



LooK SPOT Antigen Rapid Test System V.2

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Version 2 ▾

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1 Works for me dx.doi.org/10.17504/protocols.io.bp32mqqe

XPRIZE Rapid Covid Testing



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ABSTRACT

LooK SPOT COVID-19 antigen rapid test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from patients suspected of COVID-19 within the first seven (7) days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in a patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.]

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in nasal samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

LooK SPOT COVID-19 Antigen Rapid Test can deliver a diagnosis of the SARS-CoV-2 virus detection between 5 to 8 minutes by using machine learning AI. [LooK SPOT's AI algorithm has high accuracy and can identify the fluorescence response](#) when human eyes cannot identify the low positive cases. Healthcare responders in the COVID-19 test sites often need to make time-sensitive decisions to determine the test results during the time many patients are within their vicinity. But the tempo, volume, stress, fatigue, lighting, fear, and various other factors can overwhelm healthcare responders when making the visual interpretation of antigen test results. It is of paramount importance to reduce healthcare responders' cognitive load by providing accurate test results in an easy-to-read format. LooK SPOT COVID-19 Antigen Rapid Test is a COVID-19 rapid test solution designed with a tactical edge to fight COVID-19.

The LooK SPOT COVID-19 Antigen Rapid Test is intended for use at the Point of Care (POC) settings by trained personnel specifically instructed and trained in vitro diagnostic procedures. It is only for use under the Food and Drug Administration's Emergency Use Authorization.

EXTERNAL LINK

<https://laipac.com/look-spot-point-of-care-covid-19-test-kit/>

ATTACHMENTS

[LooKSPOT v3.23.png](#)

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KEYWORDS

Smartphone-based COVID-19 rapid test, AI based COVID-19 rapid test

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ATTACHMENTS

[LooK SPOT v3.23.png](#)

GUIDELINES

- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Store the kit at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight until the expiration date.
- This reagent is only authorized to detect the nucleocapsid protein antigen of the SARS-CoV-2 virus and is not authorized to detect any other viruses or pathogens.
- Do not reuse the used LooK COVID-19 Antigen Rapid Test Cassette, Extraction Buffer Tube, Nasopharyngeal Swabs, and Dropper.
- When collecting a nasopharyngeal sample, please use the nasopharyngeal swab provided in the kit. Using other swabs may result in false-negative results. During the collection process, in order to obtain as much secretion as possible, the nasal swab must be inserted into the nostril where there is more secretion. Gently push the nasal swab along with the nasal diaphragm to the posterior nasopharynx, rotate it several times, and remove it.
- Never open the sealed aluminum foil bag of the cassette, exposing it to the ambient temperature and humidity too early before the moment for immediate use.
- Discard any suspected used or damaged cassette.
- When the antigen in the sample is lower than the detection limit of the product, incorrect sample collection or transportation will lead to false-negative results. Therefore, a negative result cannot rule out the possibility of SARS-CoV-2 infection due to the mishandling of the sample collection process.
- Do not write on the barcode of the cassette or peel off the barcode sticker.
- One LooK SPOT reader can be used to conduct hundreds or even thousands of tests. Clean the surface with 75% alcohol solution for sterilization.
- For additional information on the hazard symbols, safety, handling, and disposal of the components within this kit, please consult with Laipac for the Material Safety Data Sheet (MSDS)

MATERIALS TEXT

MATERIALS SUPPLIED

LooK COVID-19 Rapid Test Kit - 10

1. LooK COVID-19 Antigen Rapid Test Cassette (10): Each individually sealed aluminum foil bag contains an antigen cassette with SARS-CoV-2 virus monoclonal antibodies
2. Dropper (10): Each individually sealed aluminum foil bag also includes the liquid dropper
3. Extraction Buffer Tube (10): Each tube contains surfactants, proteins, and salts.
4. Nasal Swab (10): Sterile nasopharyngeal swab (Puritan)
5. Package Insert (1): Instruction of use



LooK COVID-19 Antigen Cassette



LooK COVID-19 Rapid Test Kit

CROSS REACTION

LooK COVID-19 rapid test reagent for SARS-CoV-2 virus antigen uses ten (10) bacteria and twelve (12) viruses to conduct cross-reactivity tests in the clinical nasopharyngeal matrix. Bacteria detection concentration is greater than 10⁶CFU/ml; virus detection concentration is greater than 10⁵ TCID₅₀/ml(or pfu/ml), and the test results have no cross-reaction. The bacteria and viruses used are as follows.

Bacteria panel	
<i>Bordetella pertussis</i>	<i>Pseudomonas aeruginosa</i>
<i>Chlamydia pneumoniae</i>	<i>Staphylococcus aureus</i>
<i>Escherichia coli</i>	<i>Staphylococcus epidermidis</i>
<i>Haemophilus influenzae</i>	<i>Streptococcus pneumoniae</i>
<i>Mycoplasma pneumoniae</i>	<i>Streptococcus pyogenes</i>
Viral panel	
Adeno virus type 7	Influenza A virus (A/TW/344/19 (H1N1))
Corona virus (HCoV-229E)*	Influenza A virus (A/TW/1608/19 (H3N2))
Corona virus (HCoV-OC43)*	Influenza B virus (B/TW/2129/19 Victoria)
Enterovirus Type 68	Influenza B virus (B/TW/2668/19 Yamagata)
Enterovirus Type 71	Respiratory syncytial virus (18537)
Human parainfluenza virus Type 2	Rhinovirus

DISTURBANCE TEST

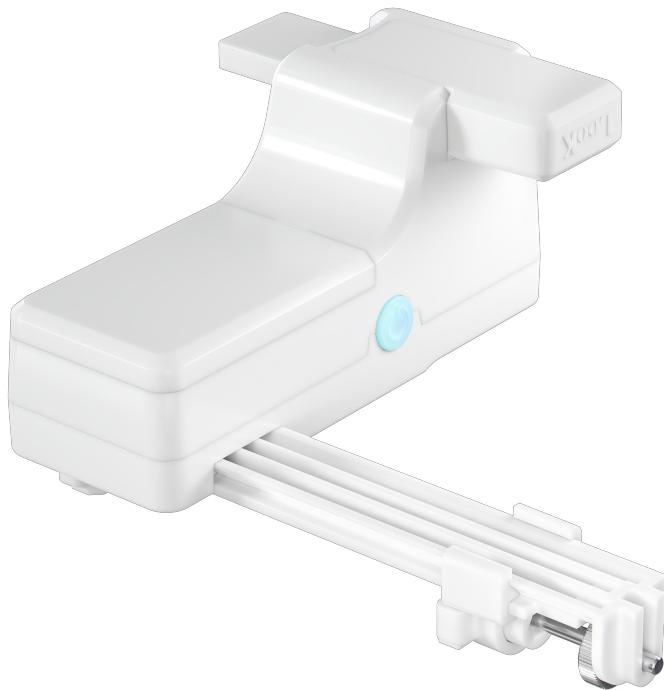
Commercially available nasal sprays and commonly used drugs were tested in the clinical nasopharyngeal matrix. The results showed that the following substances did not interfere with the test results of this reagent. The test items and dosage are as follows:

Interference substances	Testing Concentration	Interference substances	Testing Concentration
Aspirin	20 mg/ml	NASONEX Aqueous Nasal Spray	10%
Dextromethorphan	10 mg/ml	Oxymetazoline HCl	10 mg/ml
Diphenhydramine HCl	5 mg/ml	Phenylephrine HCl	100 mg/ml
Hemoglobin	20 mg/ml	Ponstan	20 mg/ml
Hosoon Troches (ROOT)	20 mg/ml	Swingin nasal sprays	10%
Mucin	4%	Whole blood	5%
Nasal Washing Salt	20 mg/ml	Ibuprofen	20 mg/ml
Nasal Ointment	10%		

LooK SPOT reader

The plastic enclosure is of material ABS + PC
 Adjustable rail for any smartphone
 Low power and BLE based
 Optical Lens
 Internal UV light is of 260nm wavelength for sterilization
 2 x AAA Alkaline battery
 Compliance to RoHs
 FCC, CE and IC approved





SAFETY WARNINGS

- Use precautions in the collection, handling, and disposal of patient samples.
- The Extraction Buffer Tube contains a saline solution and sodium azide, which is harmful if inhaled, swallowed, or in contact with the skin. Contact with acidic substances may produce highly toxic gas. If you accidentally touch your skin, please rinse immediately with plenty of water. Sodium azide may react with lead or copper pipes to form explosive compounds. Therefore, it is recommended to rinse with plenty of water to avoid the accumulation of azide.
- Do not pour the solution from the Extraction Buffer Tube into the sample window of the cassette. Use the dropper provided inside the sealed aluminum foil bag of the cassette.
- Dispose of unused contents in accordance with Federal, State, Province, and Local regulatory requirements.
- Wash hands thoroughly after completing the test.
- If you have no previous experience in collecting samples and handling the test reagents, please seek training or refer to relevant operating instructions.

DISCLAIMER:

DISCLAIMER – FOR INFORMATIONAL PURPOSES ONLY; USE AT YOUR OWN RISK

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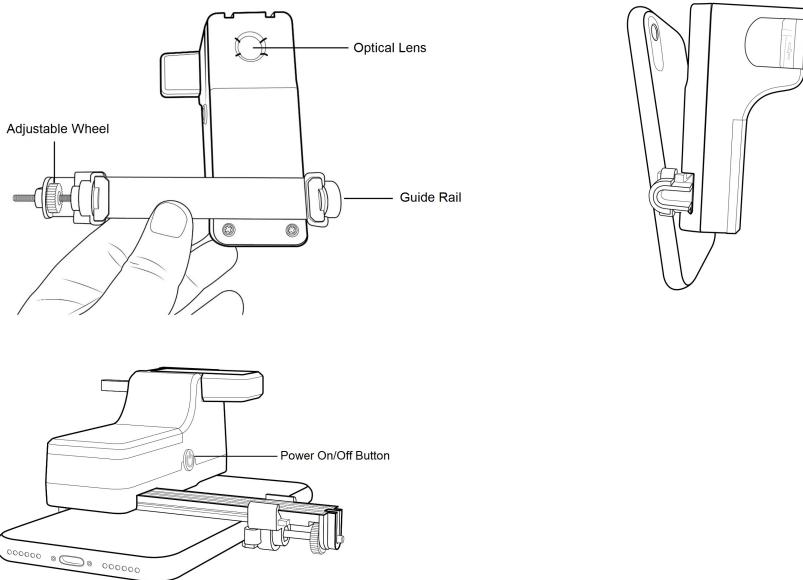
BEFORE STARTING

- Use proper personal protective equipment (PPE) for the handling of patient samples.
- Testing should be performed in an area with adequate ventilation
- LooK SPOT reader must be used to obtain good results for the test.
- LooK SPOT reader uses 2 AAA batteries
- Have a smartphone ready and fully charged
- It can save time if the apps have already been downloaded

- 1 Download LooK SPOT app from Google Play Store or Apple Store and install it. Register the app with your information. The minimum requirement for supported smartphone models and OS: iPhone 6 and above, with iOS 13 and above, with 8MP rear camera and above. Android phone with Android OS 7.1 and above, with 8MP rear camera and above. WiFi and BLE are required for the operation.



- 2 Inspect your LooK SPOT reader. Perform the Look SPOT Reader Calibration Check Procedure to have the Look SPOT reader attached to your phone. Look SPOT Reader Calibration Check is needed whenever the LooK SPOT reader is attached to a smartphone for the COVID-19 antigen test and is used to check the alignment of LooK SPOT reader's lens with the smartphone's camera. Clamp the Look SPOT reader to your smartphone by aligning the lens of LooK SPOT reader with the camera of the smartphone. Adjust the wheel and slide the guide rail to find the optimal position for the alignment.

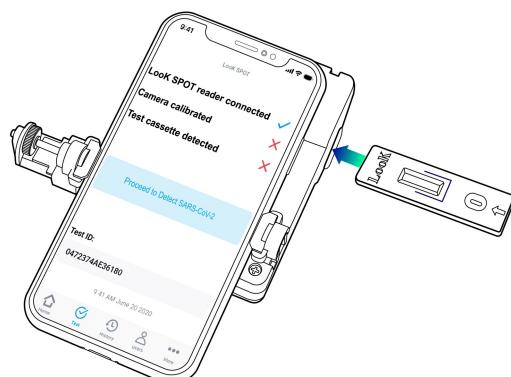
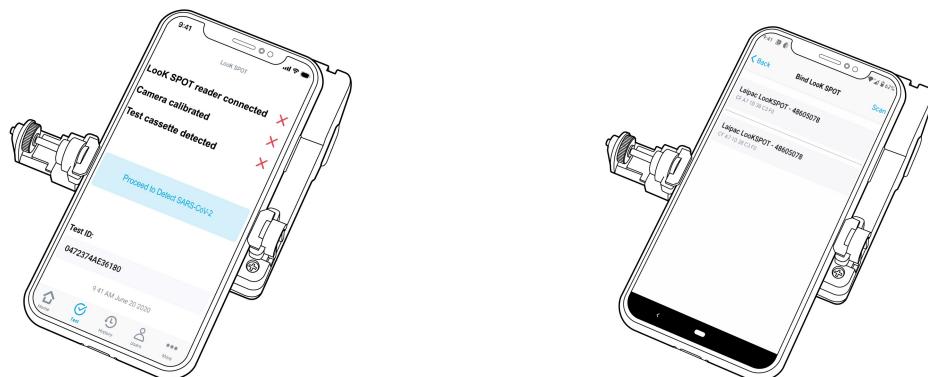


- 3 With the LooK SPOT reader attached to the phone, open the phone's camera app and look for the cross mark. The cross mark must be in the center of the screen for the test. If the smartphone has multiple cameras, this step will ensure the



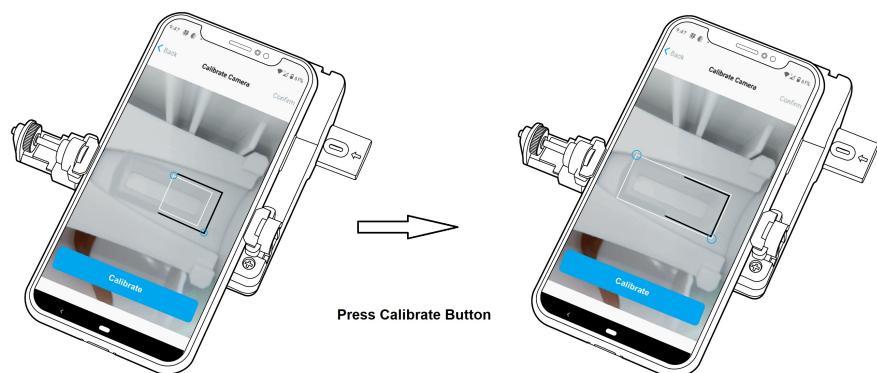
correct camera is used for the LooK SPOT reader.

- 4 Open LooK SPOT app. Make sure the Bluetooth is enabled for the phone and the LooK SPOT reader is on. Press the X mark of "LooK SPOT reader connected" to see the available LooK SPOT within the Bluetooth signal range. Select the correct LooK SPOT based on the serial number of the sticker on the reader. LooK SPOT reader is now connected via Bluetooth with the phone; insert the calibration cassette. Press the X mark of "Camera Calibrated" for the calibration process with the camera.

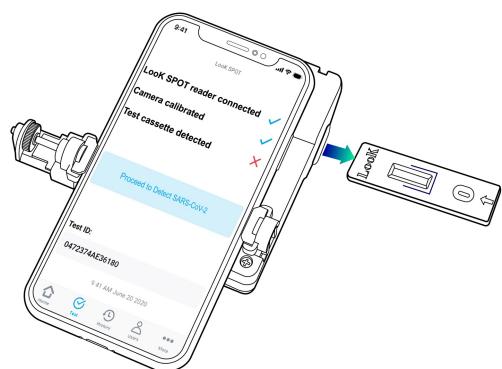


- 5 The screen will show the view of the calibration cassette and a small white box. Press the Calibrate button to calibrate

the reader. A message of Processing will appear. Wait until it is done. Then press Confirm.



- 6 The screen now shows "Camera Calibrated" checked. Remove the calibration cassette and be ready for the COVID-19 antigen test. The above control is required to obtain the correct test result for LooK SPOT COVID-19 Antigen Rapid Test. Without completing the Look SPOT Reader Calibration Check Procedure, the test result can be invalid.



- 7 NASAL SWAB SAMPLE COLLECTION For the best test results, please use the nasal swabs in the test kit to collect the nasal sample. During the collection process, in order to obtain as much secretion as possible, the nasal swab must be inserted into the nostril where there are more secretion and visible drainage, or the nostril that is most congested if drainage is not visible. Push the swab until stopping at the level of the turbinates (one inch into the nostril). Rotate the swab five (5) times or more against the nasal wall, then slowly remove it from the nostril. Repeat the same process in the other nostril with the same swab.
- 8 Place the patient nasal swab sample into the Extraction Buffer Tube. Roll the swab at least five (5) times while pressing the head against the bottom and side of the tube.



- 9 Leave the swab in the Extraction Buffer Tube for 1 minute. Roll the swab head against the inside of the tube as removing it. Dispose of the used swab in biohazard waste.

1m



⌚ 00:01:00

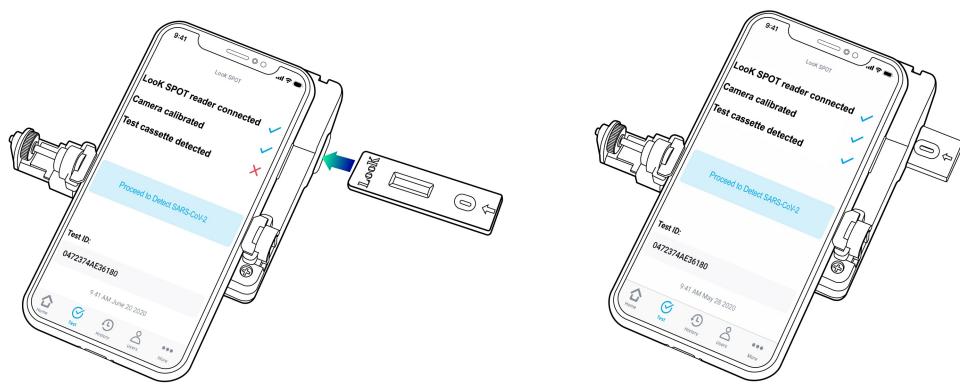
- 10 Fill the disposable dropper with the patient sample from the Extraction Buffer Tube: a) Squeeze the bulb. b) Still squeezing, place the dropper tip into the patient sample. c) Slowly release the pressure on the bulb to fill the dropper



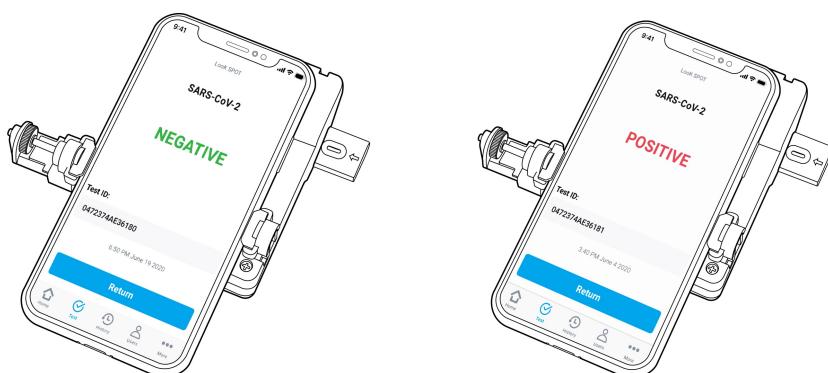
- 11 Dispense three (3) drops of sample to the round sample window above the arrow mark on the cassette. Do not touch the cassette with the tip of the dropper. NOTE: Do not pour the sample from the Extraction Buffer Tube directly to the cassette



- 12 After performing the Look SPOT Reader Calibration Check Procedure, insert the test cassette to LooK SPOT reader and press the X of Test Cassette detected. LooK SPOT reader will detect the valid test cassette with the embedded microchip inside the test cassette. Then press the tab "Proceed to Detect SARS-CoV-2" on the screen. The timer will appear to count the time for the diagnosis process. Please leave the LooK SPOT reader on a flat surface and make sure the cassette in the correct position and not moving. This antigen detection process can be stopped by pressing the Abort button at any time before the result.



- 13** The test result will be ready in 5 to 8 minutes on the LooK SPOT app screen. The results can be Positive, Negative, or Invalid. For an invalid test result, please discard the test cassette in the biohazard waste and redo the test again.





- 14** A high positive result tends to appear at 5 minutes mark. A low positive result can appear between 5 to 8 minutes. A negative result will appear at 8 minutes mark. The results can be Positive, Negative, or Invalid. For an invalid test result, please discard the test cassette in the biohazard waste and redo the test again. The test results are documented automatically in the History section of LooK SPOT app with the Test ID, location, city, country, and timestamp of the tests. If the test did not flow correctly, the test result would show Invalid. The operator can also request the cause for the invalid test result to be delivered by email. Shall the invalid test result occur, you can use the same cassette and try it again.



- 15** Remove the test cassette and dispose of it in biohazard waste. LooK SPOT reader will sterilize automatically with an internal UV light of 260nm wavelength for 5 seconds and ready for the next test.

