rapid antigen testing should be confirmed by molecular-based testing (PCR).

Additional conditions – the testing organization acknowledges that:

- Accept 11. TDH reserves the right to inspect testing supply inventory at will.
- Accept 12. TDH reserves the right to recall or redirect issued testing supplies as dictated by the department’s outbreak response needs.
- Accept 13. The timing and amounts for distribution of these testing supplies will be at the sole discretion of TDH.

Medical Director (or Authorized Designee) Signature

Date

INTERNAL USE ONLY

Dr. Lisa Piercey, MD, MBA, FAAP
Commissioner, Tennessee Department of Health

Date

COVID-19 Testing Supplies Memorandum of Understanding (MOU)

ORGANIZATIONS WITH MULTIPLE LOCATIONS

Name of Organization

FACILITY # 1			
Name of Facility or Practice			
Address where testing supplies are to be shipped			Building, Floor, Suite Number
City	State	Zip Code	County
POINT OF CONTACT (POC)			
Name	Credentials		Title
() -	() -		
Phone	Fax	E-mail	

FACILITY # 2			
Name of Facility or Practice			
Address where testing supplies are to be shipped			Building, Floor, Suite Number
City	State	Zip Code	County
POINT OF CONTACT (POC)			
Name	Credentials		Title
() -	() -		
Phone	Fax	E-mail	

FACILITY # 3			
Name of Facility or Practice			
Address where testing supplies are to be shipped			Building, Floor, Suite Number
City	State	Zip Code	County
POINT OF CONTACT (POC)			
Name	Credentials		Title
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Phone	Fax	E-mail	

COVID-19 Testing Supplies Memorandum of Understanding (MOU)

ORGANIZATIONS WITH MULTIPLE LOCATIONS (cont'd.)

Name of Organization

FACILITY # 4

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

() -

() -

Phone

Fax

E-mail

FACILITY # 5

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

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Phone

Fax

E-mail

FACILITY # 6

Name of Facility or Practice

Address where testing supplies are to be shipped

Building, Floor, Suite Number

City

State

Zip Code

County

POINT OF CONTACT (POC)

Name

Credentials

Title

() -

() -

Phone

Fax

E-mail