



EVERLYWELL™ Self-Collection COVID-19 PCR Testing Standard Operating Procedure

Please note this guidance is **specific to the Everlywell™ Self-Collection COVID-19 PCR test**. If you are using testing materials from any other manufacturer, please refer to the guidance for the use of that product.

Last Updated: October 22, 2020

Revision: Emphasized that patient creates an account with Everlywell and registers the unique ID printed on the test kit. Clarified that local health departments will not have access to test results.

Revision: Changed minimum age to 18yo, added collection instructions in Spanish

Amendments: MOU

Purpose

This Standard Operating Procedure (SOP) will guide you in the process of requesting and utilizing the **Everlywell™** Self-Collection PCR 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 are to be used for the self-collection of nasal specimens for COVID-19 PCR testing of qualifying individuals who are **18 years or older, capable of completing the procedure, and who have a valid email address and phone number**. **It is the responsibility of the receiving agency to ensure that registration, collection, and shipping processes and procedures are followed according to the guidance laid out in this document and the instructions provided by Everlywell™.**

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/1GPiOa>. 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 requesting the test kits.
- 3) Choose from the dropdown list of qualifying entities. If your organization is not listed, email COVID19.testing@tn.gov to request approval. Please provide point of contact name, phone number, and email and the complete delivery site address. Be sure to use the address where you would like the kits delivered.

- 4) Select “Nasal Swab Self-Test Kits”, the quantity needed (nasal kits come in boxes of 70), the intended use of the kits (student health, employee testing, testing event, etc)
- 5) Forecast the number of tests you anticipate will be used in the next 30 days.
- 6) Provide the number of nasal swab kits currently in stock.
- 7) 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).
- 8) Click submit
- 9) 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 the following Thursday/ Friday and should be received by within a few business days. Requests placed after 5pm CST Wednesday will ship the FOLLOWING week. 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 stored in air conditioning and protected from extreme temperatures.

Testing:

The collection kit includes everything you need to collect and ship your sample



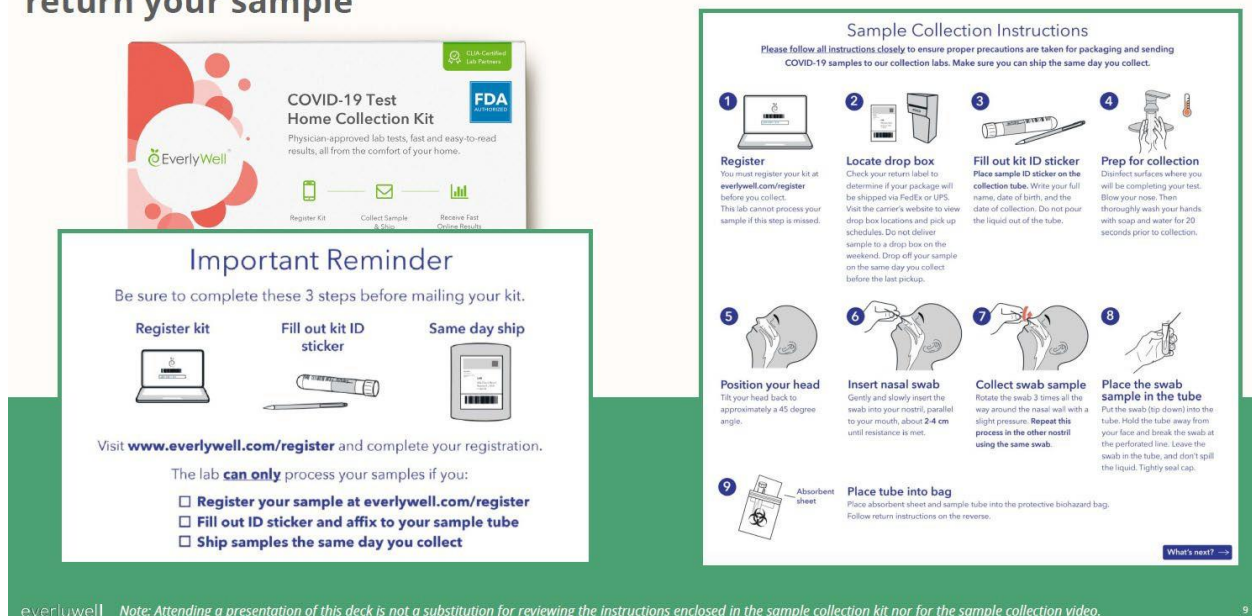
Note: Everlywell™ self-collection COVID-19 tests may only be used by patients 18 years and older. Patients are required to have an individual email address and phone number in order to register their test kit. Tests may only be collected Monday through Friday and MUST be shipped via UPS on the day of collection. Failure to follow these guidelines will result in an inability to process the specimen.

Tests shipped after the date of collection will not be processed.

Facilities are encouraged to identify the UPS drop boxes near their location and determine the time of the last pick-up to ensure tests that are collected are shipped out the same day, if possible.

- Identify patient for testing (e.g., patient experiencing symptoms of COVID-19, employee required to have regular testing, voluntary testing at a testing event, etc)
- Ask the patient to visit <https://everlywell.com/register> on their smart phone or a computer in the facility.
- Patient creates an account or logs in to an account they created previously
- Provide the patient with the test kit
- Patient registers the Unique Kit ID (printed on the test kit) on the website** and answers the demographic and screening questions.
 - Please be sure patient uses their **local** Tennessee address to ensure that the results will be reported to the correct local and state health departments (*for example, if it a college student, please have them use their dorm/ apartment address and not their home address*)
- Patient follows the directions included in the kit to fill out the ID sticker and affix it to the sample tube (please see instructions in Spanish below)

Kit includes step-by-step instructions for you to properly collect and return your sample



The image displays the Everlywell COVID-19 Test Home Collection Kit box and two instruction cards. The box is white with red and green accents, featuring the Everlywell logo and FDA approval. The instruction cards are green and white, providing step-by-step guidance for sample collection and return.

COVID-19 Test Home Collection Kit
Physician approved lab tests, fast and easy-to-read results, all from the comfort of your home.

Important Reminder
Be sure to complete these 3 steps before mailing your kit.

- Register kit
- Fill out kit ID sticker
- Same day ship

Visit www.everlywell.com/register and complete your registration.

The lab **can only** process your samples if you:

- ☐ Register your sample at everlywell.com/register
- ☐ Fill out ID sticker and affix to your sample tube
- ☐ Ship samples the same day you collect

Sample Collection Instructions
Please follow all instructions closely to ensure proper precautions are taken for packaging and sending COVID-19 samples to our collection labs. Make sure you can ship the same day you collect.

- Register**
You must register your kit at everlywell.com/register before you collect. This lab cannot process your sample if this step is missed.
- Locate drop box**
Check your return label to determine if your package will be shipped via FedEx or UPS. Visit the carrier's website to view drop box locations and pick up schedules. Do not deliver sample to a drop box on the weekend. Drop off your sample on the same day you collect before the last pickup.
- Fill out kit ID sticker**
Place sample ID sticker on the collection tube. Write your full name, date of birth, and the date of collection. Do not pour the liquid out of the tube.
- Prep for collection**
Disinfect surfaces where you will be completing your test. Blow your nose. Then thoroughly wash your hands with soap and water for 20 seconds prior to collection.
- Position your head**
Tilt your head back to approximately a 45 degree angle.
- Insert nasal swab**
Gently and slowly insert the swab into your nostril, parallel to your mouth, about 2-4 cm until resistance is met.
- Collect swab sample**
Rotate the swab 3 times all the way around the nasal wall with a slight pressure. Repeat this process in the other nostril using the same swab.
- Place the swab sample in the tube**
Put the swab (tip down) into the tube. Hold the tube away from your face and break the swab at the perforated line. Leave the swab in the tube, and don't spill the liquid. Tightly seal cap.
- Place tube into bag**
Place absorbent sheet and sample tube into the protective biohazard bag. Follow return instructions on the reverse.

What's next? →

everlywell | Note: Attending a presentation of this deck is not a substitution for reviewing the instructions enclosed in the sample collection kit nor for the sample collection video.

Recordatorio importante

Asegúrese de completar estos 3 pasos antes de enviar su kit por correo.

Registrar el kit



Completar la etiqueta
adhesiva de
identificación del kit



Enviar el mismo día



Visite www.everlywell.com/register y complete su registro.

El laboratorio **solo puede** procesar sus muestras si:

- ☐ Registre su muestra en everlywell.com/register
- ☐ Complete la etiqueta adhesiva de identificación y péguela sobre el tubo de su muestra
- ☐ Envíe las muestras el mismo día que las recolecta

Instrucciones para la recolección de muestras

Siga todas las instrucciones cuidadosamente y asegúrese de tomar las precauciones adecuadas para empaquetar y enviar las muestras de COVID-19 a nuestros laboratorios de recolección. Asegúrese de que puede enviarlas el mismo día que las recolecta.



1 Registro

Debe registrar su kit en everlywell.com/register antes de la recolección. Este laboratorio no puede procesar su muestra si no se completa este paso.



2 Localizar el buzón

Revise la etiqueta de devolución para saber si su paquete se va a enviar por FedEx o UPS. Visite el sitio web del transportista para conocer las ubicaciones de los buzones y los horarios de retiro. No coloque muestras en un buzón durante el fin de semana. Coloque su muestra el mismo día que la recolecta antes del último retiro.



3 Completar la etiqueta adhesiva de identificación del kit

Pegue la etiqueta adhesiva de identificación sobre el tubo de recolección. Escriba su nombre completo, fecha de nacimiento y fecha de recolección. No derrame el líquido fuera del tubo.



4 Preparación para la recolección

Desinfecte las superficies donde realizará la prueba. Guéñese la nariz. Luego, lávese las manos minuciosamente con agua y jabón durante 20 segundos antes de la recolección.



5 Inclinar la cabeza

Incline la cabeza hacia atrás en un ángulo de aproximadamente 45 grados.



6 Insertar el hisopo nasal

Inserte suave y lentamente en la fosa nasal, paralelo a la boca, de 2 a 4 cm de profundidad hasta que sienta resistencia.



7 Recolectar la muestra del hisopado

Rote el hisopo 3 veces por toda la pared nasal con una suave presión. Repita este proceso en la otra fosa nasal usando el mismo hisopo.



8 Coloque la muestra del hisopado en el tubo

Ponga el hisopo (con la punta hacia abajo) en el tubo. Sostenga el tubo lejos de la cara y rompa el hisopo siguiendo la línea perforada. Deje el hisopo en el tubo, y no derrame el líquido. Cierre herméticamente con la tapa.



9 Colocar el tubo en la bolsa

Coloque la hoja absorbente y el tubo con la muestra en la bolsa protectora de bioseguridad. Siga las instrucciones de devolución que figuran en el reverso.

¿Qué sigue? →

- g) The patient or facility staff prepares the specimen according to the package directions and the **facility** ships it via **UPS** (postage is pre-paid. Do not use any other carrier). Specimens received by 10am the following day will be processed within 24-48h.
- h) Facilities are encouraged to have the patient perform the swab outdoors or in a private room to avoid exposing others to aerosolized virus.

The patient **SHOULD NOT LEAVE THE FACILITY WITH THE TEST KIT.**

Test kits **MUST** be shipped via UPS on the same day as collection. **A specimen that cannot be shipped on the same day should not be collected using this test kit.** If a test must be conducted but cannot be shipped on the same day, the facility must either wait until the next weekday to collect the specimen or send a specimen to a privately contracted laboratory (using that laboratory's specific testing materials).

After self-collection, you will package your sample and return to the carrier's dropbox on the **same day as sample collection. Samples should be collected and returned on weekdays only, not on weekends.**

Return Instructions

Double check that you registered your sample at everlywell.com/register and added the sample ID sticker with your information to the sample tube.

1 

Wash your hands
Wash your hands thoroughly with soap and water for 20 seconds.

2 

Assemble box
Assemble your shipping box. Watch our box assembly video at everlywell.com/collect.

3 

Prepare sample
Place your biohazard bag inside the box. The box provides extra protection during transit.

4 

Put box in mailer
With clean hands, place the shipping box into the prepaid mailer. Apply the shipping label to the front of the envelope.

5 

Disinfect the mailer
Use the provided alcohol prep pad to disinfect the mailer, avoiding the address label, before completing the final shipping step.

6 

Ship
Deliver the pre-paid, pre-addressed return pack to the appropriate carrier's drop box. It's important you drop off your sample on the same day you collect before the last pickup for overnight shipping. Do not deliver sample to a drop box on the weekend.

Results Notification

- 1) Patient is notified via text message or email that their results are ready. Patient also receives text notifications that they have registered successfully and that their sample has arrived in the lab.
- 2) Patient logs in to their Everlywell™ account and views the result
- 3) Patient downloads their lab report and may share it electronically with their provider
- 4) If the test is positive, an Everlywell™ 's third party physician network (PWN) will contact the patient via telemedicine to provide guidance and instruct the patient to self-isolate based on current CDC guidelines.
- 5) Tennessee Department of Health receives all test results via electronic laboratory reporting (ELR) to NBS.

Billing and Payment

1. Everlywell™ test kits and processing are provided at no charge by the state of Tennessee and funded by federal COVID-19 relief funding
2. Providers are not to bill patients for the cost of these tests
3. Providers will not receive an invoice from Everlywell™; the State is billed directly

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

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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

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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

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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

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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

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Phone

Fax

E-mail