LooK SPOT

For Use Under the Emergency Use Authorization (EUA) Only

For *in vitro* Use Only
For use with nasal swab specimens
Rx Only

INTENDED USE

LooK SPOT is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein from SARS-CoV-2 in nasal swabs from patients suspected of COVID-19 within the first eight (8) days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 USC §263a, that meet the requirements to perform moderate complexity tests. This test is authorized for use at the Point of Care (POC), i.e., inpatient 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. This antigen is generally detectable in the nasal sample 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.

The LooK SPOT does not differentiate between SARS-CoV and SARS-CoV- 2.

LooK SPOT can diagnose the SARS-CoV-2 virus detection between 5 to 8 minutes by using AI LooK SPOT's AI algorithm has high accuracy and can identify the color 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 is intended for use at the Point of Care (POC) settings by medical and 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.

SUMMARY

The SARS-CoV-2 virus is a positive-stranded single-stranded RNA virus with an envelope with a virus particle diameter of about 50～200nm; it is composed of four main structural proteins: spike protein (S), an envelope protein (E), membrane protein (M) and nucleocapsid protein (N). The nucleocapsid protein binds to the viral RNA,

and the other three proteins together form the viral coat. Its gene sequence is similar to SARS and MERS viruses, but they belong to different species.

The incubation period of the SARS-CoV-2 is about 2-14 days on average; most patients will have respiratory symptoms. Typical symptoms include frequent fever, dry cough, weakness of limbs, etc. (may be accompanied by muscle pain, diarrhea, sore throat, loss of smell and abdominal pain, etc.). There is a percentage of carriers without any clinical symptoms. Severe patients may develop acute respiratory distress syndrome (ARDS), septic shock, diffuse alveolar injury, or even death.

LooK SPOT is an immunochromatographic test that uses monoclonal antibodies combined with latex particles to detect whether there are SARS-CoV-2 antigens in nasal secretions. This test is easy to execute, and the test result can be ready between five (5) to eight (8) minutes with the use of the LooK SPOT and LooK SPOT smartphone app.

TEST PRINCIPLE

LooK COVID-19 antigen immunochromatographic detection reagent uses a rapid immunochromatographic detection method to detect whether the nucleocapsid protein of the SARS-CoV-2 virus is present in the nasal swab samples using specific monoclonal antibodies. LooK COVID-19 antigen cassette reagent is designed to detect whether patients who are suspected of being infected by the SARS-CoV-2 virus have the SARS-CoV-2 antigen in the nasal swabs.

Before performing the test, the patient can download and register the LooK PASS app from Google Play Store or Apple App Store. The patient scans the QR code of the LooK COVID-19 antigen cassette with the LooK PASS app, and the information is uploaded to the LocationNow AI Cloud for the registration of the test. Each LooK COVID-19 antigen cassette has an embedded microchip for security, quality control, and identification purposes. This will guarantee the patient can receive the test result on their phone in real-time with privacy.

To perform the test, a nasal swab specimen is collected from the patient. Place the nasal swab into the Extraction Buffer tube. Stir the nasal swab in the Extraction Buffer tube for one (1) minute. The virus particles in the sample are disrupted and exposing the internal viral nucleoproteins. After disruption, use the dropper to extract the solution inside the tube and apply three drops in the sample window of the LooK COVID-19 antigen cassette. The sample migrates through the antigen cassette containing unique chemical environments. If SARS-CoV-2 viral antigen is present, they will be trapped in a specific location on the test window of the antigen cassette. Insert the LooK COVID-19 antigen cassette into the LooK SPOT attached to the smartphone. LooK SPOT sends the images of the color signal of the cassette's test window to LocationNow AI Cloud for analysis. LocationNow AI Cloud analyzes the images using proprietary AI algorithms and sends the test results to the LooK SPOT app. The test result can be Positive, Negative, or Invalid. The test result is also sent to the patient's LooK PASS app. If the test result is negative, the LooK PASS app will generate a QR code with a timestamp of the test. When it is Invalid, the test can be repeated with the same cassette or a new one. The test results will be saved in the history section of the apps and can be deleted by the users.

MATERIALS SUPPLIED FOR LOOK SPOT

1. LooK SPOT (1)
2. Calibration Cassette (1)
3. Double Side Adhesive Strip (1)
4. Package Insert (1): Instruction of use

MATERIALS REQUIRED BUT NOT SUPPLIED

1. LooK COVID-19 Antigen Cassettes
2. Droppers
3. Extraction Buffer tubes
4. Nasal swabs
5. Android Smartphone with OS 7.1 and above, iPhone 6 and above, with iOS 13+, must have a rear camera of 8 megapixels or above. See the List of Tested and Supported Smartphones in LIMITATIONS.
6. AAA Battery x 2 for LooK SPOT
7. Personal Protective Equipment (PPE.)

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Do not use the product contents beyond the expiration date printed on the outside of the box.
3. 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.
4. Use precautions in the collection, handling, and disposal of patient samples.
5. Use proper personal protective equipment (PPE) for the handling of patient samples.
6. 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.
7. When collecting nasal specimens, please use the nasal swab provided by Laipac. Do not use other swabs, which may result in false-negative results.
8. 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.
9. Discard any suspected used or damaged cassette.
10. 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.
11. 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.
12. Do not write on the barcode of the cassette or peel off the barcode sticker.
13. Testing should be performed in an indoor area with adequate ventilation.
14. The Instruction of Use must be followed for a good result.
15. LooK SPOT must be used to obtain good results for the test.
16. Use the calibration cassette first when setup the LooK SPOT before the test.
17. Do not use other types or brands of antigen cassette for LooK SPOT.
18. Use the LooK SPOT on a flat surface so the antigen cassette will not move out of focus from the camera.
19. Dispose of unused contents in accordance with Federal, State, Province, and Local regulatory requirements.
20. Wash hands thoroughly after completing the test.
21. If you have no previous experience collecting samples and handling the test reagents, please seek training or refer to relevant operating instructions. A training video can be found on www.laipac.com.
22. For additional information on the hazard symbols, safety, handling, and disposal of the components within this kit, please refer to the Material Safety Data Sheet (MSDS) at www.Laipac.com.

KIT STORAGE

Store the kit at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight until the expiration date. Do not use the kit after the expiration date.

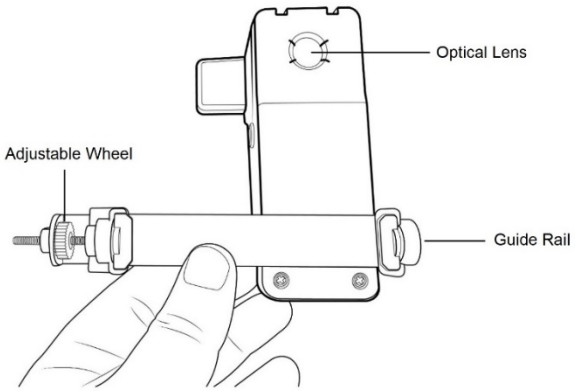
QUALITY CONTROL

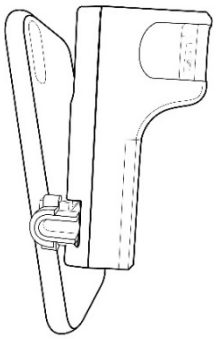
There are three types of Quality Control for LooK SPOT and LooK COVID-19 antigen cassette:

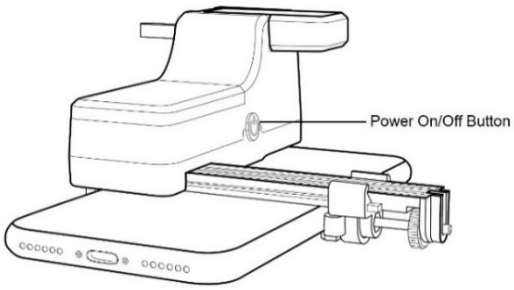
- Look SPOT Calibration Check Procedure
- Built-in Procedural Controls
- External Quality Controls

Look SPOT Calibration Check Procedure

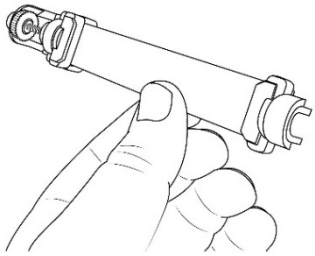
This procedure should be performed every time when the LooK SPOT is attached to a smartphone for the COVID-19 antigen rapid test. This Calibration Check is important to check the alignment of the LooK SPOT's lens with the smartphone's camera. LooK SPOT uses a specific calibration cassette that comes with the LooK SPOT. First, download the LooK SPOT app from the app stores to your smartphone and register online. Clamp the Look SPOT to your smartphone (check the list of supported phones) by aligning the lens of the LooK SPOT with the camera of the smartphone. Adjust the wheel and slide the guide rail to find the optimal position for the alignment.

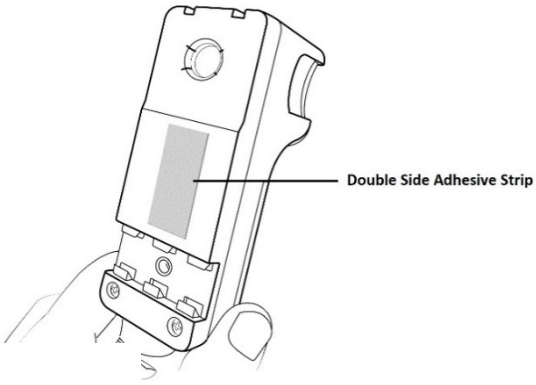


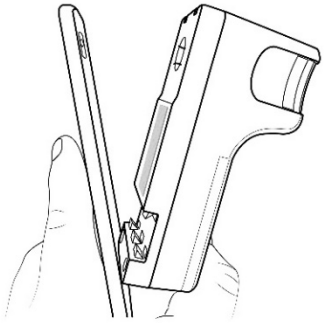




If the size of the smartphone is too big or too small to fit into the guide rail, please remove the guide rail and use the double side adhesive strip provided in the packaging. Align the lens with the camera properly and press the LooK SPOT with the smartphone. This method can also be applied to smartphones using protective cases.

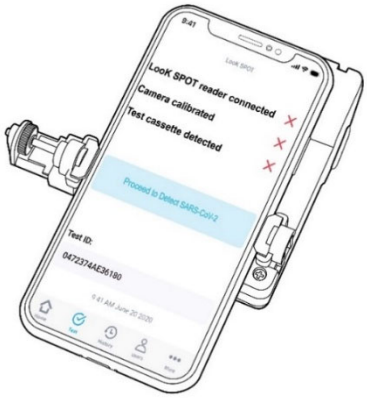




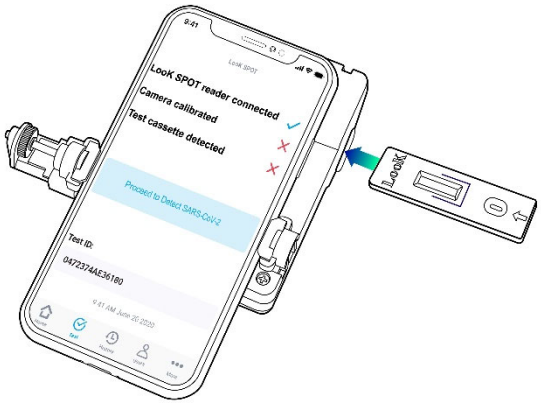


With the LooK SPOT attached to the smartphone, press the power button of the LooK SPOT to turn on the LooK SPOT. Open the smartphone's camera app and look for the cross mark. The cross mark must be in the center of the screen for the test. If the smartphone has multiple cameras, this step will ensure the correct camera is used for the LooK SPOT. Close the camera app once this process is done.

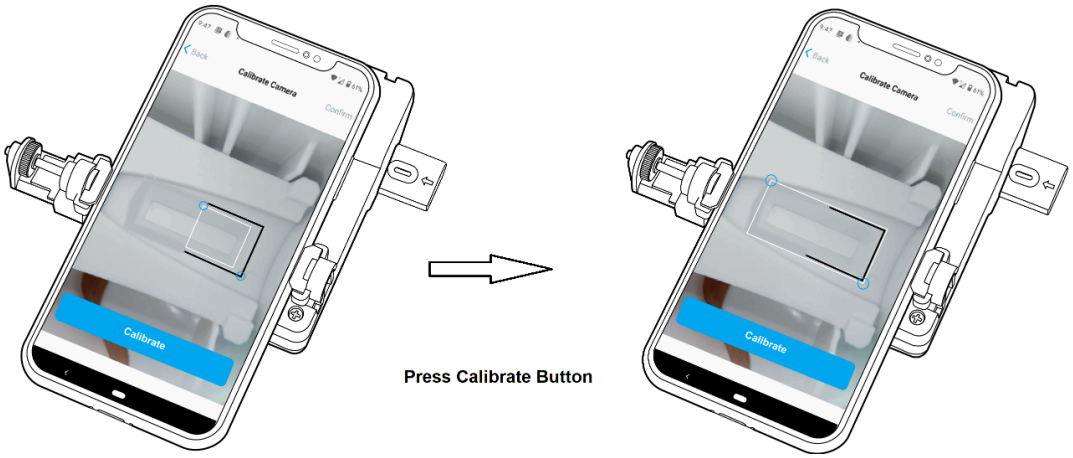
Open the LooK SPOT app. Make sure the smartphone has Bluetooth enabled (For Android OS, please also enable the Location Service for the Bluetooth connectivity to work). Press the X mark of "LooK SPOT connected" to see the available LooK SPOT to connect. Select the correct LooK SPOT based on the serial number on the sticker of the LooK SPOT. Once selected, press Back.



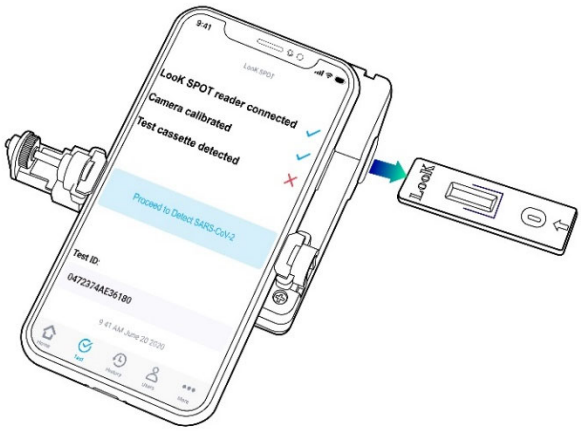
Once the LooK SPOT is connected via Bluetooth with the smartphone, insert the calibration cassette. Then press the X mark of "Camera Calibrated" to calibrate the camera.



The screen will show the view of the calibration cassette and a small white box. Press the Calibrate button to calibrate. A message of Processing will appear. Wait until it is done. Then press Confirm.



After the Calibration process, it shows "Camera Calibrated" checked. Remove the calibration cassette and be ready now for the COVID-19 antigen test.

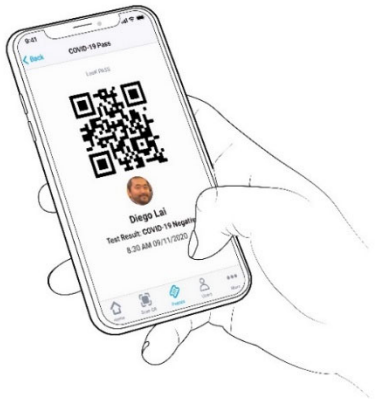


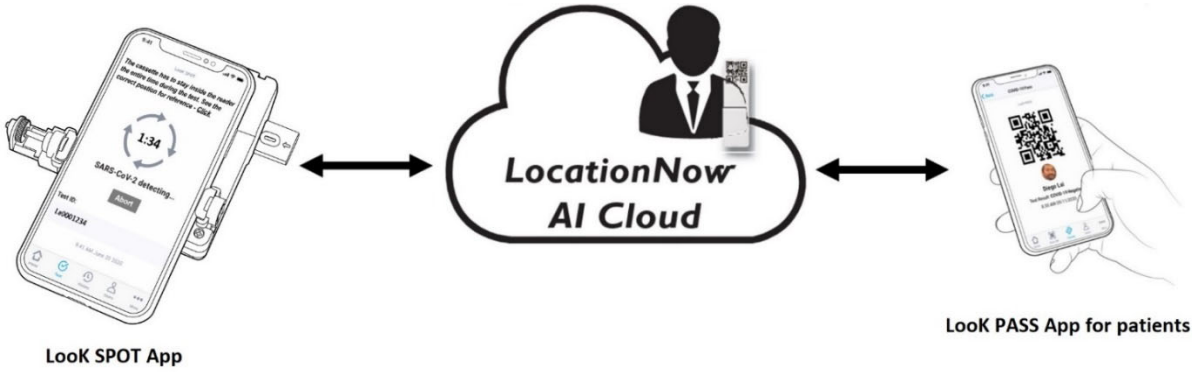
The calibration process is important to obtain the correct test result for the LooK SPOT test. Without completing the Look SPOT Calibration Check Procedure, the test result can be invalid.

NOTE: If the Look SPOT Calibration Check Procedure does not pass, contact Laipac Technology, Inc. Customer Service for assistance Monday through Friday from 9:00 a.m. to 6:00 p.m. Eastern Time at 905-7621228; info@laipac.com or contact your on-site supervisor or a local distributor.

Built-in Procedural Controls

The images of the LooK COVID-19 antigen cassette taken from the LooK SPOT app are sent to LocationNow AI Cloud for analysis. LocationNow AI Cloud has a built-in procedural controls process to detect positive, negative, or invalid test results. Each image is associated with Look COVID-19 antigen cassette built-in microchip. This microchip is associated with the unique QR code on the back of each LooK COVID-19 antigen cassette. The QR code of the cassette is scanned by the patient using the LooK PASS app before the COVID-19 antigen test. The patient with the negative test result will also receive a QR code with a timestamp.





The Built-in Procedural Controls that involve the microchip and QR code for the LooK COVID-19 antigen cassette has secured the test process to have privacy and accuracy for correct result-to-patient in a fast pace testing environment. If the test procedure does not flow correctly, LocationNow AI Cloud will alert the event to the operator of the LooK SPOT.

For example:

Using an unknown third party antigen cassette, LocationNow AI Cloud will alert immediately as an unknown antigen cassette.

The test results are documented automatically in the History section of the 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. Shall the invalid test result occur, please repeat the Calibration process and initiate a new test with the same test cassette or a new test cassette with a new nasal swab sample.

The additional Built-in Procedural Controls also display error messages on the LooK SPOT app and the LooK PASS app to follow the corrective procedures and mitigate the issues. The following table describes the errors that can occur during the test and the mitigations.

ID.	Error Notification	Cause of Error	Solution Measure
1	Fail to sign in for the LooK SPOT app and LooK PASS app	a. The account does not exist b. Wrong user name or password, forgot the password	a. Create a new account b. Choose to reset the password
2	Fail to create a new user account for the LooK SPOT app and LooK PASS app	a. Email already exists b. Email is invalid c. Mandatory fields not filled	a. Reset the password b. Re-type the email address c. Ask the user to fill all required fields
3	Fail to reset the password for the user account of the LooK SPOT app and LooK PASS app	a. Email address does not exist b. Wrong email address	a. Verify the email address b. Check the format of the email
4	LooK SPOT not found by LooK SPOT app	a. BT is disable b. LooK SPOT is off c. The permission of BT is off for Android, or the Location Service is off d. Missing to select the correct LooK SPOT with the serial number	a. Turn on Bluetooth on the phone b. Turn on LooK SPOT and attach it to the phone c. Select to allow permission for BT in Android d. Scan and select the correct LooK SPOT to pair based on the serial number on the device
5	Camera not found by LooK SPOT app	a. The phone does not support a camera b. No permission allowed for the camera	a. Use a phone with a rear camera of 8MP or more b. Select to allow permission to use the camera
6	LooK SPOT app fails to get antigen test cassette's ID and show unknown cassette	a. No BT connection to LooK SPOT b. Invalid test cassette or the cassette been used before c. LooK SPOT issue	a. Scan and select the correct LooK SPOT to pair via BT based on the serial number on the device b. Use a new test cassette c. Contact Laipac Tech Support
7	LooK SPOT app fails to take pictures	a. No permission allowed for using the camera	a. Set to allow the required permission

8	LooK SPOT responds with "INVALID" test result	a. Incorrect alignment of the test cassette b. Test cassette failed to show Control line c. AI Cloud technical issue d. The camera was not calibrated	a. Verify the test cassette is inserted correctly b. Check to see if the test cassette is showing the control line c. Contact Laipac Tech Support d. Proceed with the calibration process again.
9	LooK SPOT responds with a false negative result	a. Incorrect alignment of the test cassette b. AI misdiagnosis of the intensity of fluorescence response	a. Verify the test cassette is inserted properly b. Verify the image taken by the LooK SPOT and train the machine learning algorithm for positive
10	LooK SPOT app fails to access LocationNow AI cloud API	a. No permission to access network b. No wireless connection c. AI cloud server technical issue	a. Configure permission to access the network b. Check WiFi or Cell network connection c. Contact Laipac Tech support
11	LooK SPOT does not turn on with the pressing of the power button	LooK SPOT hardware failure due to manufacture workmanship	Contact Laipac customer service to initiate support and RMA procedure.
12	LooK SPOT app detected a different cassette ID than the real one	Paired to a wrong LooK SPOT close by	Re-Pair the LooK SPOT. Make sure the LooK SPOT 's serial number is the one to pair via Bluetooth
13	Not receiving test results from AI cloud	The operator has aborted the test process	Check with the operator of LooK SPOT, and the history will show the information of the test

External Quality Controls

This process is to use Positive and Negative controls to ensure the test reagents and assay perform correctly. Laipac recommends that Positive and Negative External Quality Controls be used once for each untrained operator, once for each shipment received, and as necessary by your internal quality control procedures, and following Local, State, Provincial, and Federal regulations requirements and accrediting groups.

External Positive and Negative control swabs are included in the shipment and should be tested using the swab test procedure provided in the Instruction of Use. If the correct control results are not obtained, do not perform patient tests. Contact Laipac Technology, Inc. Customer Service for assistance Monday through Friday from 9:00 a.m. to 6:00 p.m. Eastern Time at 905-7621228; info@laipac.com or your local distributor. Additional External Control Swabs may be obtained separately.

SAMPLE COLLECTION AND HANDLING

SAMPLE COLLECTION

The correct sampling method, storage, and transportation have a critical influence on this reagent. The test should be carried out immediately after sampling. In addition, the quality of the sample has a significant impact on product efficiency, and it is recommended to train the sample collection process. For the best test results, please use the nasal swabs in the kit to collect the nasal sample. It has the highest amount of virus in the early stage of symptoms. If the test is taken eight (8) days after the onset of symptoms, it can lead to a false-negative result. In addition, incorrect sample collection, improper sample handling, or transportation errors may all produce false-negative results.

SAMPLE STORAGE

The freshly collected sample should be processed as soon as possible, and it is recommended to complete the test within 1 hour after sampling. During the process, the correct sample collection and preparation procedures must be followed.

NASAL SWAB SAMPLE COLLECTION

For the best test results, please use the nasal swabs provided by Laipac 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.

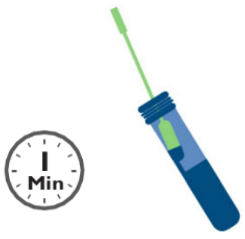
TEST PROCEDURES

All clinical samples must be at room temperature before the test. Check the expiration date on each antigen cassette package or outer box, DO NOT use any antigen cassette or nasal swabs past the expiration date on the label.

Nasal Swab Test Procedure

1. 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.

2. 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.



3. 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

4. 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

Using LooK SPOT (The following steps 1-3 must be completed before the Nasal Swab Procedure)

1. Download the LooK SPOT app from Google Play Store or Apple Store and install it. Register the app with your information. It is strongly recommended to use an Android smartphone or iPhone with a camera of 8 Megapixels and above. *See the List of Tested and Supported Smartphones in LIMITATIONS.*

LooK SPOT app

ANDROID APP ON Google play

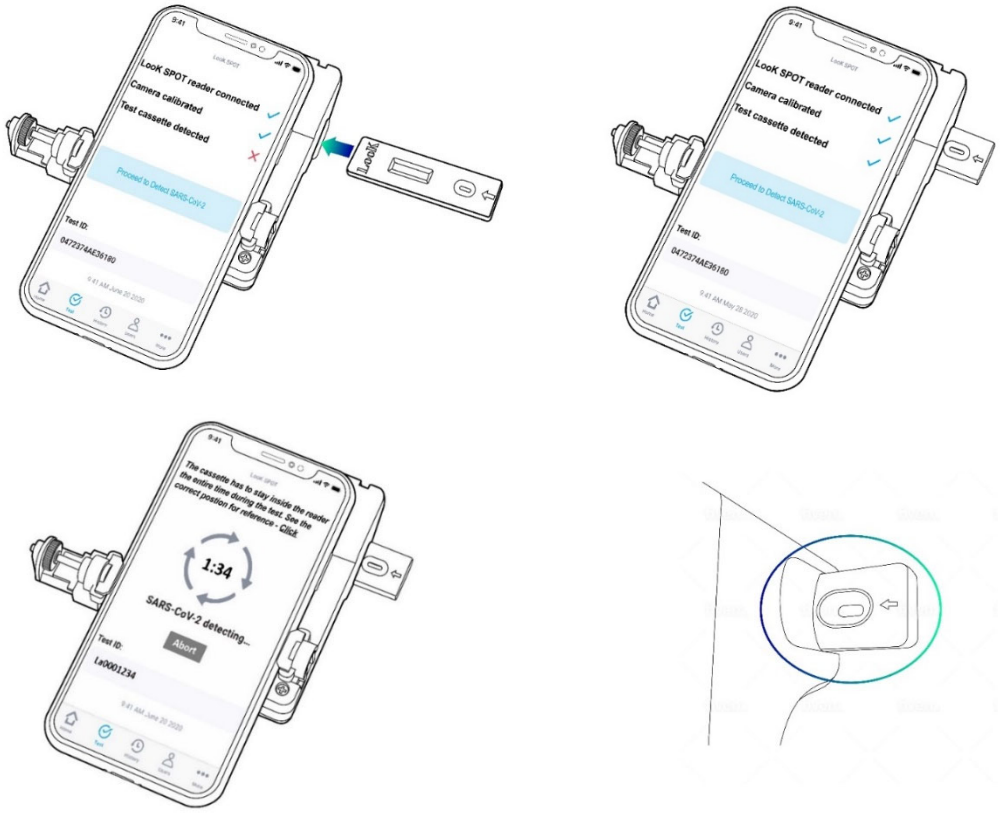
Google Play and Google Play logo are trademarks of Google LLC.

Download on the App Store

Apple and the Apple logo are trademarks of Apple Inc., registered in the U.S. and other countries and regions. App Store is a service mark of Apple Inc.

2. Inspect your LooK SPOT. Perform the **Look SPOT Calibration Check Procedure** under **Quality Control** to have the Look SPOT attached to your smartphone.

3. After performing the Look SPOT Calibration Check Procedure, insert the test cassette into the LooK SPOT. The LooK SPOT 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 on a flat surface and make sure the cassette in the correct position and not moving. This testing process can be stopped by pressing the Abort button at any time before the result.



4. The test result will be ready between 5 to 8 minutes on the LooK SPOT app screen. The results can be Positive, Negative, or Invalid. For an invalid test result, please proceed with the Calibration process and redo the test again because the phone may clean up the settings due to a long period of use.

5. Remove the test cassette and dispose of it in biohazard waste. The LooK SPOT will sterilize automatically with an internal UV light for 10 seconds and ready for the next test.

CLINICAL PERFORMANCE

The LooK SPOT COVID-19 Antigen Rapid Test clinical performance was evaluated with patient specimens collected in multiple sites. In this study, 95 patients with suspected COVID-19 have participated. Patients who presented within eight (8) days of symptom onset were included in the study. There were eleven (11) asymptomatic patients, and one (1) of them was tested positive for SARS-CoV-2. A Real-Time Polymerase Chain Reaction (RT-PCR) assay was utilized as the comparator method for this study. The BioMerieux MucliSENS extraction system was used to extract total nucleic acid. Extracted nucleic acid was then amplified in three separate reactions using the CDC N1, N2, and RNase P primer set using the Promega GoTaq kit on a BioRAD C.F.X. Real-time PCR system.

The collected specimens were transported in Universal Transport Medium (UTM), and all sites shipped the UTM samples to the lab center for this clinical performance study. The samples were run as per test protocol where the swab was mixed in the extraction buffer (450uL) and left in for one minute. Then apply three drops (100uL) of the buffer onto the LooK COVID-19 Antigen Cassette to start the test.

LooK SPOT COVID-19 Antigen Rapid Test Performance within eight (8) days of symptom onset:

LooK SPOT COVID-19 Antigen Rapid Test	Comparator Method		
	Positive	Negative	Total
Positive	37	1	38
Negative	1	56	57
Total	38	57	95
Positive Agreement: 37/38	97.4% (95% CI: 86.2% – 99.9%)		
Negative Agreement: 56/57	98.3% (95% CI: 90.6% – 100%)		

Patient Demographics

Patient demographics (gender, age, asymptomatic, number of days since the onset of symptoms) are available for the 95 samples used in the analysis. The following table shows the results vs. age of the patient:

Age	LooK SPOT COVID-19 Antigen Rapid Test		
	Total #	Positive	Prevalence
≤ 5 years	4	2	50.0%
6 to 21 years	3	1	33.3%
22 to 59 years	51	20	39.2%
≥ 60 years	37	14	37.8%

LooK SPOT COVID-19 Antigen Rapid Test vs. The Comparator Method

Based on the Cycle Threshold Counts

LooK SPOT COVID-19 Antigen Rapid Test	Comparator Method	
	POSITIVE (Ct < 32)	POSITIVE (Ct ≥ 32)
Positive	29	8
Negative	0	1
Total	29	9
Positive Agreement (95% CI)	100% (88.1%-100%)	88.9% (51.75%-99.72%)

LIMIT OF DETECTION (ANALYTICAL PERFORMANCE)

The LOD was determined by limiting dilution studies using positive nasal specimens collected from multi-sites with UTM as the transport agent. The samples were diluted in the extraction buffer tenfold until we reached a 1/100,000 dilution. 100 uL of each were applied on the LooK COVID-19 Antigen cassettes according to the test procedure and using the LooK SPOT to record the results. The remaining buffer was then extracted, and the viral load was determined. The LOD was determined as the lowest virus concentration that was detected ≥ 95% of the time, at which at least 19 out of 20 replicates tested positive for the SARS-CoV-2 virus. The LooK SPOT COVID-19 Antigen Rapid Test in nasal swab matrix was confirmed with the LOD at 3.11 x 10^3 viral copies.

Limit of Detection (LoD) Study Results

Concentration	Number Positive/Total	% Detected
3.11 x 10^3 viral copies	20/20	100%

CROSS REACTION

The LooK COVID-19 antigen rapid test for SARS-CoV-2 virus antigen uses ten (10) bacteria and twelve (12) viruses to conduct cross-reactivity tests in the clinical nasal 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	
Bordetella pertussis	*Pseudomonas aeruginosa*
Chlamydia pneumoniae	*Staphylococcus aureus*
Escherichia coli	*Staphylococcus epidermidis*
Haemophilus influenzae	*Streptococcus pneumoniae*
Mycoplasma pneumoniae	*Streptococcus pyogenes*
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

*Unit: pfu/ml

DISTURBANCE TEST

Commercially available nasal sprays and commonly used drugs were tested in the clinical nasal matrix. The results showed that the following substances did not interfere with the test results of the LooK SPOT COVID-19 Antigen Rapid Test. 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%		

LIMITATIONS

1. This product qualitatively detects whether the nasal swab sample has the SARS-CoV-2 virus antigen.
2. Failure to use this product by standard operating procedures may affect product performance and produce invalid results.
3. The sample should be tested as soon as possible after collection.
4. As the number of days of the disease course increases, the number of viral antigens in the sample may decrease. Compared with the molecular diagnosis (RT-PCR) method, the sample after the 8th day of the symptoms may show a false-negative test result.
5. The test results should be comprehensively evaluated with the medical history, epidemiological data, and the patient's clinical symptoms.
6. A positive test result cannot exclude the possibility of co-infection with other pathogens.
7. The negative test result may be because the antigen concentration of the sample is lower than the detection limit of this product or if the sample was collected or transported improperly.
8. A negative test result cannot rule out the possibility of SARS-CoV-2 virus infection; the test result can be confirmed with an authorized molecular diagnosis.
9. When the amino acid on the epitope of the SARS-CoV-2 virus is changed, the monoclonal antibody may not be able to detect or cause low sensitivity
10. The test must be performed with a good internet connection for the smartphone with a LooK SPOT. If the internet connection is not available or not stable, the test result can be invalid.
11. LooK SPOT's operation temperature: -10C to 45C, storage temperature: -25C to 60C

12. The LooK SPOT is for multiple uses and can conduct hundreds of tests. LooK SPOT has automatic UV sterilization after each test for 10 seconds for the interior compartment.
13. LooK SPOT is supported by the following list of smartphones. List of Tested and Supported Smartphones:
    - Apple iPhone 6, 7, 8, 10, 11, 12, SE, XR
    - Google Pixel, 2, 3, 4 & 5 series
    - Samsung Galaxy A70, A50, A40, A30, A20, A11, A10
    - Huawei P30, P40 and Mate
    - Honor 20 & 30

REFERENCES

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3. D. B. Larremore et al., Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance. medRxiv https://www.medrxiv.org/content/10.1101/2020.06.22.20136309v3 (27 June 2020).
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6. US Food and Drug Administration, Template for manufacturers of molecular and antigen diagnostic COVID-19 tests for non-laboratory use (Food and Drug Administration, Silver Spring, MD, 2020).
7. US Food and Drug Administration, FAQs on testing for SARS-CoV-2. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2. Accessed 4 September 2020.

Label/Symbol	Description
	Manufacturer
	*In vitro* diagnostic medical device
	Prescription use only
	Consult instructions for use
	Authorized Representative in the European Community
	Temperature limitation
	Product Expiration Date

	Humidity limitation
	Waste electrical and electronic equipment (WEEE)
SN	Serial Number
REF	Catalog Number
	Warning/Caution
	Ultraviolet Radiation
	Potential Biohazard

Safety Precautions

The LooK SPOT is designed to provide safe and reliable operation when used according to this Instruction of Use. All warnings and precautions should be followed in order to avoid unsafe actions that could potentially result in personal injury or damage to the device.

Warning!

To reduce the risk of electrical shock:

- Do not immerse in water or cleaning solutions.

Ultraviolet Radiation!

To reduce the risk of UV Exposure:

- Do not attempt to open or disassemble LooK SPOT
- Do not attempt to look inside LooK SPOT while operating or use protective glasses
- Product tested against EN62471

Failure to follow these warnings will invalidate the warranty.

Potential Biohazard!

To reduce the risk of biohazard:

- Dispose of used specimens in accordance with Federal, State and Local requirements.
- Treat specimens and patient samples as potentially biohazardous material.
- Ensure the LooK SPOT is cleaned by using solution with 70% alcohol.
- Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
- Use of Nitrile, Latex, or other gloves is recommended when handling patient samples.

Caution!

To reduce the risk of incorrect results:

- The LooK SPOT should only be used by trained operators.
- Do not use if the LooK SPOT is reporting an error condition that cannot be corrected.
- To obtain accurate results, refer to the Instruction of Use on specific topics.
- Use the test kit within the expiration date.

To reduce the risk of LooK SPOT damage:

- The LooK SPOT is designed for countertop operation.
- The LooK SPOT is not designed to withstand moisture, extreme humidity, or extreme temperatures.
- The LooK SPOT is not designed to withstand severe shock or vibration.
- Do not open or disassemble the device.

Failure to follow the precautions mentioned above will invalidate the warranty.

To reduce the risk of environmental contamination:

- Contact Laipac Technical Support at +1-905-7621228 for return or disposal of the LooK SPOT.
- Clean the LooK SPOT per the **Guideline & Maintenance** section of this Instruction of Use prior to return or disposal.
- The LooK SPOT must be disposed of in a safe and compliant manner. Applicable Federal, State and Local regulatory requirements shall be followed to ensure the LooK SPOT is not disposed of as municipal waste. If you are unsure on the proper methods for disposal, contact a certified waste broker for guidance.

Note: Medical equipment that may have come into contact with potentially infectious materials (e.g., patient samples, blood, serum, etc.) must be properly decontaminated prior to disposal or recycling.

ORDERING & CONTACT INFORMATION

REF

Reorder Numbers:

1. 105A – LooK SPOT (1)
2. 105B – LooK COVID-19 Antigen Rapid Test (10 tests)

LooK SPOT : 6.25" (L) x 5.5" (W) x 3" (H) – 0.38lbs (1pcs)
LooK COVID-19 Antigen Cassette Kit: 9.875" (L) x 4.125" (W) x 2.125" (H) – 0.35lbs (10 tests)

IVD

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LEGAL INFORMATION

FCC Statement (USA) / Part 15 of the FCC Rules

The LooK SPOT has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no warranty that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio or television technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including

interference that may cause undesired operation.
WARNING! Exposure to Radio Frequency Radiation: the radiated output power of this device is below the FCC and Industry Canada radio frequency exposure limits.
This device must not be co-located or operating in conjunction with any other antenna or transmitter.
FCC requires the user to be notified that any changes or modifications made to this device that are not expressly approved by the manufacturer may void the user's authority to use the device.

RSS Canada

IC

This device complies with Industry Canada's license-exempt RSS standards. Operation is subject to the following two conditions:

1. This device may not cause interference; and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

RF Radiation Exposure Statement:

1. To comply with the Canadian RF exposure compliance requirements, this device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.
2. For body-worn operation, this device has been tested and meets RF exposure guidelines when used with an accessory that contains no metal. Use of other accessories may not ensure compliance with RF exposure guidelines.

ICES-003 (Canada)

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus set out in the interference-causing equipment standard entitled: "Digital Apparatus", ICES-003 of the Canadian Department of Communications. This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Industry Canada ICES-003 Compliance Label: CAN ICES-3 (B)/NMB-3(B)

Industry Canada statement

This device complies with RSS-210 of Industry Canada.
Operation is subject to the following two conditions: This device may not cause interference, and this device must accept any interference, including interference that may cause undesired operation of the device.
This class B digital apparatus complies with Canadian ICES-003. This class B digital apparatus complies with Canadian NMB-003.

EUROPE

CE / EU Declaration of conformity

Document dated 13/01/2021