

QuickVue At-Home User Instructions Video – Descriptive Transcript

Audio	Visual
[intro music]	Quidel logo animates in.
This video provides step-by-step instructions on how to use the QuickVue At-Home OTC COVID-19 Test.	QuickVue At-Home COVID-19 Test [logo] and User Instructions [title] appears. Transition to the 2-Count QuickVue At-Home COVID-19 Test product package, a prefilled tube, nasal swab, test strip and timer on a counter. A disclaimer appears at the bottom of the screen: "Actual packaging and components may vary. For use under FDA Emergency Use Authorization (EUA) only."
Before you start testing, wash your hands or use sanitizer.	Woman's hands washing with soap under running water.
The first step is to remove the content from the box and identify all of the components within the test tray...	The package, test kit components and timer are shown on the counter, with instructional copy "Step 1 - Check Your Test Kit" appearing on screen. There is a disclaimer in the bottom right of the screen: "Test kit portrayed. Kit configuration may vary."
...including the step-by-step User Instructions, a Prefilled Tube, a Nasal Swab, and a Test Strip.	Transition to the User Instructions document. Then, woman's hand removes the prefilled tube, nasal swab, and concealed test strip from the tray.
To begin running the test, select one prefilled tube from the tray and remove the cap. Now, place the open tube back in the hole labeled Tube Holder, built into the tray. This will keep the tube secure while performing the test.	Instructional copy "Step 2 - Place Tube in a Tube Holder" appears on screen as the woman picks up a prefilled tube and twists the cap to open the tube. The woman then places the tube in a hole within the tray. A closer look at hole within the tray shows the label "Tube Holder".
If you are performing a test from the 25-test kit, your tube tray will look like this.	Transition to a 25-test kit image to show 12 closed test tubes and 1 opened test tube with a test strip inside.
Now, open the Nasal Swab by peeling open the wrapper and removing the swab by the handle. Be careful not to touch the swab head.	Instructional copy "Step 3 - Swab the Nostrils" appears on screen as the woman peels open the swab wrapper and pulls out the swab by its handle.
Gently insert the swab ½ to ¾ of an inch into the nostril, depending on the size of your nose. Firmly rub both nostrils with the same swab before proceeding.	Instructional copy "Step 3 - Swab the Nostrils" remains on screen as the woman inserts the swab and swirls it inside her right nostril, then her left nostril.
If you are swabbing others, please wear a face mask. The procedure is the same. Rub both nostrils with the same swab before proceeding.	Transition to woman wearing a face mask, swabbing another woman's nostrils.

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<p>With children or small adults, the maximum depth of insertion into the nostril may be less than ¾ of an inch.</p>	<p>Transition to another woman wearing a face mask, who pulls down a boy's mask and swabs his nostrils. A disclaimer appears at the bottom of the screen: "For ages 2 and up. For ages 2 to 14, an adult must perform the test."</p>
<p>Once you've collected the sample with the swab, immediately place the swab into the liquid inside the tube and swirl 3 or 4 times.</p>	<p>Instructional copy "Step 4 - Place Swab in the Tube" appears on screen as the woman inserts the swab into the prefilled tube and swirls.</p>
<p>After swirling, leave the swab in the tube for one minute. Set a timer for 1 minute.</p>	<p>Woman sets timer for 1 minute. A disclaimer appears at the bottom of the screen: "Leave the Swab in for 1 minute. If the swab is left in the solution for more than 10 minutes, it should not be used."</p>
<p>When 1 minute is complete, carefully remove the swab from the tube. As you remove it, rotate the swab head against the inner wall of the tube to squeeze out as much liquid as possible. Then, discard the swab into your household waste.</p>	<p>Instructional copy "Step 5 - Remove Swab from the Tube" appears on screen as the woman rotates the swab head against the inner wall of the tube to remove the liquid. Woman disposes of the swab in the trash.</p>
<p>Next, open the test strip pouch carefully, tearing from the slit at the end of the wrapper and hold the test strip as indicated. Place the test strip into the tube with the arrows pointing downward.</p>	<p>Instructional copy "Step 6 - Open the Test Strip" appears on screen as the woman opens the test strip pouch and removes the test strip. She then inserts the test strip into the tube, with the arrows pointing downward into the tube. Instructional copy "Step 7 - Place Test Strip in Tube" appears on screen.</p>
<p>Set a timer for 10 minutes. Leave the test strip in the tube for the full 10 minutes. Do not handle or remove the test strip before the 10 minutes is complete.</p>	<p>Woman sets timer for 10 minutes. A disclaimer appears at the bottom of the screen: "Set timer for 10 minutes."</p>
<p>At 10 minutes, remove test strip from the tube and place it on the strip outline included on the User Instructions sheet. The results should be read within 5 minutes after the 10-minute timer stops. Invalid or inaccurate results may occur if the test strip is read beyond the recommended 5-minute time period.</p>	<p>Instructional copy "Step 8 - Remove Test Strip from the Tube" appears on screen. Woman removes the test strip from the tube and places it on the strip outline included on the User Instructions sheet. A disclaimer appears at the bottom of the screen: "Read results immediately after the 10-minute timer stops. Results should not be read more than 5 minutes after the timer has stopped."</p>
<p>The result of your test is displayed in the center area of the test strip. Compare your results with the diagrams on the User Instructions sheet.</p>	<p>Instructional copy "Step 9 - Check your Results" appears on screen as the camera zooms in on the image of the User Instruction guide.</p>

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<p>A positive result is indicated by the presence of a blue line and a pink line. Look closely. Even a faint pink line is considered positive.</p>	<p>Instructional copy "Step 10 - Check for a Positive COVID-19 Result" appears on screen. Display images of a positive result.</p>
<p>A negative result is indicated by the presence of a blue line, without the presence of the pink line.</p>	<p>Instructional copy "Step 11 - Check for a Negative COVID-19 Result" appears on screen. Display images of a negative result.</p>
<p>An invalid result is indicated if the blue line does not appear, even if a pink line appears. An invalid result also is indicated if you see no line. If the test is invalid, a new test should be performed.</p>	<p>Instructional copy "Step 12 - Check for an Invalid COVID-19 Result" appears on screen. Display images of an invalid result.</p>
<p>Discard your materials and begin again with a new Prefilled Tube, a new Swab and a new Test Strip.</p>	<p>Woman disposes of the test strip and tube in the trash. Transition to woman lifting another prefilled tube, swab and test strip from the tray.</p>
<p>Once you've completed performing the test, all the test components should be disposed of in your household waste.</p>	<p>Woman disposes of the test strip and tube in the trash.</p>
<p>Once you have the results of your QuickVue At-Home OTC COVID-19 Test, refer to your User Instructions or contact your Healthcare Provider for next steps.</p>	<p>The package, test kit components and timer are shown on the counter. There is a disclaimer in the bottom right of the screen: "Test kit portrayed. Kit configuration may vary."</p>
<p>For Customer Support in the United States, call (833-784-2588) or visit us at QuickVueAtHome.com.</p>	<p>The package and test kit components are shown on a table. The Customer Support phone number and website URL animate in. [Phone number] 833-Quickvue (833-784-2588) or [URL] QuickVueAtHome.com.</p>
<p>[Ending music]</p>	<p>Quidel logo animates in. Transition to the legal disclaimers and copyright statements.</p>
<p>[Legal Disclaimer]</p>	<p>Legal disclaimers and copyright statements appears on screen. "The QuickVue At-Home OTC COVID-19 Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests.</p>

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This home test is authorized for nonprescription home use with self-collected (unobserved) direct anterior nasal (NS) swab specimens from individuals aged 14 years and older or with adult-collected anterior NS samples from individuals aged 2 years or older.

This home test has not been FDA cleared or approved, but has been authorized by the FDA under an Emergency Use Authorization (EUA) for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The home test 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 authorization is terminated or revoked sooner.

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QuickVue At-Home User Instructions Video – Descriptive Transcript

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