

COVID-19 HOME COLLECTION KIT INSTRUCTIONS – FOR ON-SITE USE

Inside your kit:













Fact sheet for individual

Please read all instructions before collecting your sample.

1. Register Your Kit

To register your kit, scan the provided QR Code located on your registration card using your smart device or visit <u>SimplicityHomeTest.com</u>. Follow the provided online instructions using your unique Kit ID/barcode labels found on the collection tube and registration card. Remember to register your kit before you collect your sample. *Samples are not eligible for processing if registration is not complete.*



2. Kit ID/Barcode Label

Ensure the collection tube has a sample Kit ID/barcode label. If it does not, place the spare Kit ID/barcode label on the collection tube (this can be found on the registration card).



3. Prep for Collection

Wash your hands thoroughly with soap and water for at least 20 seconds. Remove the swab from the packaging. (Ensure the tip of the swab does not come in contact with any surface.*)

surface.)

4. Sample Collection

- a. Place the swab inside one nostril until it meets resistance (about 1/2 to 3/4 inch).
- b. Rotate the swab against the nasal wall 3 to 5 times taking at least 15 seconds.
- c. Repeat the process in the second nostril using the same swab.
- d. Place the swab in the collection tube and break the shaft at the breakpoint. Be careful not to spill the liquid in the tube. (If the liquid is absent, the lab will reject the sample.*)
- e. Leave the swab in the collection tube and tightly screw the lid back on the collection tube. Ensure the lid is tight. (The lab will reject the sample if there is leakage.*)





Place the collection tube containing your sample in the plastic biohazard bag. Ensure the bag is well sealed.









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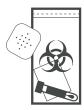
6. Rewash Your Hands

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



7. Clean the Biohazard Bag

With the supplied alcohol pad, wipe the outside of the biohazard bag before dropping the biohazard bag at the designated collection location.



8. Drop Off Your Sample

Immediately after finishing step #7, deliver the biohazard bag containing your sample to the designated collection location. It is important the sample is dropped off on the same day of collection. Do not drop off your sample on the weekend.



9. Final Packaging

Kits will be collected in a corrugated box labeled with a UN3373 sticker and placed in a clinical pack for shipment.



IVD

For use by people 18 years of age or older. This test kit requires access to the Internet and email account. Not for resale. Intended for sale and use in the U.S. only. Store kit at room temperature.

Simplicity by Assurance Scientific Laboratories offers this product with a FDA Emergency Use Authorization (EUA). This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA; This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal, Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.



COVID-19 HOME COLLECTION KIT INSTRUCTIONS

by Assurance Scientific Laboratories



Please read all instructions before collecting your sample.

For help assembling your kit, please watch our Home Collection Video at SimplicityHomeTest.com.

1. Register Your Kit

To register your kit, scan the provided QR Code located on your registration card using your smart device or visit Assurance. Genera Medical.com. Follow the provided online instructions using your unique Kit ID/barcode labels found on the collection tube and registration card. Remember to register your kit before you collect your sample. Samples are not eligible for processing if registration is not complete.





2. Arrange for Shipping

Check the return label on the return mailer to identify the shipping carrier, either UPS or FedEx. Confirm the nearest drop box location and hours. Ship the sample the same day as collection and before the last pickup. Do not ship over the weekend.



3. Kit ID/Barcode Label

Remove all contents from the shipping box and bag. Ensure the collection tube has a sample Kit ID/barcode label. If it does not, place the spare Kit ID/barcode label on the collection tube (this can be found on the registration card).



4. Prep for Collection

Wash your hands thoroughly with soap and water for at least 20 seconds. Remove the swab from the packaging. (Ensure the tip of the swab does not come in contact with any surface.*)

5. Sample Collection

- a. Place the swab inside one nostril until it meets resistance (about 1/2 to 3/4 inch).
- b. Rotate the swab against the nasal wall 3 to 5 times taking at least 15 seconds.
- c. Repeat the process in the second nostril using the same swab.
- d. Place the swab in the collection tube and break the shaft at the breakpoint. Be careful not to spill the liquid in the tube. (If the liquid is absent, the lab will reject the sample.*)
- e. Leave the swab in the collection tube and tightly screw the lid back on the collection tube. Ensure the lid is tight. (The lab will reject the sample if there is leakage.*)
- *If any liquid spills, leaks, or the swab comes in contact with any surface, please contact CustomerService@SimplicityHomeTest.com to order a new kit.







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6. Assemble the Biohazard Bag

Place the collection tube containing your sample in the plastic biohazard bag with the absorbent sheet. Ensure the bag is well sealed.



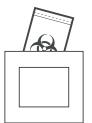
7. Rewash Your Hands

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



8. Assemble the Transport Box

With clean hands, assemble the provided transport box and place the sealed biohazard bag into the box. Close the transport box and make sure the content inside is secure. For help assembling the transport box, please watch our Home Collection Video at SimplicityHomeTest.com.



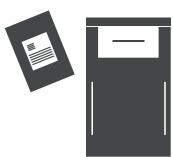
9. Assemble the Return Mailer

Place the transport box inside the provided return mailer. If not already applied, apply the pre-paid shipping label to the return mailer, ensuring you do not cover up the UN 3373 label. Remove the mailer's cover strip and seal the package closed. Make sure the transport box is secure inside the return mailer. With the supplied alcohol pad, wipe the outside of the mailer, avoiding the label, before dropping the mailer at the drop box.



10. Ship Your Sample

Immediately after finishing step #9, deliver the package to the appropriate carrier's drop box using the prepaid, pre-addressed return mailer containing your sample. <u>It is important</u> the sample is shipped on the same day of collection. Ensure you drop your sample off at the drop box location before the last pickup. **Do not ship your sample on the weekend.**

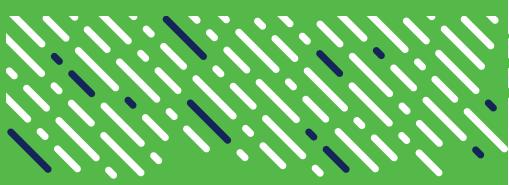


IVD

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This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA; This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal, Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

SimplicityHomeTest.com



Must be 18+ to use this test kit

Online Results Quick, Reliable



Collection & Shipping Easy Sample



Registration Online Kit



Home Collection Kit COVID-19 TEST

FDA



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by Assurance Scientific Laboratories

by Assurance Scientific Laboratories







Why Choose Simplicity?

Simplicity by Assurance Scientific Laboratories was created to provide convenient, at-home COVID-19 sample collection to the public. Your sample will be tested with an FDA authorized PCR test performed at Assurance Scientific Laboratories or another laboratory designated by Assurance Scientific Labs, which are CLIA labs that meet requirements to perform high complexity testing.

Inside your kit:











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1. Kit Purchase & Registration

Purchase your kit online or at a retail location. Register your kit by scanning the provided QR code using your smart device or online at Assurance.GeneraMedical.com.

2. Easy Sample Collection & Shipping

Follow the collection and shipping instructions found in your kit to obtain your sample and mail it back to our lab. Make sure to collect your sample and ship it on the same day at your nearest dropbox location.

3. Quick, Reliable Online Results

Once your test is processed and results are confirmed, you will receive an email and text with a link to view your

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