Detect Covid-19 Test™ Instructions for Use

Your Detect Covid-19 Test can be used for serial testing

If you are suspected of Covid-19 (symptomatic or exposed), you can use a single test. If you have no reason to suspect Covid-19, you should use the Detect Covid-19 Test as a serial test. If your first test result is negative, you must perform a second Detect Covid-19 Test after at least 24 hours but within 48 hours to ensure an accurate result.

What is serial testing?

Serial testing involves testing the same person multiple times within a few days. Such testing for Covid-19 increases the chances of detecting infections earlier - even in people who are not exhibiting any symptoms.

How can the Detect Covid-19 Test be used for serial testing?

If your first test is negative, you must use a second test at least 24 hours (and no more than 48 hours) from your first test result. If your first or your second test is positive, then you are likely to have a current infection with SARS-CoV-2, the virus that causes Covid-19, and should consult with your healthcare provider, if needed. A second test is not needed if your first result is positive.

First time taking the Detect Covid-19 Test?

Download the Detect App™ from the iOS or Android app stores to activate your test and follow the step-by-step video instructions within the app to take the test.

Get the app at **detect.com/app**

The Detect Hub™ is sold separately and is required to use the Detect Covid-19 Test.

If you have no symptoms or other reasons to suspect exposure to Covid-19 and your first Detect Covid-19 Test result is negative, you must perform a second Detect Covid-19 Test within 48 hours to ensure an accurate negative result. Please make sure you have enough tests available to repeat the test in case your first test is negative.

Need assistance? Contact support@detect.com or (855) 322-3692

Information about the Test

- For in vitro diagnostic use.
- For use under FDA Emergency Use Authorization only.
- This product has not been FDA cleared or approved but has been authorized 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.
- 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 IVDs 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.

Read before using

False negative results are possible in individuals who take high dose biotin (vitamin B7) supplements. Please inform your Healthcare Provider if you are taking biotin–containing supplements and obtained a negative result for the Detect Covid-19 Test.

In addition, invalid results may occur if you are using certain nasal sprays used to fight allergies. You may wish to discuss this with your healthcare provider if you are concerned.

Make sure to wash and rinse your hands well before taking this test. If high amounts of moisturizing lotion or hand soap come into direct contact with the Swab and are introduced into the test reaction, they could interfere with your result.

Detect Covid-19 Test Instructions

⚠ **Please follow these step-by-step instructions carefully as you use the test. If you have not used the test before, please download and use the Detect App for a video tutorial.**

Need assistance? Contact support@detect.com or (855) 322-3692

Before you begin

- Have a sealed Detect Covid-19 Test and a Detect Hub (sold separately) ready.
  - Each Detect Test is single-use, while the Detect Hub is reusable.
- Check the “Use By” date on the test box to ensure the test hasn’t expired.
- Set aside time - the test takes about an hour.
  - Have a timer available.
- Use the test on a flat, clean surface.
- Wash your hands - rinse off any soap completely.
- If performing the test on someone else, put on gloves and mask if needed.
- Follow these step-by-step instructions carefully as you use the test.
- Please refer to additional product information available on the detect.com website.
  - Product Information Sheets: detect.com/legal/product_information_sheets
- **If you have no symptoms or other reasons to suspect exposure to Covid-19 and your first Detect Covid-19 Test result is negative, you must perform a second Detect Covid-19 Test after at least 24 hours but within 48 hours to ensure an accurate result. Please make sure you have enough tests available.**

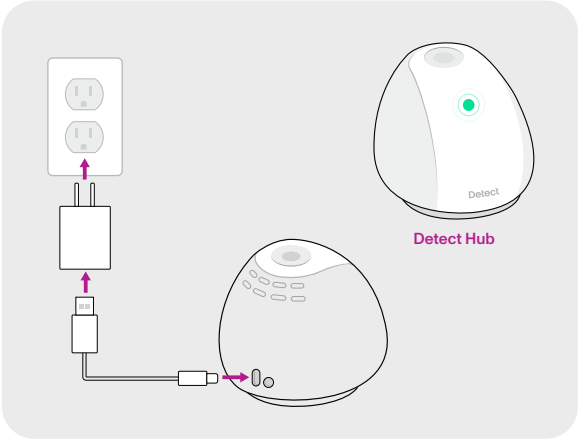
WARNINGS

- The test can be used for individuals 2 years or older. Adults should administer the test for children 13 years old or younger.
- Store and use the test between 59 °F (15 °C) and 86 °F (30 °C).
- Keep away from children and pets - small parts can be choking hazards.

01 Set up the Detect Hub

The Detect Hub is sold separately and is required to use the Detect Covid-19 Test.

- Plug the Detect Hub into a wall outlet using the included power adapter.
- A solid green light will indicate that the Hub is ready.



Set aside the Hub manual - refer to it only if any troubleshooting is needed to operate the Hub.

02 Open the Detect Covid-19 Test

Each test box includes a Prepare Pack, a cardboard divider, and a Result Pack.

Do not open any packaging until instructed to do so.

- The Prepare Pack contains a Swab, a Test Tube, and the Detect Cap™. (Open only when instructed to do so.)

Swab

Test Tube

Detect Cap

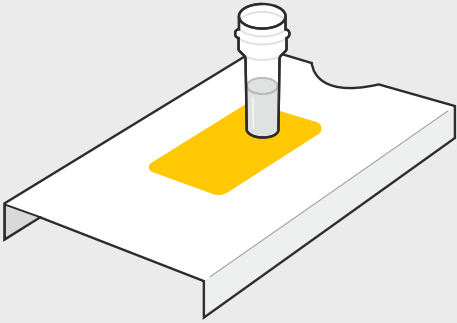
- The Result Pack contains a Dropper and the Reader. (Open only when instructed to do so.)

Dropper

Reader

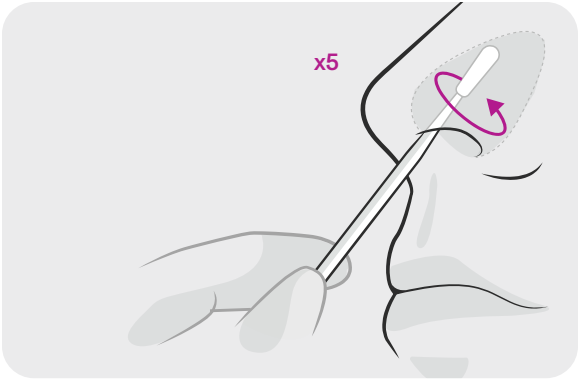
03 Set up the Test Tube

- Take out the Prepare Pack and the cardboard divider.
- Place the cardboard divider on a flat surface.
- Open the Prepare Pack.
- Take out the Swab, Test Tube, and the pouch containing the Detect Cap.
  - Do not remove the Detect Cap from its package yet.
- **Open the Test Tube carefully, as it contains a liquid.**
- Discard the cap.
- Place the open tube in the cardboard divider.



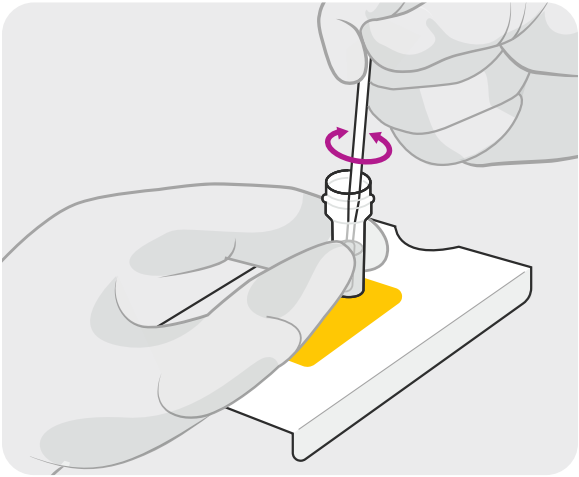
04 Collect Sample with the Swab

- Open the Swab from the end marked “Peel here▲” without touching the soft tip.
- Insert the Swab in one nostril until just the soft tip is completely inside.
  - For adults - insert less than one inch.
  - For younger children - insert less than 1/2 inch.
- Swab the inside wall of the nostril in a circle 5 times.
  - The Swab tip should remain in contact with the nostril wall at all times.
- Repeat with the other nostril.
- If you are helping someone else take the test, follow the same steps to swab their nostrils.



05 Stir the Swab in the Test Tube

- Immerse the Swab fully inside the liquid in the Test Tube placed in the cardboard divider.
- Hold onto the tube and stir the Swab vigorously in the liquid for **15 seconds.**
- Once done, discard the Swab wrapped in its packaging.



WARNING

- Do not break off the Swab tip and leave it inside the Test Tube.

06 Use the Detect Cap

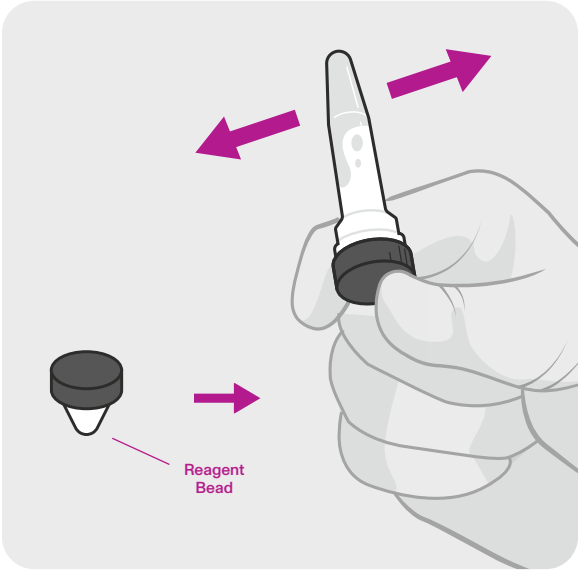
- Carefully open the Detect Cap package and take out the cap.
  - The small cap can get lost if dropped.
  - You may need to remove the silica packet first.
  - The cap contains a reagent bead.
- Screw the Detect Cap **tightly** onto the Test Tube.
  - Ensure the cap is locked so that you cannot unscrew it.
  - If you can unscrew it, screw it on again until you can no longer unscrew it.

WARNING

- Do not open the Test Tube after this step.

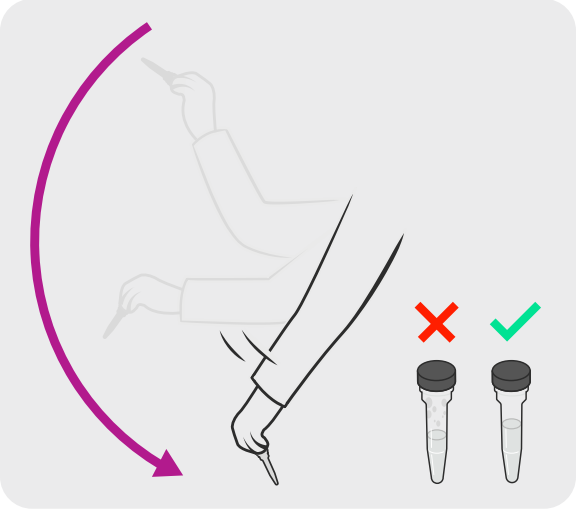
This step continues on the next page.

- Hold the Test Tube by the cap, turn it **upside down**, and shake it hard side-to-side for **10 seconds.**
  - The tube should remain upside down during the shaking step.
  - The reagent bead in the cap will dissolve into the sample.



07 Flick the Test Tube

- Hold the tube **right side up** with the cap.
- Standing up, forcefully bring down your whole arm to collect all the liquid at the bottom of the Test Tube.

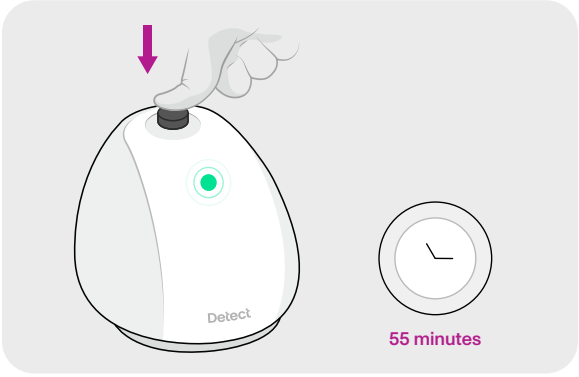


WARNING

- No liquid drops should remain toward the top of the tube.

08 Process the sample

- Place the Test Tube into the well of the Detect Hub that is plugged in and ready.
  - Push the tube all the way in.



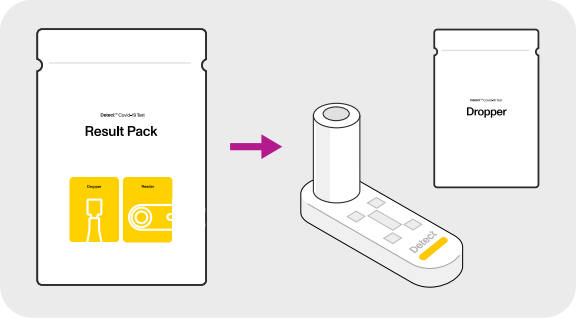
- The Hub will beep once, and the green light will start blinking.
- This step takes about 55 minutes - set a timer.
- The green light will stop blinking and the Hub will beep once the Hub processing is complete.

WARNING

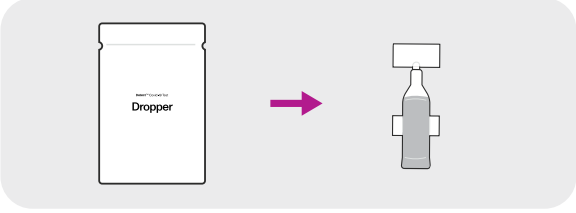
- Do not take out the tube from the Hub until processing is complete.

09 Use the Dropper

- Open the Result Pack and take out the Dropper pouch and the Reader.

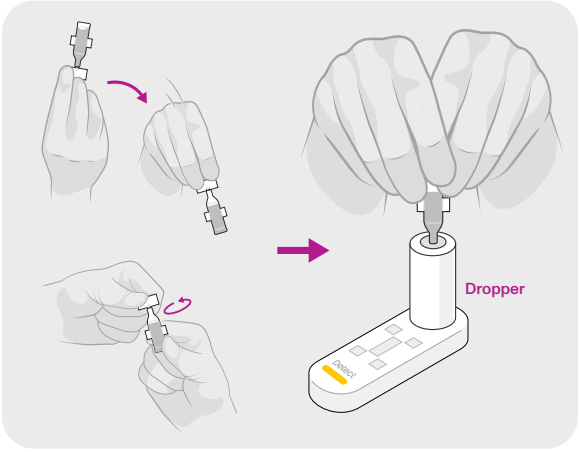


- Remove the Dropper from its pouch.
  - The Dropper contains liquid.



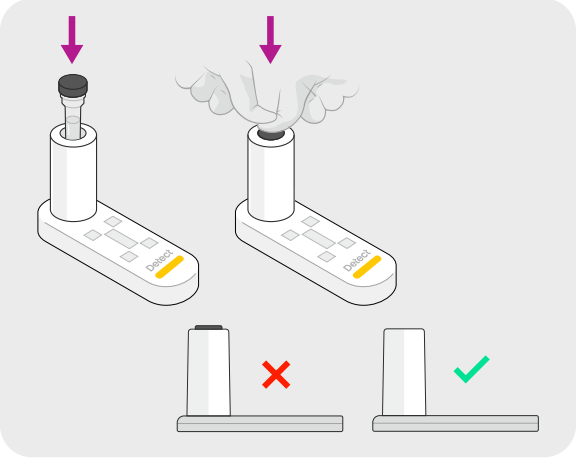
This step continues on the next page.

- Pick up the Dropper by the tip and flick it down to collect all the liquid at the bottom.
- Twist off the tip of the Dropper.
  - Be careful not to spill any of the liquid.
- Insert the Dropper tip into the Reader chimney as far as it will go.
- Squeeze the Dropper firmly to dispense all the liquid.
- Discard the Dropper.



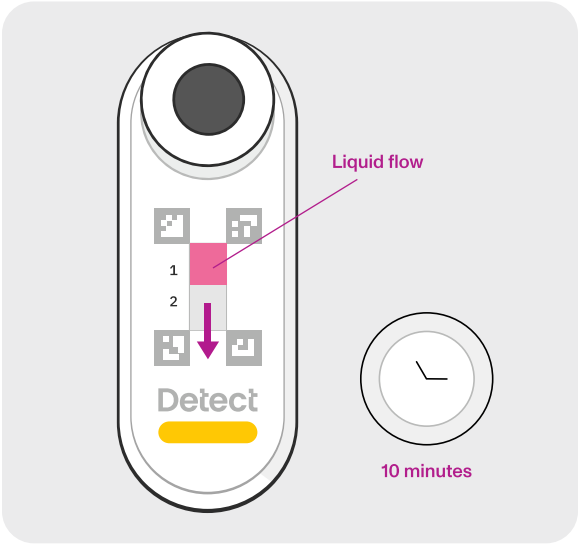
10 Insert the Test Tube into the Reader

- Remove the Test Tube from the Detect Hub after the processing step is complete.
  - Do not open the tube.
- Place the tube into the Reader chimney, and using both thumbs, press it down firmly.
  - The tube cap should be flush with the lip of the Reader chimney.
  - You may hear a “pop” sound as the tube bottom is opened inside the chimney, allowing the sample to flow through the Reader.



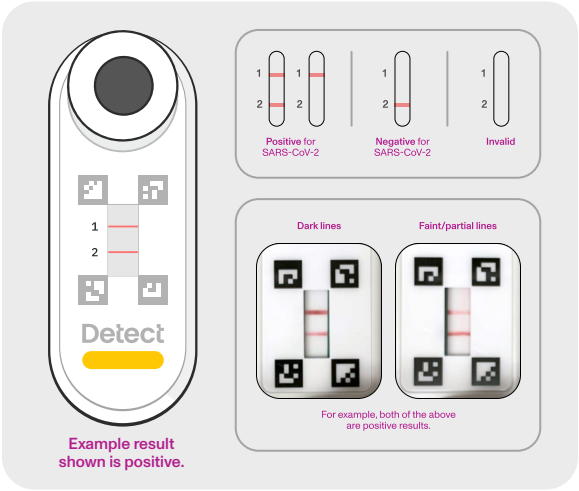
11 Watch for liquid flow

- Liquid should be seen flowing through the Reader within 10 seconds.
  - If there is no flow, tap the Reader firmly against a hard surface 3 times until liquid starts flowing.
- Results will be ready in 10 minutes. Set a timer.



12 Get results

- After 10 minutes, you should see one or two red lines in the Reader window.
  - Check carefully, as lines may be faint or incomplete.
- Use the guide below to determine the test result based on lines present next to labels 1 and 2.



Please refer to the Fact Sheet for Individuals available at detect.com.

What do the results mean?

NEGATIVE

A negative test result indicates that your nasal sample does not contain detectable amounts of viral RNA (the genomic material from the virus that causes Covid-19). This means you are unlikely to have Covid-19 currently.

If you have no symptoms or reasons to suspect Covid-19 infection and this was your first result, you must collect and test a second sample at least 24 hours after your first test and within the next 48 hours. If this is your second test, you are unlikely to have Covid-19 currently.

The Detect Covid-19 Test can only tell you about your current Covid-19 status. It cannot tell you if you had a previous infection with the virus that causes Covid-19.

If you have symptoms of Covid-19: Consult a healthcare provider for additional testing. It's possible your symptoms are a result of another illness or that you need further molecular testing for Covid-19. Be extra vigilant about quarantining, wearing a mask when you must leave your home, and washing your hands.

Results meaning continues on the next page.

What do the results mean?

POSITIVE

A positive test result indicates that your nasal sample contains detectable amounts of viral RNA (the genomic material from the virus that causes Covid-19). This means you are likely to have Covid-19 currently. Positive results do not rule out bacterial infection or co-infection with other viruses.

The Detect Covid-19 Test is intended as a single test for people who are symptomatic or exposed, and for serial screening of people with no reason to suspect Covid-19 infection. Whether this is your first or second test, please consult with a healthcare provider immediately. Let them know you tested positive and provide them with your Detect test results.

If you have symptoms of Covid-19: Consult a healthcare provider. You may need additional molecular testing to confirm your result. Be extra vigilant about quarantining, wearing a mask when you must leave your home, and washing your hands.

Results meaning continues on the next page.

What do the results mean?

INVALID

If the result is invalid, retest. You must use a new Detect Covid-19 Test and a new Swab. Contact Detect customer support at support@detect.com or call toll-free at (855) 322-3692 for a replacement test.

Using certain nasal sprays containing flunisolide or dexamethasone may lead to an invalid result. Please refer to our FAQs for details.

Until you retest, continue to be vigilant about social distancing, wearing a mask when you must leave your home, and washing your hands.

Reporting your test results to public health agencies

You have the option to report your Detect Covid-19 Test result to public health agencies as part of the CARES (Coronavirus Aid, Relief, and Economic Security) Act. This information helps them track the virus and determine appropriate public health measures and guidelines in response to the Covid-19 pandemic.

You can choose to report your results to only the Centers for Disease Control (CDC) in a completely anonymous way. You may also choose to report your results along with some information about you to your local health agencies, if local/state regulations permit.

Please go to **detect.com/publichealth/reporting**

Or scan the QR code below with your mobile device to access details:

Disposal instructions

➔ Put away the reusable Detect Hub.

- Unplug the Hub and store it for use with any other Detect Tests.

➔ Dispose of all used test components from the Detect Test box.

- All components from the test box, including the Reader, can be disposed of in the trash.
- Want to keep a record of your Detect Covid-19 Test result? Take a picture of the Reader before disposing it as the lines will fade over time and the result will not be valid.

Detect™

detect.com
support@detect.com
+1 (855) 322-3692

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