Detect

Detect™ Covid-19 Test

Covid-19 Molecular Home Test

Instructions For Use
For Healthcare Providers

For in vitro diagnostic use.

For use under Emergency Use Authorization only.

A smartphone with the Detect™ App is required for running this test.
Go to detect.com/app for the list of compatible smartphones.

Contents

1. Intended Use

The Detect™ Covid-19 Test (the Detect™ test) is a molecular *in vitro* diagnostic test for the qualitative detection of nucleic acid from the novel coronavirus SARS-CoV-2 that causes Covid-19.

This test is authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older suspected of Covid-19. This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older suspected of Covid-19.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, without symptoms or other epidemiological reasons to suspect Covid-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

SARS-CoV-2 viral RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral RNA, but clinical correlation with past medical 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. Individuals who test positive with the Detect™ Covid-19 Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive and confirmation with a molecular assay performed in a laboratory, if necessary for patient management, may be performed. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with Covid-19.

Individuals who test negative and continue to experience Covid-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Test results will be reported to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC. Automatic test result reporting will be performed by the Detect™ App and the Detect™ secure cloud server.

The Detect™ Covid-19 Test is authorized for non-prescription self-test by individuals aged 14 years or older and/or, as applicable, for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The Detect™ Covid-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. Summary and Explanation of the Test

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) in December 2019. Chinese authorities identified a novel coronavirus SARS-CoV-2 (cause of Covid-19 respiratory disease) which has resulted in confirmed human infections worldwide, including the United States. Cases of severe respiratory illness and deaths have been reported. Patients can become infected with SARS-CoV-2 virus through contact with a contaminated environment or person.

Detect™ is a molecular in vitro diagnostic test that aids in the diagnosis of Covid-19 through the identification of the SARS-CoV-2 RNA in nasal swab specimens.

In asymptomatic individuals (those without Covid-19 symptoms), the Detect™ Covid-19 Test should be used as a serial test.

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 identifying infections earlier and should be used for people who are not exhibiting any symptoms.

How do I use the Detect™ Covid-19 Test for serial testing?

Your test comes as a pack of two tests. If you're asymptomatic and your first test is negative, you should use the second test after at least 24 hours but within 48 hours. If your first test is positive, then you are likely to have Covid-19 currently and should consult with a healthcare provider without waiting to use the second test. If only your second test is positive, then you are also likely to have Covid-19 and should consult with a healthcare provider.

3. Principles of the Procedure

The Detect™ test uses RT-LAMP (Reverse Transcription Loop-mediated Isothermal Amplification) and lateral flow strip technologies to Detect™ nucleic acids from the Open Reading Frame 1ab (ORF1ab) region of the SARS-CoV-2 genome. The Detect™ test also identifies nucleic acids from a human gene that serves as a control for sample collection, extraction, reagent integrity, and test execution.

Isothermal amplification occurs at elevated temperature within a disposable tube placed into the reusable Detect™ Hub. After amplification, the tube is inserted into the Reader and the tube's liquid wicks onto the lateral flow strip. On the lateral flow strip's sample pad, SARS-CoV-2 and control amplicons bind colored particles and flow through the lateral flow strip's membrane, where they are captured by immobilized antibodies at distinct lines on the strip. A valid negative result must show the Sample Processing Control line. A positive result must show the SARS-CoV-2 line and may or may not also show the Sample Processing Control line.

In asymptomatic patients, serial testing is required to assist in identifying infected individuals and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing done on a weekly basis may decrease the risks of false negative results.

For asymptomatic users, an initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing with two or more negative results may require ongoing serial testing or confirmatory testing with this or a different SARS-CoV-2 test, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing with one or more positive results indicates that SARS-CoV-2 RNA is present but does not rule out coinfection with other pathogens.

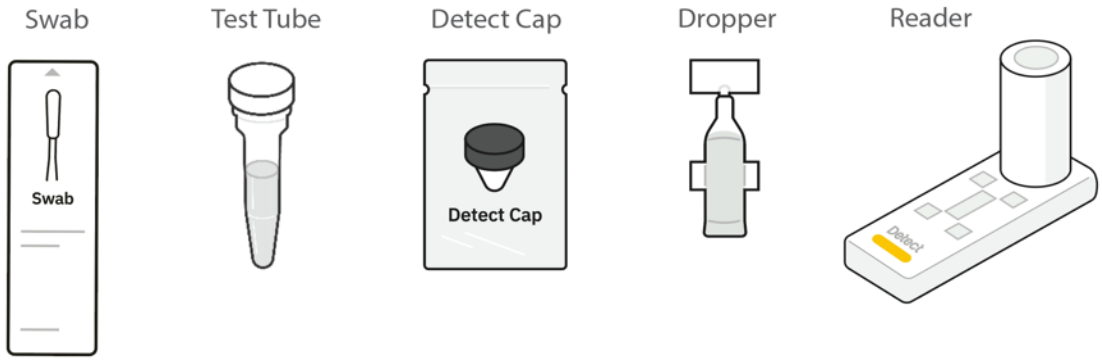
4. Assay/Reagents

4.1 Materials

The Detect™ Covid-19 Test contains enough reagents to process one self-collected sample.

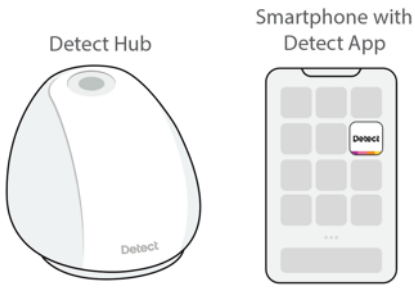
Materials Provided

- Swab (sterilized)
- Test Tube (contains Collection Buffer)
- Detect™ Cap (contains lyophilized reagent bead)
- Dropper (contains buffer)
- Reader (contains lateral flow strip inside of plastic housing)



Required but Not Provided

- Detect™ Hub (Model 21101, device sold separately)
- Detect™ App (free)
- Smartphone - visit detect.com/app to see the list of compatible devices and download the app



Minimum smartphone requirements:

iOS Models released after 2013 and using the operating system iOS 13 or higher.

Android Models released after 2013 using the Android API level 26 (Android 8 or higher) with XHDPI or better resolution (720x1280 px), including models from Samsung, Google, Motorola, Huawei, LG, Nokia, Alcatel, and ZTE.

5. Warnings and Precautions

5.1 General

IVD

- 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 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.
- For more information on EUAs please visit: https://www.fda.gov/emergencypreparednessand-response/mcm-legal-regulatory-and-policy-framework/emergency-useauthorization
- For the most up to date information on Covid-19, please visit: https://www.cdc.gov/coronavirus/2019-ncov/index.html
- The intensity of the test line does not necessarily correlate to the amount of SARS-CoV-2 virus in the sample.
- Samples should be tested as quickly as possible after sample collection.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- Only use the test components provided. Do not use swabs from other tests. Do not re-use any of the components included in the Detect™ Covid-19 Test. Only the Detect™ Hub may be re-used for testing other samples.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.

- Treat all biological specimens, including used test components, as if capable of transmitting infectious agents. Because it is often impossible

to know which might be infectious, all biological specimens should be handled using standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention [1, 2] and the Clinical and Laboratory Standards Institute [3].

- Do not ingest.
- Keep out of reach of children.
- Avoid contact with skin and eyes.
- Do not apply the Test Tube buffer directly onto the skin or mucous membranes or ingest. If contact with the body occurs, rinse with water. If irritation persists, seek medical advice. If swallowed: call a poison center/doctor if you feel unwell.
- Do not apply the buffer contained in the Dropper directly onto the skin or mucous membranes or ingest. If contact with the body occurs, rinse with water. If irritation persists, seek medical advice. If swallowed: call a poison center/doctor if you feel unwell.

5.2 Storage & Handling

- Store all components at 59 °F to 86 °F (15 °C to 30 °C).
- Do not open components until you are ready to perform testing.
- Open all packages carefully to avoid losing small components.
- Do not use Test Tubes that are wet or have leaked or spilled.
- Do not use the Detect™ Cap if its storage pouch is punctured or not fully sealed. The cap contains a freeze-dried bead of reagents that is sensitive to moisture.
- Do not use the Detect™ Covid-19 Test past the Use By date on the test box label.
- All components other than the Detect™ Hub are single-use and should be disposed of after use.
- Follow all instructions carefully as shown in the Detect™ App.
- Touch only the plastic handle of the Swab with your hands to avoid contaminating the soft tip of the Swab.

- Do not insert the Swab deeper than 1-2 cm into your nose. A deeper swabbing will not yield more accurate results.
- See Section 8 for detailed instructions on the control included with the test. It helps indicate whether the reaction is taking place correctly.

5.3 Components & Reagents

- Do not remove the Detect™ Cap after screwing it onto the Test Tube.
- Do not use a Detect™ Cap that has been dropped after removing it from the packaging.
- Do not shake the Test Tube except as described in Section 7, Step 4-5 (Test Tube Preparation).
- Begin Test Tube processing for each sample within 1 hour of collecting the sample.
- Place swab immediately into the Test Tube after collecting samples. Failure to do so may result in dried swabs and yield an incorrect test result.
- Do not put anything into the chimney of the Reader until instructed to do so. Doing so may lead to indeterminate results.


- Each single-use Swab is used for one test. Do not reuse Swabs or use a Swab other than the one provided in the test.


- Each single-use Test Tube is used for one test. Do not reuse Test Tubes.


- Each single-use Detect™ Cap is used for one test. Do not reuse Detect™ Caps.


- Each single-use Dropper is used for one test. Do not reuse Droppers.


- Each single-use Reader is used for one test. Do not reuse Readers.
- Do not process the samples using any protocol other than the one described in Section 7, Step 4-6 as other protocols have not been tested.
- Do not tamper with the Reader or attempt to remove the Test Tube once inserted into the Reader.

6. Operating Conditions

- The test should be used between 59 °F and 86 °F (15 °C and 30 °C). Failure to do so may yield invalid or inaccurate results.
- The test is best used in a room with adequate lighting and away from glare. Failure to do so may result in an inability to see the results on the test.
- The Hub must be run on a level surface and should not be moved during operation. Failure to do so may yield invalid or inaccurate results.
- If a power failure occurs or if the Hub is unplugged while the Test Tube is in the Hub, the test result is invalid and the user should be retested following the retest procedure described in Section 9.2.

7. Procedure

Step 1: Obtain items required but not provided in the test

You will need the items listed below to run your Detect™ Covid-19 Test. These items are not included in the Detect™ test.

- Detect™ Hub. You can purchase the Hub from Detect, Inc. at detect.com.
- Smartphone. Go to detect.com/app for the list of compatible smartphones.
- The Detect™ App installed on your smartphone. Download the Detect™ App from detect.com/app.

Step 2: Prepare to run your test

Carefully read the Detect™ Covid-19 Test Getting Started instructions (on the inner lid of the test box) before you run your test. These directions will help you download the Detect™ App and complete the test correctly and safely.

If you do not understand the instructions, do not run the test. Contact Detect™ customer support at support@detect.com or call toll-free at 855-322-3692 for help.

Step 3: Open the Detect™ App on your smartphone and follow the instructions

The Detect™ App will use pictures, videos, and on-screen instructions to guide you through collecting your nasal sample and running the Detect™ Covid-19 Test. Be sure to carefully follow all the instructions given within the Detect™ App. If you do not, your test may give an invalid result.

If you do not understand the directions, contact Detect™ customer support at support@detect.com or call toll-free at 855-322-3692 for help.

- You may need to update your Detect™ App to the latest version before running your test. Follow any on-screen prompts to update the Detect™ App.
- Within the Detect™ App, tap on the “Start new test” button.

Step 4: Run the Detect™ test

Follow on-screen instructions to run the Detect™ test.

Step 4-1: Get ready to run the Detect™ test

Review and complete the instructions on the “Getting ready” screens:

- Check that the test has not expired by reviewing the Use By date on the box.
- Wipe down your work surface and wash your hands, being careful to rinse them thoroughly.
- Plug in the Detect™ Hub.
- Set aside time (approximately 65 minutes) to run the test.
- Tap “Next step” to continue to the test activation step.

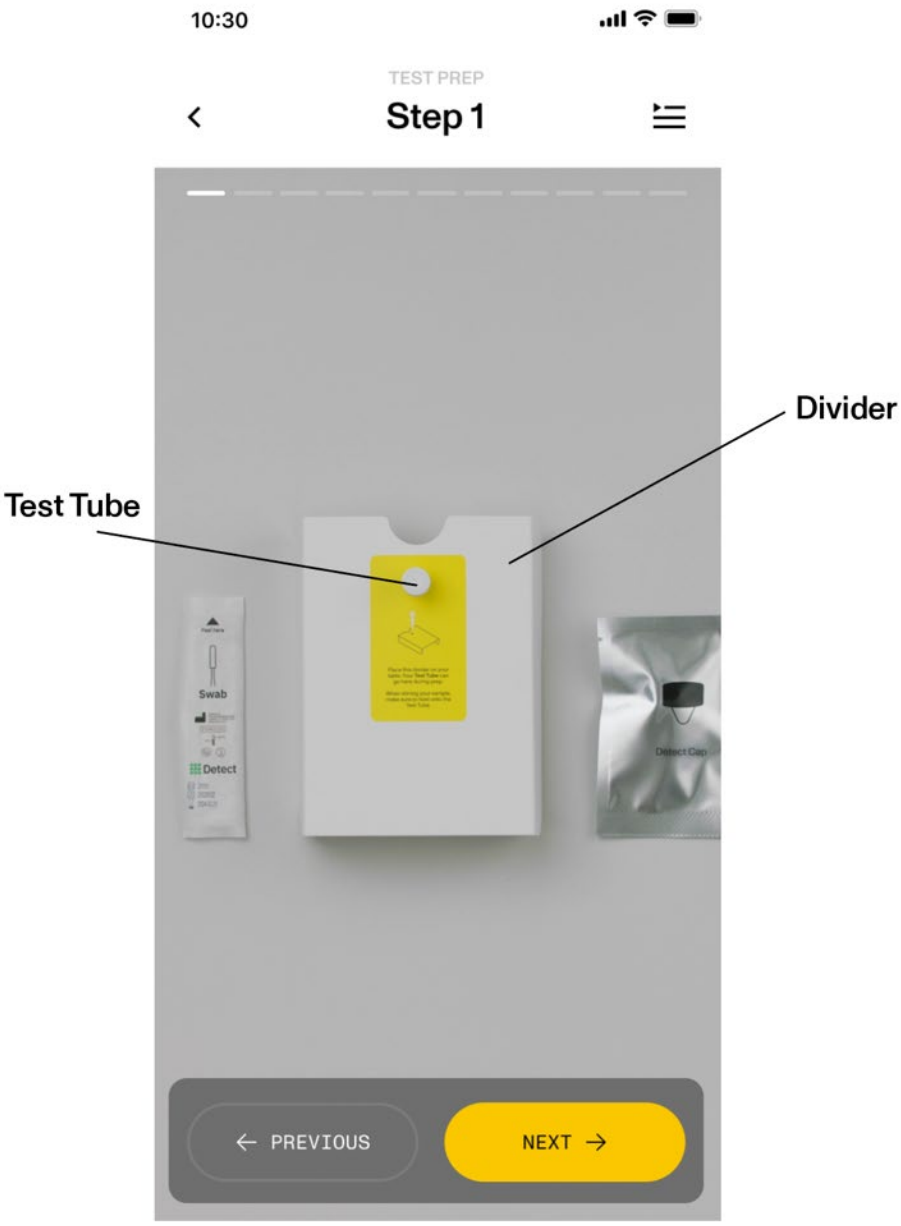
Step 4-2: Activate the Detect™ test

Open your test and find the activation code on the inner lid of the box. Use your smartphone camera to scan the activation code or manually enter the 7-word activation code printed on the inner lid of your test box.

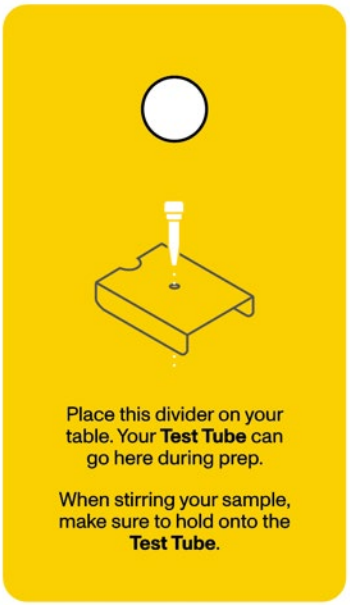
Step 4-3: Gather the components required to run the test

Place the Prepare Pack pouch and the divider on a flat surface. See the Detect™ App video showing materials that you need to run a test as shown here.

- Unpack the Swab, Detect™ Cap, and Test Tube from the Prepare Pack pouch.


10:30
TEST PREP
Step 1
Test Tube
Divider
Swab
Detect
PREVIOUS
NEXT

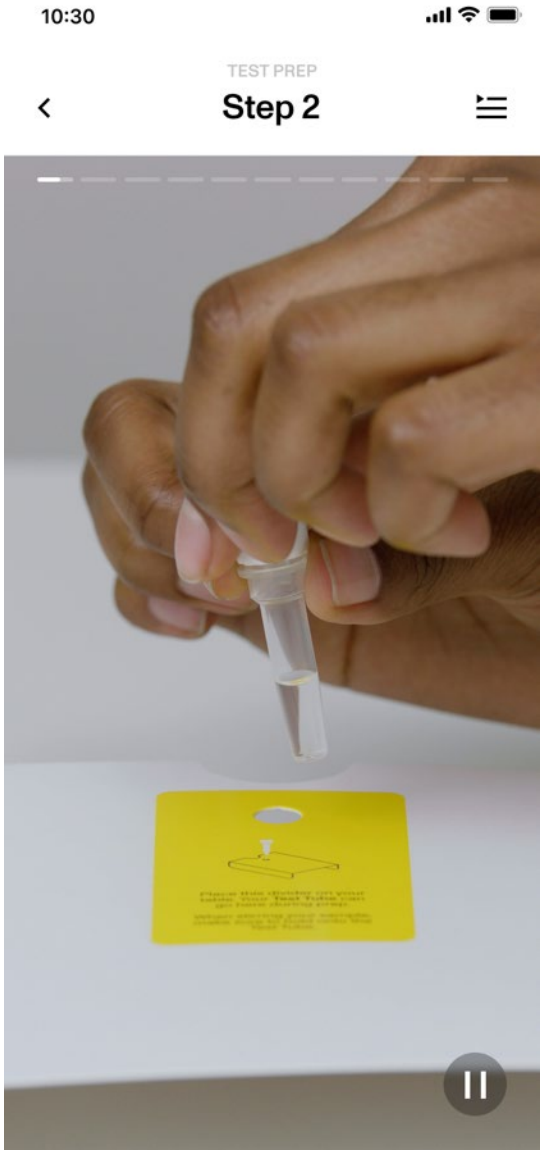
Follow the directions printed on the divider to place the Test Tube in the divider.



REMINDER: Do not open the Detect™ Cap pouch yet.

Step 4-4: Prepare and collect a nasal sample

- Unscrew the cap from the Test Tube. Be careful since the Test Tube contains liquid. Place the Test Tube back into the divider as shown in the Detect™ App video.

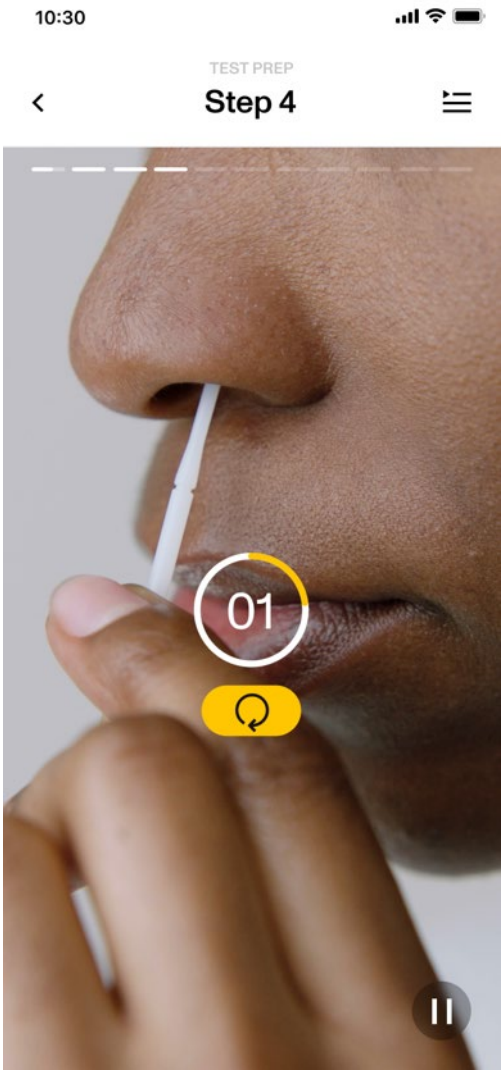


- Remove the Swab on the side that says “peel here”. Make sure that the soft tip of the Swab does not touch anything besides your nose.
- The Detect™ App video will demonstrate how to collect a nasal sample.

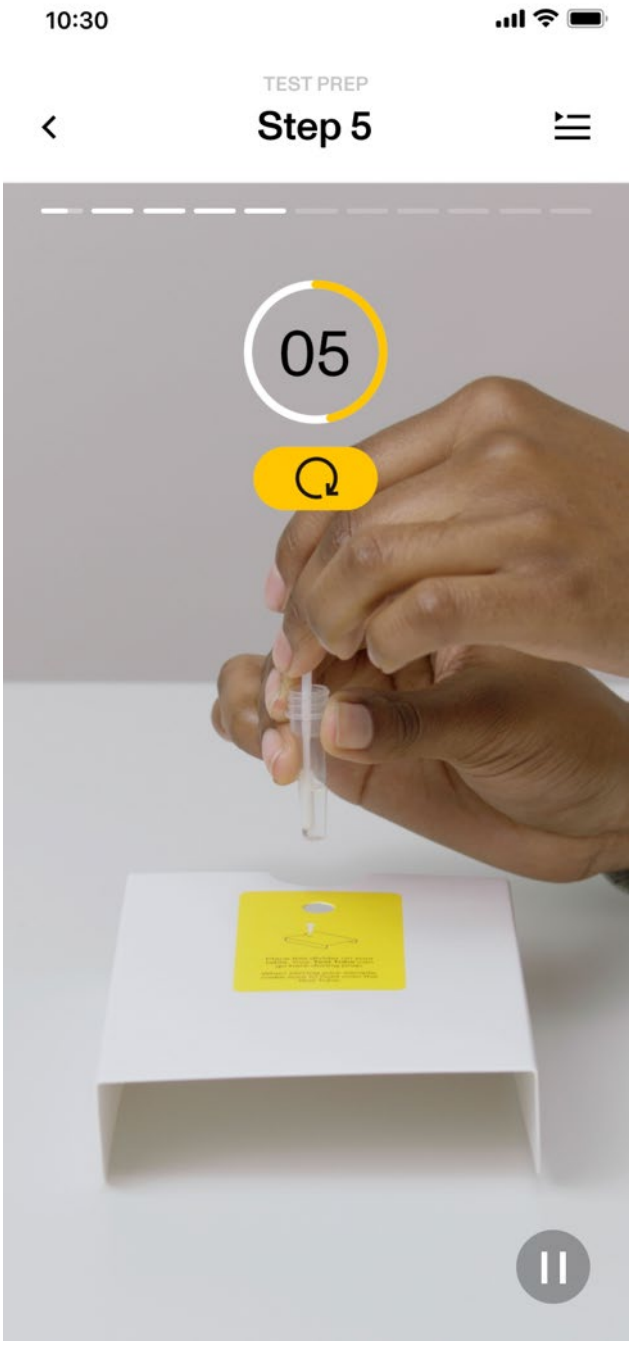
REMINDER: To properly collect a nasal sample, swab both of your nostrils with the same Swab following the directions below.

The Detect™ test is for use with self-collected samples for individuals aged 14 years and older and for samples collected and tested by an adult caregiver for individuals aged 2 years and older.

- For adult collection, insert the Swab into the nostril until just the soft tip is completely inside (about 1 inch). For pediatric collection insert the Swab into the child's nostril only ½ inch. Swab in a circle around the inside wall of the nostril 5 times. Then gently remove the Swab, insert into your other nostril, and repeat. Make sure the Swab stays in full contact with the inside of the nostril.



- Hold the Test Tube with one hand and fully submerge the Swab tip in the Test Tube and vigorously twirl the Swab for 15 seconds, as shown in the Detect™ App video. Do not break off the Swab tip. Discard the Swab by placing it back inside its package.

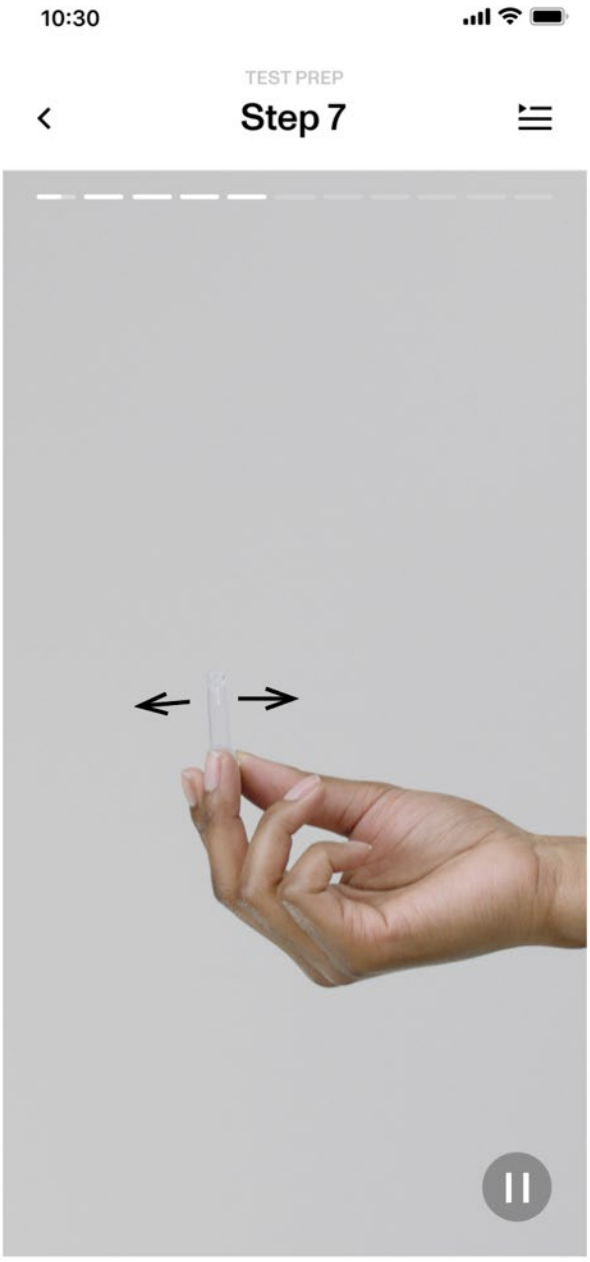


Step 4-5: Test Tube Preparation

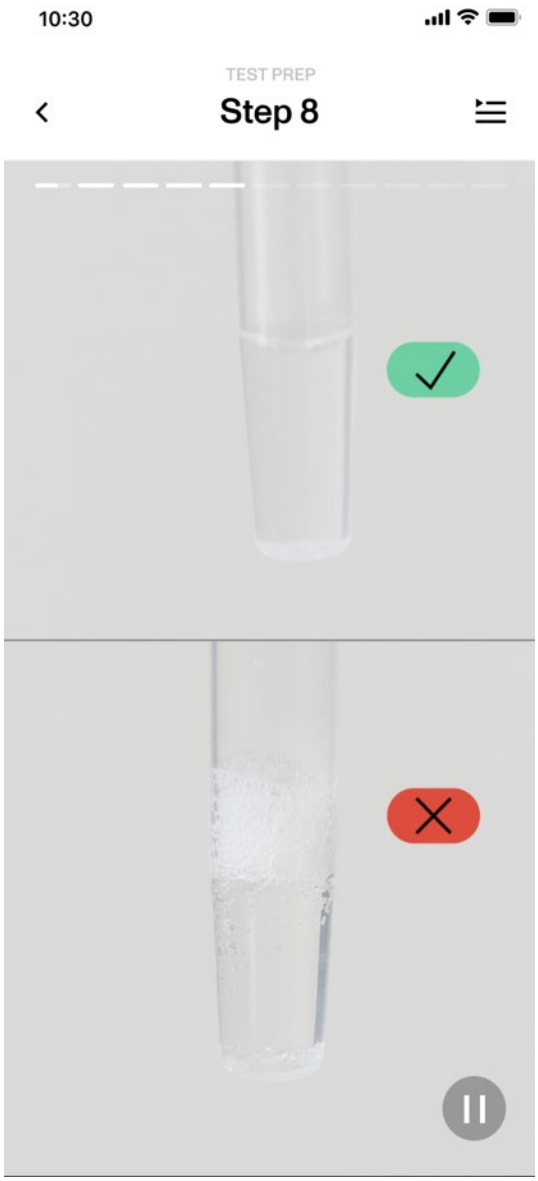
REMINDER: Pick up the Detect™ Cap pouch. While it's closed, gently push the contents inside down toward the bottom of the pouch. The Detect™ Cap can fly out of the pouch if opened too quickly.

- Slowly and carefully open the pouch and gently remove the Detect™ Cap. You may need to remove the silica packet first.
- On the inside of the Detect™ Cap you'll see a small white reagent bead—this contains the reagents to run your test.
- Screw the Detect™ Cap onto the Test Tube, tightening as much as possible. Do not open the Test Tube after this step.
- Hold the Test Tube by the cap, turn it upside down, and shake it vigorously side to side for 10 seconds, as shown in the Detect™ App video. Then turn the tube right side up again, continuing to hold it by the cap.

REMINDER: Do not shake the Test Tube up and down. Shake it side to side to ensure the reagent bead contained within the Detect™ Cap is always in contact with the liquid. This will help dissolve the reagents needed to run the Detect™ test.



- Forcefully bring your whole arm downward to move the liquid to the bottom of the tube. Do this a few times to ensure the liquid is not stuck in the cap or against the walls of the tube.



REMINDER: Liquid clinging to tube walls or cap may result in an invalid test.

Step 4-6: Process the sample

- Place the Test Tube into the well of the Detect™ Hub, pushing all the way in, as shown in the Detect™ App video. The Hub will beep once and the green light will start blinking. Your sample will start processing automatically and will take 55 minutes. The blinking green light will turn solid when it's complete.

REMINDER: Do not remove the Test Tube from the Hub until it is time to use it.

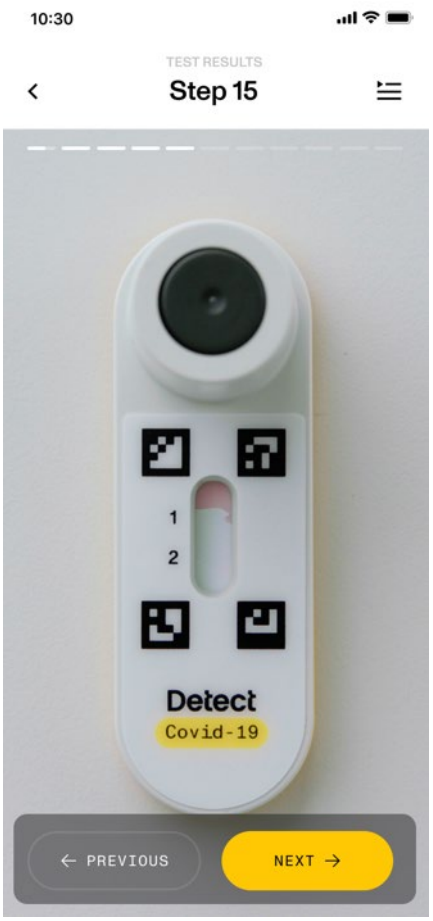
Step 4-7: Results

- Pick up the Dropper by the rectangular tip and snap your wrist downward to collect the liquid at the bottom as shown in the Detect™ App video. Carefully twist off the tip of the Dropper. Hold the Dropper gently to avoid squeezing it and spilling the liquid.
- Insert the dropper as far as it will go into the Reader chimney to avoid spilling, and using both hands, squeeze it firmly to dispense all the liquid, as shown in the Detect™ App video. Discard the Dropper.

- Remove the Test Tube from the Detect™ Hub, and place it in the chimney of the reader. Using both thumbs, press down on the tube, as shown in the Detect™ App video. You may hear a pop as the blade at the

bottom of the chimney opens the tube, allowing the liquid inside to flow through the Reader.

REMINDER: Keep pressing until the tube is completely flush with the lip of the Reader chimney. Liquid should begin to flow through the Reader and should be visible within the Reader's window in about 10 seconds. If there's no flow, firmly tap the Reader against a hard surface 3 times to help trigger flow.

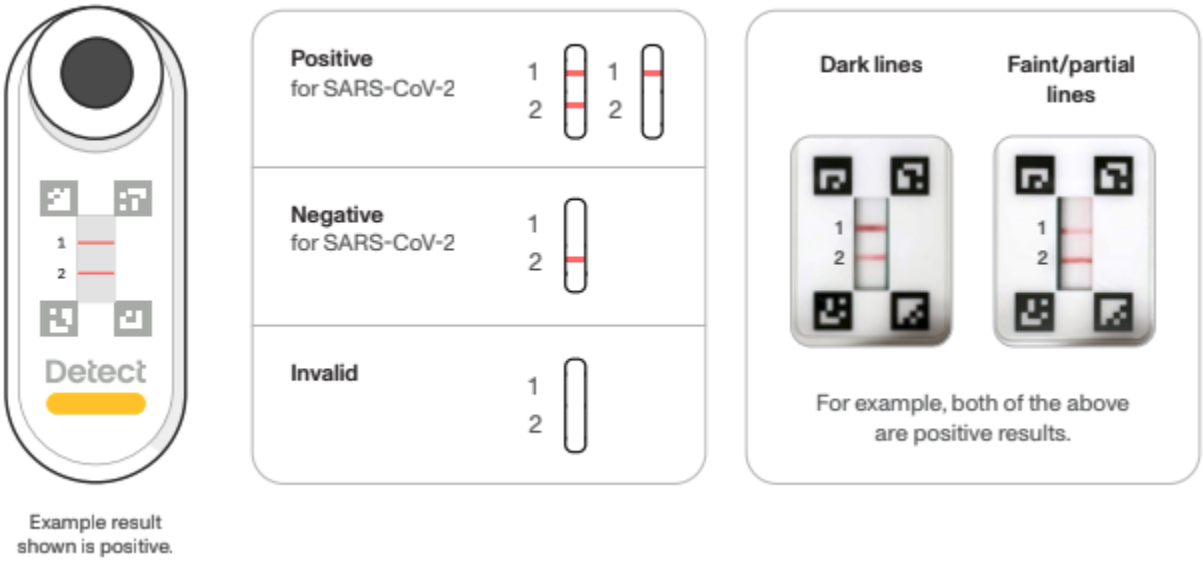


- The red lines will take approximately 10 minutes to fully develop. Line darkness and fullness may vary.

  REMINDER: Do not tamper with the Reader or try to remove the Test Tube from the Reader.

- The Detect™ App will then guide you through identifying the visible lines on the Reader to interpret the result of the test.
- Line 1 is the test line, which tells you whether SARS-CoV-2 (the virus that caused Covid-19) was identified in your sample.
- Line 2 is the control line, which tells you if the test was performed correctly for a negative test result.

- As shown below on the right, lines can be faint or incomplete.

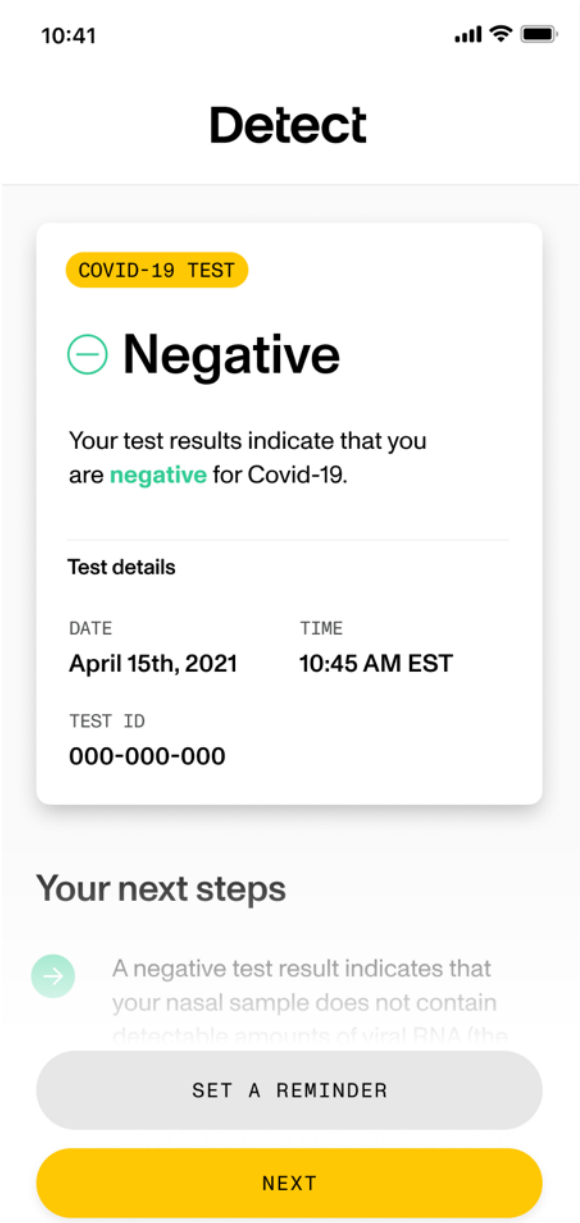


Step 5: Understanding the test result

The app will show results as Negative, Positive, or Invalid. Please see Detect's Fact Sheet for Individuals (resources.detect.com) for more information on understanding the test result.

- Regardless of the test result, it is important that when you are sick you practice social distancing and good hygiene.
- If you develop symptoms or your symptoms persist or become more severe, if you are concerned about your health, or if you develop one of the emergency warning signs (www.cdc.gov/coronavirus), then you should seek medical attention immediately.

Step 5-1: Understanding a Negative result

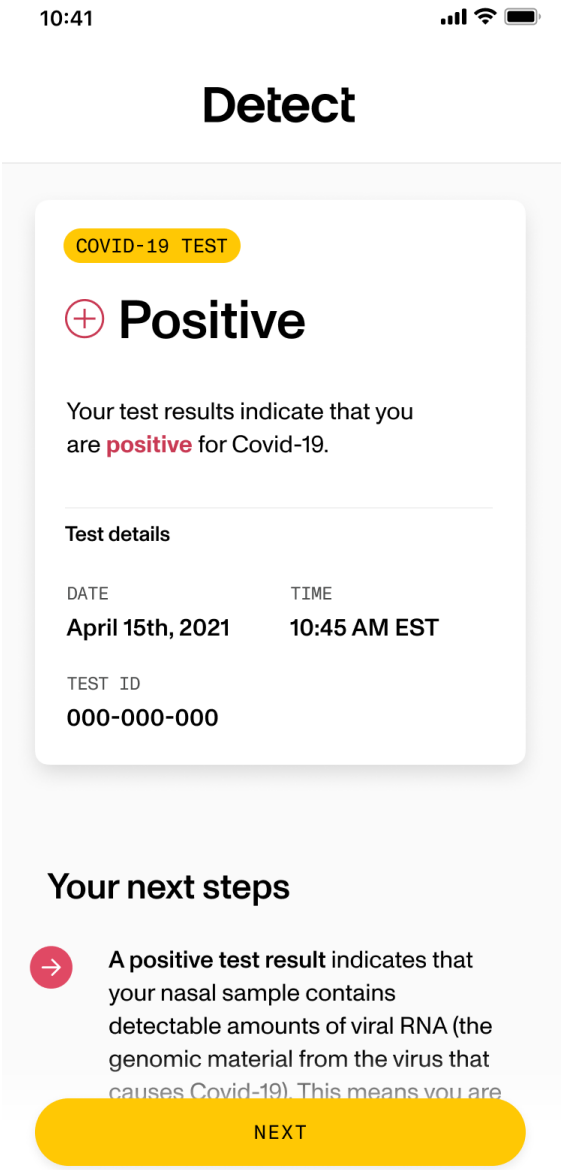


A Negative result means that the Detect™ Covid-19 Test did not identify the SARS-CoV-2 virus that causes Covid-19 in your sample and it is unlikely that you currently have a Covid-19 infection.

- If you are symptomatic and your symptoms persist or become more severe, and you obtained a negative result for your sample, seek help from your HCP even if the results remain negative based on serial testing.

- If you have no symptoms or reasons to suspect Covid-19 infection, this was your first result, and your result was negative, you must collect and test a second sample at least 24 hours after your first test and within the next 48 hours.
- In the following scenarios it is possible that the test may give a negative result even if you have Covid-19 (called a false negative result).
    - A false negative can occur if the sample was not collected or processed properly.
    - if you are too early or late in your Covid-19 infection to accurately identify a low amount of SARS-CoV-2 virus in your sample.
    - A false negative can also occur if the SARS-CoV-2 virus's genetic material changes (mutates) such that the Detect™ Covid-19 Test cannot identify the virus.
- For serial testing programs, additional testing is required when a negative result is obtained for the first sample. Additional testing may also be necessary if the individual was exposed to someone who tested positive for SARS-CoV-2 (the virus that can cause Covid-19), or in communities with high numbers of positive cases (high prevalence of infection).
- Even if you do not have Covid-19, you may still have another type of infection. Many other viruses can cause similar symptoms to Covid-19, and these may be the cause of your current illness.
- Tell your healthcare provider whether or not you have symptoms.

Step 5-2: Understanding a Positive result

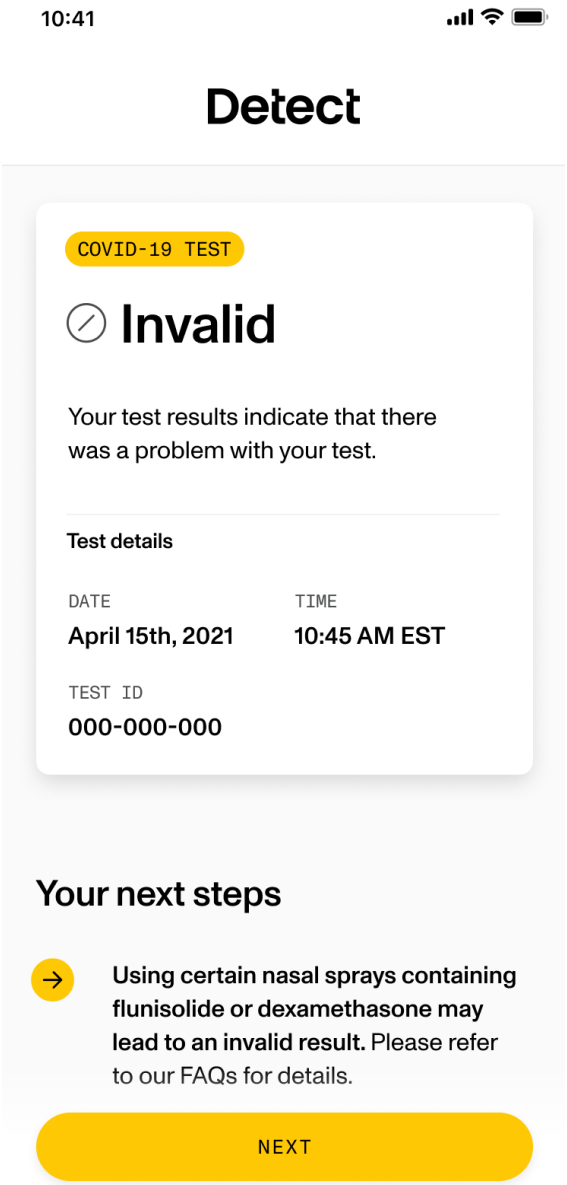


A Positive result means the Detect™ Covid-19 Test identified the SARS-CoV-2 virus that causes Covid-19 in your sample, and it is very likely that you currently have a Covid-19 infection.

- You should self-isolate at home per CDC recommendations to stop spreading the virus to others. Consult the CDC recommendations regarding self-isolation at cdc.gov/coronavirus.

- Consult your healthcare provider as soon as possible and tell him or her that you tested positive for Covid-19 using the Detect™ Covid-19 Test.
- Tell your healthcare provider if you have symptoms or no symptoms.
- Tell your healthcare provider to view the Detect™ Covid-19 Test Fact Sheet for Healthcare Professionals at resources.detect.com.
- There is a small possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19 infection. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms
- There is still a chance of co-infection with another type of illness.
- If you do not have any symptoms, particularly if you live in an area with low numbers of Covid-19 infections and have had no exposure to anyone diagnosed with Covid-19, additional testing to confirm your result may be required.

Step 5-3: Understanding an Invalid result



An Invalid result means that there was an error, and the Detect™ Covid-19 Test was unable to provide a result. You will need to perform a retest.

Some common causes of Invalid results are:

- The sample was improperly collected and did not include enough nasal material. Make sure to thoroughly swab both nostrils as directed in Step 4-4.

- The Test Tube was not prepared correctly (either the reagent was not properly dissolved or the liquid was not fully collected into the bottom of the Test Tube). See Step 4-5 for details.
- The processing step was run incorrectly. Make sure you fully insert the Test Tube into the Detect™ Hub until it beeps and do not remove the Test Tube until the processing step is complete. See Step 4-6 for details. A power failure or interruption during test processing can also cause an invalid result.
- 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.

8. Quality Control

8.1 Internal Control

CONTROL Each reaction includes a Sample Processing Control (SPC) that is shown as a separate line in the reader.

Sample Processing Control (SPC, Line 2) - Ensures that the sample was processed correctly. The Sample Processing Control is designed to amplify a human control gene that will be present in a swab sample collected by a subject. The SPC determines whether sample collection was performed correctly and whether amplification reaction conditions were appropriate (temperature, time, and reagent mixing). The SPC should be positive in a human sample that tests negative and positive in a human sample that tests positive; however, a positive sample that lacks the SPC is still valid.

9. Retests

9.1 Reasons to Retest

If an **INVALID** test result occurs, repeat the test once according to instructions in 9.2 (Retest Procedure). If the repeat test fails to produce a valid result, please contact Detect™ Customer Support at 855-322-3692 or support@detect.com.

If you have no reason to suspect Covid-19 infection, this was your first result, and your result was negative, you must collect and test a second sample at least 24 hours after your first test and within the next 48 hours.

9.2 Retest Procedure

1. Prepare the work surface as detailed in Section 7.1 (Setup).
2. Obtain a new Detect™ Covid-19 Test.
3. Repeat the test procedure outlined in Section 7 (Procedure).

10. Limitations

- Performance has only been evaluated for self-collected nasal swab samples. Use of the Detect™ Covid-19 Test with other specimen types (such as saliva) has not been evaluated.
- A false negative result may occur if the individual's nose is swabbed incorrectly. False negative results may also occur if the amount of SARS-CoV-2 virus present on the swab is below the test's limit of detection.
- False negative results may occur in patients currently taking high dose biotin (vitamin B7) supplements. Biotin levels of 0.88 µg/mL or higher in the nasal sample may result in incorrect test results (false negatives).
- Invalid results may occur if:
    - The patient is currently using certain nasal sprays used to fight allergies, such as dexamethasone or flunisolide-containing products. Dexamethasone and flunisolide levels higher than 0.25 mg/mL and 7.5% volume, respectively, in the nasal sample may result in invalid test results in some cases.
    - High amounts of moisturizing lotions or hand soap comes in direct contact with the swab and is introduced into the test reaction. Hands should therefore be washed and well-rinsed before performing this test.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the common variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- Test results should be interpreted together with the patient's medical history, clinical signs and symptoms, and the results of other diagnostic tests performed.
- As with other tests, negative results do not rule out SARS-CoV-2 infections and should not be used as the sole basis for patient management decisions.

- This is a qualitative test. Test line intensity is not related to the quantity of virus in the sample.
- The material identified by this test–viral nucleic acid–may persist in the body, even after the patient is not infectious anymore. A positive result on this test does not imply that the patient is infectious, or that the virus is causing the subject's clinical symptoms.

11. Performance Characteristics

11.1 Analytical Sensitivity (Limit of Detection)

The Limit of Detection (LoD) is the lowest amount of virus that can be determined in 95% of samples and was determined by testing the Detect™ test's analytical sensitivity with heat-inactivated SARS-CoV-2 BEI, USA-WA1/2020) in pooled nasal matrix. Over two lots of tests, the LoD of the Detect™ Covid-19 Test was determined to be 313 copies per swab, which is equivalent to 800 copies per mL if all virus is transferred from the swab to the buffer.

Viral Load (genomic copies/swab)	Lot 1 SARS-CoV-2 Detection Rate	% Detected	Lot 2 SARS-CoV-2 Detection Rate	% Detected
313	20/20	100%	20/20	100%
156	20/20	100%	18/20	90%
78	15/20	75%	14/20	70%

11.2 Analytical Reactivity (Inclusivity)

An *in silico* inclusivity study was performed to analyze the Detect™ test's primer binding sequences in the SARS-CoV-2 genome to demonstrate that the primers will identify all variants of the SARS-CoV-2 virus identified to date (July 2021) and predict inclusivity of the Detect™ Covid-19 Test. A total of 2,397,589 sequences from the GISAID EpiCoV database (www.gisaid.org) were evaluated in the study.

Based on the *in silico* analysis combined with laboratory testing, at least 98.6% of U.S. viral genomes from the past 90 days are expected to be robustly identified by the Detect™ test's SARS-CoV-2 primer set.

11.3 Analytical Specificity/Exclusivity (Cross-Reactivity)

The Detect™ test's cross-reactivity with closely related pathogens, common disease agents, and normal and pathogenic flora that may be present in the respiratory tract was tested in triplicate by spiking the organism or genomic material from the organism directly into Detect™ reactions at the concentrations listed in the table below. The Detect™ test showed no interaction with any of the 31 organisms tested. The Detect™ test was also tested repeatedly with pooled human nasal matrix (>500 replicates in all) and showed no cross-reactivity.

Organism	**Target**	**Concentration Tested (in final reaction)**	**SARS-CoV-2** #Positive /# tested	**Cross-reactivity with Detect**
Human coronavirus 229E	Virus	1.00E+05 $TCID_{50}$/mL	0/3	No
Human coronavirus OC43	Virus	1.00E+05 $TCID_{50}$/mL	0/3	No
Human coronavirus HKU1	Synthetic RNA	6.85E+05 copies/mL	0/3	No
Human coronavirus NL63	Virus	4.00E+04 $TCID_{50}$/mL	0/3	No
MERS-coronavirus	Virus	5.00E+03 $TCID_{50}$/mL	0/3	No
SARS-coronavirus	Virus	1.50E+03 $TCID_{50}$/mL	0/3	No
Adenovirus (Adenoid 71)	Virus	1.00E+05 $TCID_{50}$/mL	0/3	No
Human Metapneumovirus (hMPV)	Virus	1.00E+05 $TCID_{50}$/mL	0/3	No
Parainfluenza virus 1	Virus	5.00E+04 $TCID_{50}$/mL	0/3	No
Parainfluenza virus 2	Virus	1.00E+05 $TCID_{50}$/mL	0/3	No
Parainfluenza virus 3	Virus	1.00E+05	0/3	No

		$TCID_{50}$/mL		
Parainfluenza virus 4	Virus	1.60E+04 $TCID_{50}$/mL	0/3	No
Influenza A	Virus	1.00E+05 $CEID_{50}$/mL	0/3	No
Influenza B	Virus	1.00E+05 $TCID_{50}$/mL	0/3	No
Enterovirus 68	Virus	1.00E+05 $TCID_{50}$/mL	0/3	No
Respiratory syncytial virus (Subgroup A)	Virus	1.00E+05 PFU/mL	0/3	No
Rhinovirus 89	Virus	8.00E+04 $TCID_{50}$/mL	0/3	No
Chlamydia pneumoniae	Bacteria	1.00E+06 IFU/mL	0/3	No
Haemophilus influenzae	Bacteria	1.00E+06 CFU/mL	0/3	No
Legionella pneumophila	Bacteria	1.00E+06 CFU/mL	0/3	No
Mycobacterium tuberculosis	Bacteria	1.00E+06 CFU/mL	0/3	No
Streptococcus pneumoniae	Bacteria	8.80E+04 CFU/mL	0/9	No
Streptococcus pyogenes	Bacteria	1.00E+06 CFU/mL	0/3	No
Bordetella pertussis	Bacteria	1.00E+06 CFU/mL	0/3	No
Mycoplasma pneumoniae	Bacteria	1.00E+06 CFU/mL	0/3	No
*Pneumocystis jirovecii (PJP)-S. cerevisiae**	Yeast	1.00E+06 CFU/mL	0/3	No
Candida albicans	Yeast	1.00E+06 CFU/mL	0/3	No
Pseudomonas aeruginosa	Bacteria	1.00E+06 CFU/mL	0/3	No

Staphylococcus epidermis	Bacteria	1.00E+06 CFU/mL	0/3	No
Streptococcus salivarius	Bacteria	1.00E+06 CFU/mL	0/3	No

* Due to limited pathogen availability, cross-reactivity was tested with a recombinant version of *S. cerevisiae* containing genomic material from PJP.

In addition, *in silico* cross-reactivity analysis of Detect™ primer sequences was performed by comparing them to representative genomic sequences of the specific respiratory microorganisms below, downloaded from the NCBI database. The table below details all instances of ≥80% homology between a primer and respiratory microorganism genome.

Greater than 80% homology was only apparent for a single SARS-CoV-2 primer with *Pneumocystis jirovecii (PJP)* and two primers with *Candida albicans*. Further, none of the labelled primers required for identification of the amplified nucleic acid target showed ≥80% homology with any of the listed respiratory microorganism genomes. Therefore, *in silico* analysis identified no potential unintended cross-reactivity of the Detect™ test with the listed respiratory pathogens, including other coronaviruses.

Organism	**SARS-CoV-2 primer set**
Human coronavirus 229E	no alignment found
Human coronavirus OC43	no alignment found
Human coronavirus HKU1	no alignment found
Human coronavirus NL63	no alignment found
MERS-CoV	no alignment found
SARS-CoV	no alignment found
Adenovirus (e.g. C1 Ad. 71)	no alignment found
Human Metapneumovirus (hMPV)	no alignment found
Parainfluenza virus 1	no alignment found
Parainfluenza virus 2	no alignment found
Parainfluenza virus 3	no alignment found

Parainfluenza virus 4	no alignment found
Influenza A	no alignment found
Influenza B	no alignment found
Enterovirus (e.g. EV68)	no alignment found
Respiratory syncytial virus	no alignment found
Rhinovirus A	no alignment found
Rhinovirus B	no alignment found
Rhinovirus C	no alignment found
Chlamydia pneumoniae	no alignment found
Haemophilus influenzae	no alignment found
Legionella pneumophila	no alignment found
Mycobacterium tuberculosis	no alignment found
Streptococcus pneumoniae	no alignment found
Streptococcus pyogenes	no alignment found
Bordetella pertussis	no alignment found
Mycoplasma pneumoniae	no alignment found
Pneumocystis jirovecii (PJP)	single primer only, 83%
Candida albicans	Two primers at 82% and 89%
Pseudomonas aeruginosa	no alignment found
Staphylococcus epidermidis	no alignment found
Staphylococcus salivarius	no alignment found

11.4 Analytical Specificity (Interfering Substances)

Common endogenous and exogenous substances that might be present in clinical nasal swab samples were tested for interference with the Detect™ test. Each potentially interfering substance was spiked into both negative pooled nasal matrix and contrived positive pooled nasal matrix spiked with heat-inactivated SARS-CoV-2 virus at 2X LoD. From these pools, triplicate swabs were tested using the Detect™ test. The interfering substances and their concentrations are listed in the table below. The results show that the Detect™ test is robust to a wide range of potentially interfering substances.

Interfering Substance	**Final Concentration in Nasal Matrix Pool**	**Negative Samples** # Negative /# tested	**Positive Samples** # Positive /# tested	**Interference Observed**
Rhinocort Allergy	15% v/v	3/3	3/3	No
Afrin Nasal Congestion Relief Spray	15% v/v	3/3	3/3	No
Zicam Cold Remedy Nasal Spray	15% v/v	3/3	3/3	No
Chloraseptic Sore Throat Spray	15% v/v	3/3	3/3	No
Flonase Allergy Relief Nasal Spray	15% v/v	3/3	3/3	No
Mupirocin	1 mg/mL	3/3	3/3	No
Neo-Synephrine	15% v/v	3/3	3/3	No
Nasal Saline Spray	15% v/v	3/3	3/3	No
Tobramycin	600 µg/mL	3/3	3/3	No
Fresh whole blood	15%	3/3	3/3	No
Biotin	3.5 µg/mL	3/3	1/3*	Yes
	0.875 µg/mL	3/3	3/3	No
Dexamethasone	0.5 mg/mL	2/3**	3/3	Yes
	0.25 mg/mL	3/3	3/3	No
Flunisolide	15%	2/3**	3/3	Yes
	7.5% v/v	3/3	3/3	No

Mucin	1 mg/mL	3/3	3/3	No
Triamcinolone	15% v/v	3/3	3/3	No
Mometasone nasal spray	1 mg/mL	3/3	3/3	No
Method All-Purpose Surface Cleaner	15% v/v	3/3	3/3	No

* The positive samples that could not be detected had false negative results.
** The samples without a negative result had invalid results.

Other potentially interfering substances (hand soap and lotion) that might be present in the home environment were tested for interference under real-world use cases. Hand soap and lotion were tested by having users wash their hands with hand soap without rinsing or apply hand lotion immediately prior to grasping the swab by the tip. These intentionally contaminated swabs were then spiked with contrived positive nasal samples at 2x LoD and assayed on the Detect™ test. Neither of the tested substances interfered with the test's ability to identify SARS-CoV-2.

Interfering Substance	**Contamination delivery route**	**Positive Samples** # Positive /# tested	**Interference Observed**
Dial Antibacterial Liquid Hand Soap	On operator's hands	3/3	No
Aveeno Daily Moisturizing Lotion	On operator's hands	3/3	No

11.5 Clinical Evaluation

A prospective, multi-center clinical study was conducted in the United States in subject's homes or a simulated home environment. Testing was performed by the untrained subject or the subject's parent/guardian for children under 14. The study enrolled symptomatic subjects and asymptomatic subjects with a recent exposure, each of whom self-collected two nasal swab samples. For each subject, one swab was collected and sent to a reference laboratory and tested using a high sensitivity FDA-authorized SARS-CoV-2 RT-PCR test by trained laboratory personnel as a comparator, while the other swab was run through the Detect™ test by the untrained subject or parent/guardian.

Comparing the Detect™ test's results to those produced by the high sensitivity FDA-authorized SARS-CoV-2 RT-PCR test, the Positive Percent Agreement (PPA) was 90.9.% (30/33) and the Negative Percent Agreement (NPA) was 97.5% (77/79). Both apparent false positives were due to subject's misinterpreting the test result; the Detect™ App has since been modified to significantly reduce the frequency of this user error.

Clinical Study Results Summary

	FDA-authorized SARS-CoV-2 RT-PCR Assay	
Detect	Positive	Negative
Positive	30	2*
Negative	3**	77

*Both of the apparent false positive results were due to subject misinterpretation using an older version of the Detect™ App. A modified version of the Detect™ App has since been developed and shown to be effective in reducing the frequency of subjects misinterpreting the test result.
**One of the three apparent false negative samples gave a negative result when tested with a second highly sensitive EUA SARS-CoV-2 RT-PCR assay.

Positive Percent Agreement (PPA): 90.9% (30/33), (95% CI: 76.4%-96.9%)
Negative Percent Agreement (NPA): 97.5% (77/79), (95% CI: 91.2%-99.3%)

A second evaluation was conducted testing the ability of untrained lay users to correctly identify and interpret near-cutoff positive samples with the Detect™ test. Twelve subjects were each given three blinded contrived swab samples, a mix of negative and low-positive (1.9x LoD) to test. Comparing their results to those expected, the PPA was 94.4% (17/18) and the NPA was 100.0% (18/18), demonstrating that in the hands of lay users the Detect™ Covid-19 Test can reliably identify low-positive samples.

Near-Cutoff Results Summary

	Contrived Sample Expected Result	
Detect	Positive	Negative
Positive	17	0
Negative	1	18

Positive Percent Agreement (PPA): 94.4% (17/18), (95% CI: 74.2%-99.0%)
Negative Percent Agreement (NPA): 100.0% (18/18), (95% CI: 82.4%-100.0%)

12. Bibliography

1 Centers for Disease Control and Prevention. "Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (Covid-19)." (Refer to latest edition.) https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

2 Centers for Disease Control and Prevention. "Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition." (Refer to latest edition.) https://www.cdc.gov/labs/BMBL.html

3 Clinical and Laboratory Standards Institute. "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline." Document M29 https://clsi.org/standards/products/microbiology/documents/m29/ (Refer to latest edition).

13. Symbols and Abbreviations

The following symbols are used throughout this manual:

Symbol	Definition
	Biohazard – Potentially infectious materials. Precautions must be observed.
IVD	For *in vitro* diagnostic use
CONTROL	Internal control
	Do not re-use

	Manufacturer

Manufacturer:

Detect, Inc.
530 Old Whitfield St.
Guilford, CT 06437 USA

Customer Support: support@detect.com or call toll-free +1 855-322-3692