LooK SPOT 2 COVID-19 Test System
Instruction of Use

For LooK SPOT 2
For *in vitro* Use Only
For use with nasal swab specimens

INTENDED USE

LooK SPOT 2 COVID-19 Test System 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. LooK SPOT 2 COVID-19 Test System is intended for use by trained professionals. For laboratory and point of care use. This assay is not intended for home testing.

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 are required to report all positive results to the appropriate public health authority.

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 2 COVID-19 Test System does not differentiate between SARS-CoV and SARS-CoV- 2.

LooK SPOT 2 COVID-19 Test System can detect the SARS-CoV-2 virus and its variants between 5 to 8 minutes with normal mode and within 15 seconds using SPEED mode. LooK SPOT AI cloud 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 2 COVID-19 Test System is intended for use at the Point of Care (POC) settings by medical and trained professional in vitro diagnostic procedures.

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.

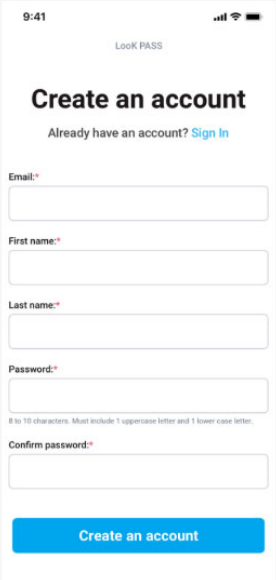
LooK SPOT 2 COVID-19 Test System is an immunochromatographic test that uses monoclonal antibodies combined with latex particles to detect whether there are SARS-CoV-2 antigens in nasal secretions. This test is easy to execute, and the test result can be ready between five (5) to eight (8) minutes using the LooK SPOT 2. The patients can also download a free LooK PASS app for the Android and iOS systems to receive the test result in real-time. LooK PASS will generate a test certificate with detailed information about the test.

TEST PRINCIPLE

LooK SPOT 2 COVID-19 Test System 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 rapid test 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 LooK SPOT AI Cloud for the registration of the test. Each LooK COVID-19 antigen rapid test 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 full privacy.

LooK PASS app



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 one of the slots of LooK SPOT 2. LooK SPOT 2 sends the images of the color signal of the cassette's test window to LooK SPOT AI Cloud for analysis. LooK SPOT AI Cloud analyzes the images using proprietary AI algorithms and sends the test results to the LooK SPOT 2. The test result can be Positive, Negative, or Invalid. The test result is also sent to the patient's LooK PASS app to generate a test certificate.

MATERIALS SUPPLIED FOR LOOK SPOT 2

1. LooK SPOT 2 (1)
2. AC/DC Power Adaptor (1)
3. Cable for Power Adaptor (1)
4. Package Insert (1): Instruction of use

MATERIALS REQUIRED BUT NOT SUPPLIED

1. LooK COVID-19 Antigen Cassettes (10)
2. Droppers (10)
3. Extraction Buffer (10)
4. Nasal swabs (10): Puritan
5. Package Insert (1): Instruction of Use
6. 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 13.
7. AAA Battery x 2
8. 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 LooK COVID-19 Antigen Rapid Test kit. 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 2 must be used to obtain good results for LooK COVID-19 Antigen Rapid Test.
16. Use the LooK COVID-19 Antigen Rapid Test with LooK SPOT 2 on a flat surface so the antigen cassette will not move out of focus from the camera.
17. Dispose of unused contents in accordance with Federal, State, Province, and Local regulatory requirements.
18. Wash hands thoroughly after completing the test.
19. 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.
20. 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 using LooK COVID-19 Antigen Rapid Test with LooK SPOT 2:

- Built-in Procedural Controls
- External Quality Controls

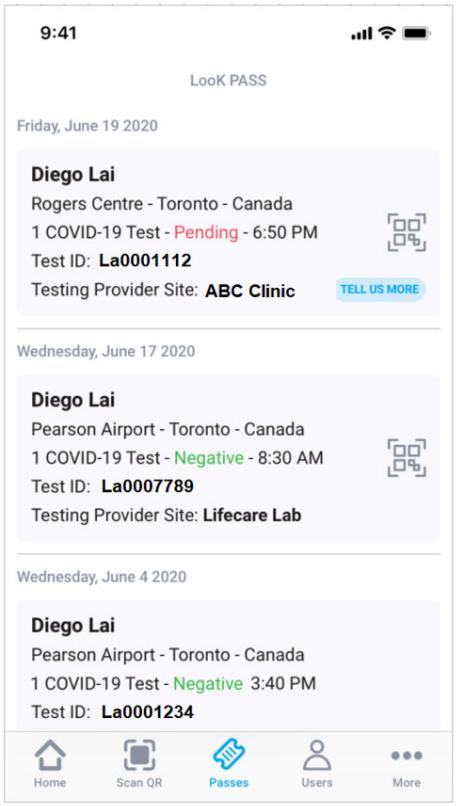
Built-in Procedural Controls

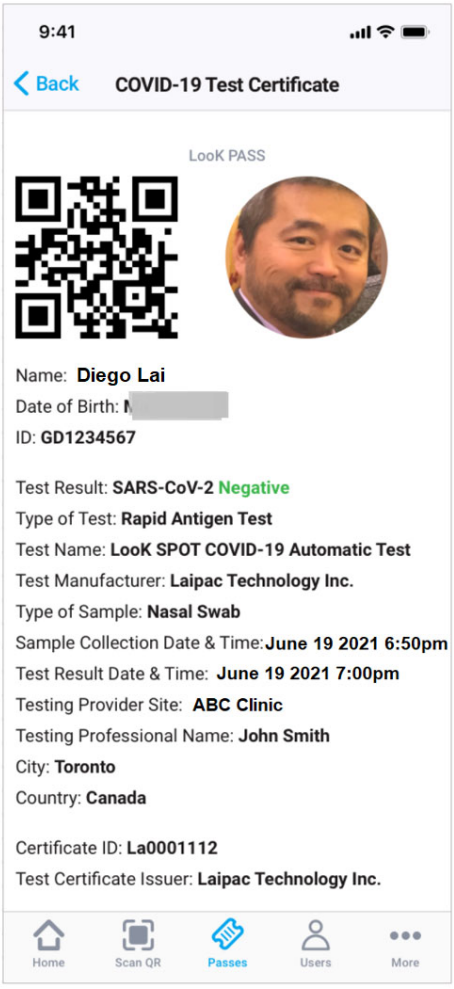
The images of the LooK COVID-19 antigen cassette taken from the LooK SPOT 2 are sent to LooK SPOT AI Cloud for analysis. LooK SPOT AI Cloud has a built-in procedural controls process to detect positive, negative, or invalid test results. Each image is associated with LooK COVID-19 antigen cassette built-in 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 will receive a test certificate once the test is completed.

The test certificate contains the following information on the test:

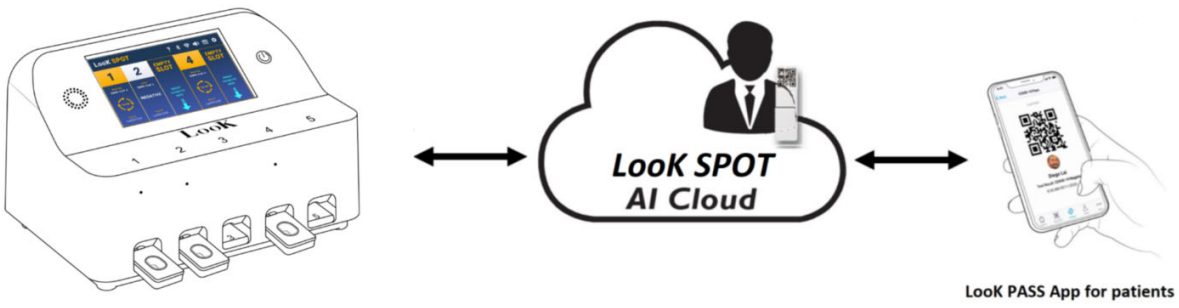
- The name of the patient, date of birth, personal ID and picture
- The test result, type of test, type of sample, sample collection date and time
- The name of the test name, manufacturer of the test
- The testing provider name, operator name, test completion date and time

- City, country, test certificate ID and the issuer





The Built-in Procedural Controls that involve the microchip and QR code for the LooK SPOT 2 COVID-19 Test System have 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, LooK SPOT AI Cloud will alert the event to the operator of the LooK SPOT 2 on the display screen.



The test results are documented automatically in the History section of the LooK SPOT 2 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 additional Built-in Procedural Controls also display error messages on the LooK SPOT 2 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 2 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 2 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 2 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 2 fails to get the antigen test cassette's ID and show an unknown cassette	a. Check WiFi connection to LooK SPOT 2 b. Not Laipac's antigen cassette c. LooK SPOT 2 device issue	a. Verify WiFi connection of LooK SPOT 2 b. Use a original antigen cassette c. Contact Laipac Support
5	LooK SPOT 2 responds with "INVALID" test result	a. Antigen cassette failed to show the Control line b. AI Cloud technical issue c. Sample applied to the cassette over two hours, the contamination on the cassette appears	a. Check to see if the test cassette is showing the control line c. Contact Laipac Tech Support d. Discard the antigen cassette with biosafety and use a new antigen cassette with a new sample
6	LooK SPOT 2 responds with a false negative result	a.Asymptomatic patients with low viral low above Ct 30	a. Verify the test result with RT-PCR test
7	LooK SPOT 2 fails to access LooK SPOT AI cloud for diagnosis	a. No wireless connection b. AI cloud server technical issue	a. Check WiFi network connection c. Contact Laipac Tech support
8	LooK SPOT 2 does not turn on with the pressing of the power button	a. Missing the power source b. Device issue	a. Check the AC/DC adaptor and cable connection b. Contact Laipac Support
9	Not receiving test results from AI cloud	The operator has aborted the test process	Check with the operator of LooK SPOT 2, and the history will show the information of the test

External Quality Controls

This process is using 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 905-604-3759; 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.

TEST PROCEDURES

Nasal Swab Sample Collection

For the best test results, use the nasal swabs provided in the LooK COVID-19 Antigen Rapid Test kit to collect the nasal sample. During the collection process, 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 most congested nostril if drainage is not visible. Push the swab until stopping at the level of the turbinate (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.

Insert the nasal swab one inch into one nostril
Turn 5 times against the nasal wall
Repeat the same process in another nostril

The freshly collected sample should be processed as soon as possible, and it is recommended to complete the test within 1 hour after sampling. All clinical samples must be at room temperature before the test. Check the expiration date on each LooK COVID-19 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.

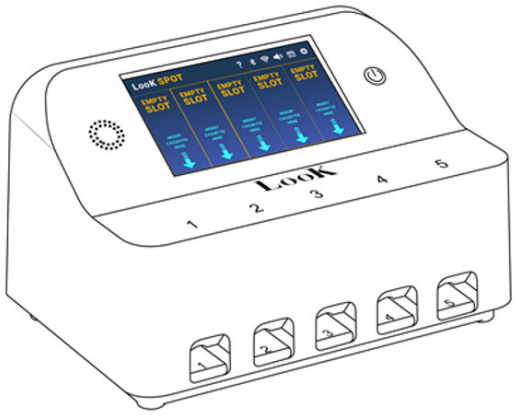
3. Fill the disposable dropper with the patient sample from the Extraction Buffer Tube:

- **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.

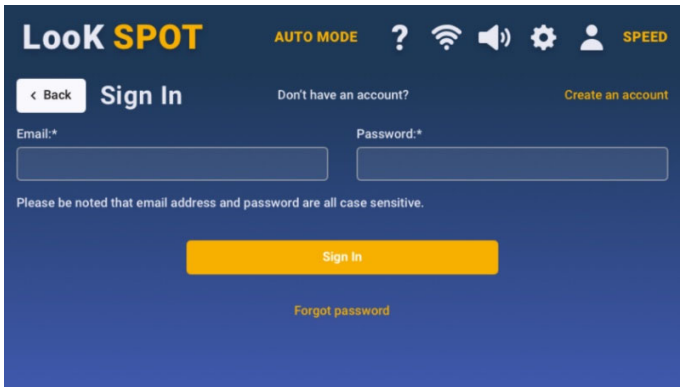
NOTE: Do not pour the sample from the Extraction Buffer Tube directly to the cassette

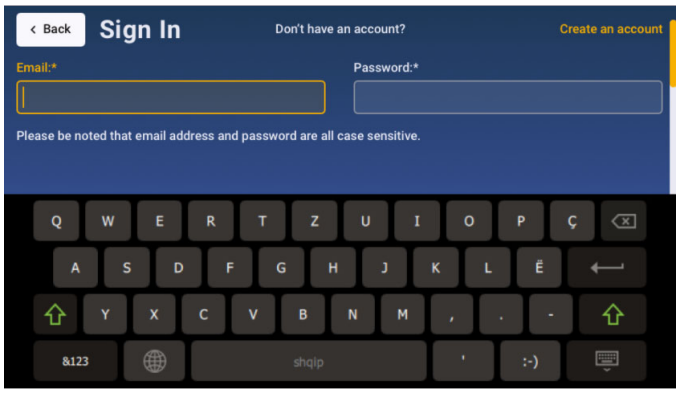
Using LooK SPOT 2



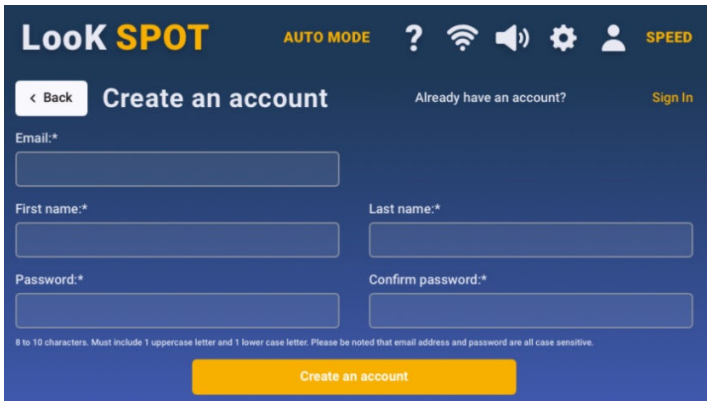
1. The first step is to connect the LooK SPOT 2 with an AC 110/220V electrical socket using the AC/DC adaptor. Wait for the initialization, and the main screen will appear. LooK SPOT 2 uses a touch screen display. Select the WiFi hotspot to connect to the internet. Internet connection with WiFi is fundamental for this test.

2. Click the Profile icon to sign in with the user's email address and password.

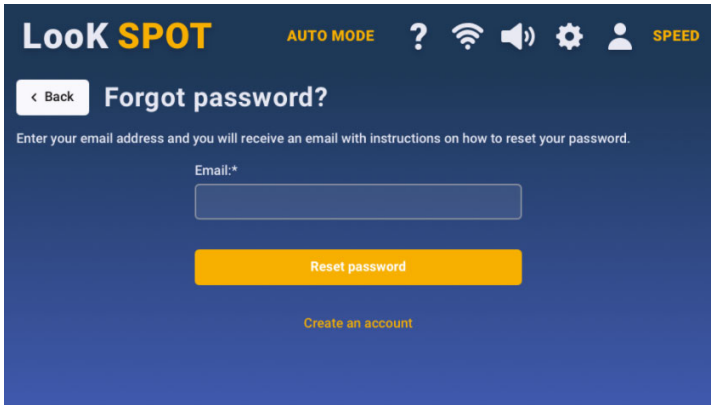




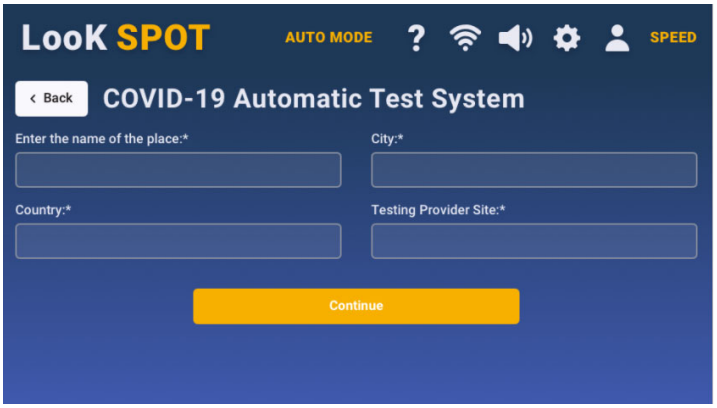
3. For new users, select **Create an account** and enter your basic info. You shall receive an email to confirm the email address and validate your account with LooK SPOT AI cloud.



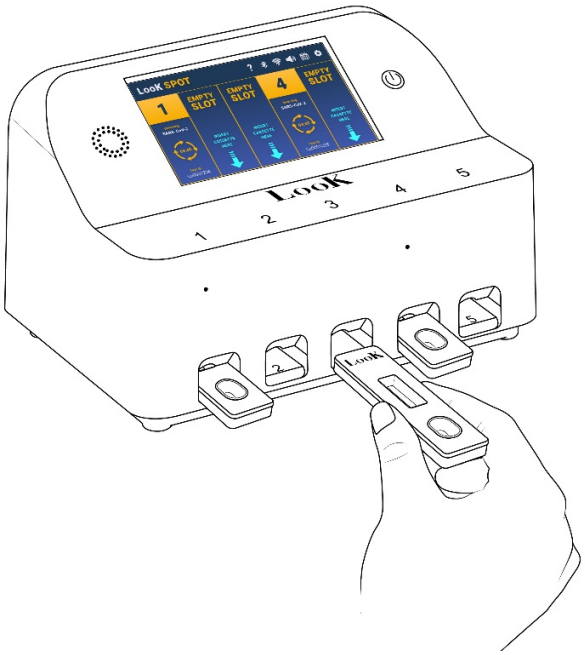
4. If you forget the password, please choose to reset the password, and you shall receive an email with a temporary password for the access.



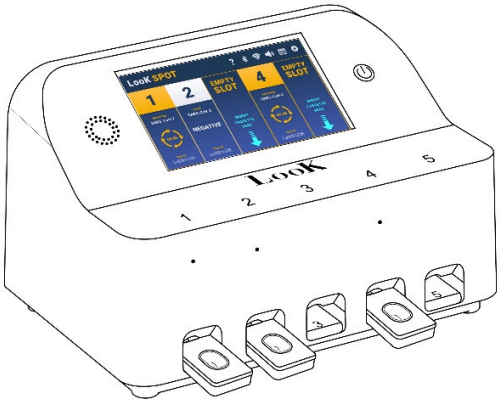
5. After login, enter the info of the place, city, country and the testing provider site. These are mandatory info to start the test. Press Continue, the main test screen shows up with the default setting of Auto Mode and NORMAL mode. AUTO MODE means the test will detect the LooK COVID-19 antigen rapid test cassette with a built-in microchip. NORMAL mode is the regular test procedure that will take between 5 to 8 minutes per test. SPEED mode is a fast test procedure that will take between 10 to 20 seconds. To conduct a SPEED mode test, ensure the LooK COVID-19 antigen rapid test cassette has the nasal sample on for at least 8 minutes before inserting it to LooK SPOT 2. Switching the test mode by touching the screen.

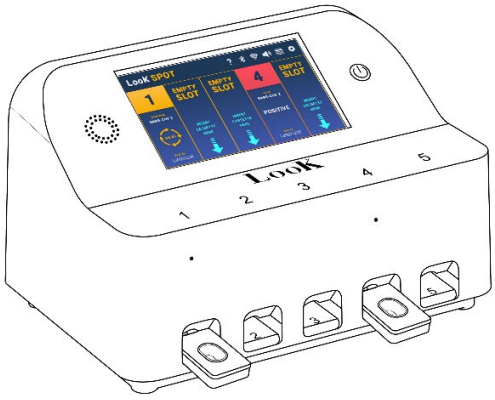


6. Now insert the LooK COVID-19 antigen test cassette into a slot, and the detection will start automatically.



7. Under Normal mode, the test result shall appear between 5-8 minutes showing Negative (white), Positive (red) or Invalid (yellow).





8. Remove the test cassette and dispose of it in biohazard waste. The LooK SPOT 2 will sterilize automatically with an internal UV light for 5-10 seconds.

CLINICAL PERFORMANCE

The LooK SPOT 2 COVID-19 Test System clinical performance was evaluated with patient specimens collected in multiple sites in Ontario Canada. 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 (45-60uL) of the buffer mix onto the LooK COVID-19 Antigen Cassette to start the test with LooK SPOT.

LooK SPOT 2 COVID-19 Test System Performance within eight (8) days of symptom onset:

LooK SPOT 2 COVID-19 Test Systemt	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 (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 2 COVID-19 Test System		
	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%

Description of Study Cohort

Gender [%F, (n/N)]	**49.47% F**, (47/95)
Symptoms present [% Yes, (n/N)]	**47.37% Yes**, (45/95)
Days from symptom onset [median(Q1-Q3); N]	**3** (-2.5); 40
Days < 0-3 (n, %)	22 (53.66%)
Days 4-7 (n, %)	14 (34.15%)
Days > 8 (n, %)	0 (0%)
Positivity [%, (n/N)]	**40%**, (38/95)
PCR Ct [median (Q1-Q3); N]	**0** (-23.02); 190
Ct > 33 (n, %)	6, (3.16%)
Ct > 30 (n, %)	20, (10.53%)
Ct > 25 (n, %)	39, (20.53%)

LooK SPOT 2 COVID-19 Test System Clinical Performance Summary

Clinical Sensitivity (95% CI), N	**97.37%** (86.19% to 99.93%), 95
Sensitivity days ≤7, N	97.06% (84.67% to 99.93%), 91
Sensitivity Ct ≤ 33, N	97.06% (84.67% to 99.93%), 91
Sensitivity Ct ≤ 25, N	100.00% (82.35% to 100.00%), 76
Clinical Specificity (95% CI), N	**98.25%** (90.61% to 99.96%), 95
Invalid Rate (%, n/N)	**0%,** (0/95)
Analytical Sensitivity (Ct, viral gene copies/mL)	**30.93 Ct**, $1.29X10^5$ viral gene copies/mL

LooK SPOT 2 COVID-19 Test System Test Results vs. Age of Patients

Age (yr.)	LooK SPOT 2 COVID-19 Test System			RT-PCR		
	Total	Positive	Prevalence	Total	Positive	Prevalence
≤ 5	4	2	50.00%	4	2	50.00%
6 – 21	3	1	33.30%	3	1	33.30%
22 -59	50	20	40.00%	50	21	42.00%
≥ 60	38	15	39.47%	38	14	36.84%

Specificity vs Sensitivity for all samples

		RT-PCR Results		
		+	-	Total
LooK™ SPOT Results	+	37	1	38
	-	1	56	57
	Total	38	57	95

LooK SPOT 2 COVID-19 Test System Sensitivity: 97.37%
LooK SPOT 2 COVID-19 Test System Specificity: 98.25%

Specificity vs Sensitivity for samples with Ct ≤ 33

		RT-PCR Results		
		+	-	Total
LooK™ SPOT Results	+	33	1	34
	-	1	56	57
	Total	34	57	91

LooK SPOT 2 COVID-19 Test System Sensitivity: 97.06%
LooK SPOT 2 COVID-19 Test System Specificity: 98.25%

LooK SPOT 2 COVID-19 Test System and RT-PCR for samples with Ct ≤ 25

		RT-PCR Results		
		+	-	Total
LooK SPOT Results	+	19	1	20
	-	0	56	56
	Total	19	57	76

LooK SPOT 2 COVID-19 Test System Sensitivity: 100.00%
LooK SPOT 2 COVID-19 Test System Specificity: 98.25%

LIMIT OF DETECTION (ANALYTICAL PERFORMANCE)

The LOD (Limit of Detection) studies determined the lowest detectable concentration of SARS-CoV-2, at which at least 95% of all (true positive) replicates tested positive. The LoD for the LooK SPOT 2 COVID-19 Test System was 1.29×10^5 $TCID_{50}$ /ml based on 20 replicates. This was established by spiking increasingly dilute amounts of heat-inactivated SARS-CoV-2 (ATCC® VR-1986HK™) in the nasal extract of a COVID-19 negative donor. ATCC® VR-1986HK™ is a preparation of Severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2) strain 2019-nCoV/USA-WA1/2020 that has been inactivated by heating to 65°C for 30 minutes and is therefore unable to replicate.

Limit of Detection (LoD) Study Results

Concentration	Number Positive/Total	% Detected
1.29×10^5 $TCID_{50}$ /ml	19/20	95%

HOOK EFFECT

No noticeable high dose hook effect was observed when tested with up to a concentration of $3.01\text{x}10^5$ $TCID_{50}$ /Sample (70 ul), or 4.30 x 10^6 $TCID_{50}$ /ml heat-inactivated SARS-CoV-2 virus using LooK SPOT 2 COVID-19 Test System.

CROSS-REACTIVITY

The LooK SPOT 2 COVID-19 Test System has no cross-reactivity with microorganisms (Virus, Bacteria) and other materials listed in the following table except for Autoimmune disease (Rheumatoid factor) plasma.

Virus, Bacteria and Fungi	Concentration	Cross-Reactivity
Coronavirus (Strain: 229E) Culture Fluid,	6.3 x 10^5 $TCID_{50}$/ml	Negative
Coronavirus (Strain: OC43) Culture Fluid	2.5 x 10^5 $TCID_{50}$/ml	Negative
Coronavirus (Strain: NL63) Culture Fluid,	8.5 x 10^4 $TCID_{50}$/ml	Negative
MERS-CoV (Strain: Florida/USA-2_Saudi Arabia_2014) Culture Fluid	2.1 x 10^5 $TCID_{50}$/ml	Negative
NATtrol Coronavirus-SARS Stock	Nucleic Acid Detection by PCR; Amount not specified	Negative
Adenovirus Type 1 Culture Fluid	3.80 x 10^6 $TCID_{50}$/ml	Negative
Human Metapneumovirus (hMPV) 9 Type A1 Culture Fluid, IA3-2002	8.5 x 10^4 $TCID_{50}$/ml	Negative
Human Metapneumovirus (hMPV) 5 Type B1 Culture Fluid, Peru3-2003	5 x 10^5 U/ml	Negative
Parainfluenza Virus Type 1 Culture Fluid	6.3 x 10^5 $TCID_{50}$/ml	Negative

Parainfluenza Virus Type 2 Culture Fluid	7.6 x 10^5 $TCID_{50}$/ml	Negative
Parainfluenza Virus Type 3 Culture Fluid	1.7 x 10^7 $TCID_{50}$/ml	Negative
Parainfluenza Virus Type 4A Culture Fluid	7.05 x $10^4$$TCID_{50}$/ml	Negative
Influenza A H1N1 (New Cal/20/99) Culture Fluid	2.04 x 10^5 $TCID_{50}$/ml	Negative
Influenza B (Florida/02/06) Culture Fluid	2.34 x 10^4 $TCID_{50}$/ml	Negative
Respiratory Syncytial Virus Type A (RSV-A) Culture Fluid	1.5 x 10^6 $TCID_{50}$/ml	Negative
Respiratory Syncytial Virus Type B (RSV-B) Culture Fluid, CH93-18(18)	7.71 x 10^3 $TCID_{50}$/ml	Negative
Enterovirus Type 68 Culture Fluid	2.51 x 10^5 $TCID_{50}$/ml	Negative
Rhinovirus Type 1A Culture Fluid	7.05 x 10^4 $TCID_{50}$/ml	Negative
***Haemophilus influenzae* type b; Eagan**	2.81 x 10^8 CFU/ml	Negative
Steptococcus pneumoniae	5 x 10^{10} cells/ml	Negative
***Streptococcus pyogenes* Z018, Serotype M58**	2.39 x 10^9 CFU/ml	Negative
Candida albicans	5 x 10^9 cells/ml	Negative
Pooled human Nasal wash, representative of normal microbial flora	1X	Negative
Bordetella pertussis A639	1.68 x 10^9 CFU/ml	Negative
***Mycoplasma pneumoniae* M129**	1.35 x 10^8 CCU/ml	Negative
***Clamydia pneumoniae*, CWL-029**	12.35 Ct	Negative
***Legionella longbeachae* Long Beach 4**	7.5 x 10^7 CFU/ml	Negative
***Staphylococcus epidermidis* MRSE; RP62A**	1.24 x 10^9 CFU/ml	Negative
Staphylococcus aureus	5 x 10^{10} cells/ml	Negative
Staphylococcus epidermidis	5 x 10^{10} cells/ml	Negative
NATSARS(COV2)-NEG.	5.01 x 10^4 Cells/ml	Negative

Endogenous and Exogenous Substances	Concentration	Cross-Reactivity
Whole Blood.	4%	Negative
Mucin, recombinant human	0.50%	Negative
Mucin, Bovine submaxillary gland,	0.50%	Negative
Vicks VapoCOOL Sore throat (Menthol/Benzocaine)	1.5 mg/mL	Negative
Naso GEL (NeilMed)	5% v/v	Negative
CVS Nasal Drops (Phenylephrine)	15% v/v	Negative

Afrin (Oxymetazoline)	15% v/v	Negative
NasalCrom (5.2mg Cromolyn sodium/spray at RiteAid	15% v/v	Negative
Zicam Cold Remedy (Galphimia glauca 4x, Luffa operculata 4x, Sabalilla 4x)	5% v/v	Negative
Homeopathic (Alkalol)ALKALOL Mucus Solvent & Cleaner, 16 FL OZ, made by THE ALKALOL Company, Boston	1:10 dilution	Negative
Chloraseptic SORE THROAT (1.4% Phenol, Methanol)	15% v/v	Negative
Tobramycin	40 µg/mL	Negative
Mupirocin	1 mg/mL	Negative
Mupirocin	10 mg/mL	Negative
Fluticasone Propionate Aller-Flo by Kirkland, 50mcg Fluticasone Propionate (glucocorticoid)	5% v/v	Negative
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	Negative
Autoimmune disease (Human Anti-mouse Antibody (HAMA)	50%	Negative
Autoimmune disease (Rheumatoid factor)	50%	Positive
Serum protein (Whole Blood (human), EDTA anticoagulated, Human serum albumin)	4% as whole blood	Negative

INTERFERENCE

The LooK SPOT 2 COVID-19 Test System showed no interference with the potentially interfering substances at the designated concentrations in negative and contrived positive pooled nasal samples.

Virus, Bacteria and Fungi	Concentration	Interference Result in Positive Contrived Samples	Interference Result in Negative Samples
Coronavirus (Strain: 229E) Culture Fluid,	6.3 x 10^5 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Coronavirus (Strain: OC43) Culture Fluid	2.5 x 10^5 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Coronavirus (Strain: NL63) Culture Fluid,	8.5 x 10^4 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
MERS-CoV (Strain: Florida/USA-2_Saudi Arabia_2014) Culture Fluid	2.1 x 10^5 $TCID_{50}$/ml	Negative (3X)	Negative (3X)

NATtrol Coronavirus-SARS Stock	Nucleic Acid Detection by PCR; Amount not specified	Negative (3X)	Negative (3X)
Adenovirus Type 1 Culture Fluid	3.80 x 10^6 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Human Metapneumovirus (hMPV) 9 Type A1 Culture Fluid, IA3-2002	8.5 x 10^4 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Human Metapneumovirus (hMPV) 5 Type B1 Culture Fluid, Peru3-2003	5 x 10^5 U/ml	Negative (3X)	Negative (3X)
Parainfluenza Virus Type 1 Culture Fluid	6.3 x 10^5 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Parainfluenza Virus Type 2 Culture Fluid	7.6 x 10^5 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Parainfluenza Virus Type 3 Culture Fluid	1.7 x 10^7 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Parainfluenza Virus Type 4A Culture Fluid	7.05 x $10^4$$TCID_{50}$/ml	Negative (3X)	Negative (3X)
Influenza A H1N1 (New Cal/20/99) Culture Fluid	2.04 x 10^5 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Influenza B (Florida/02/06) Culture Fluid	2.34 x 10^4 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Respiratory Syncytial Virus Type A (RSV-A) Culture Fluid	1.5 x 10^6 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Respiratory Syncytial Virus Type B (RSV-B) Culture Fluid, CH93-18(18)	7.71 x 10^3 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Enterovirus Type 68 Culture Fluid	2.51 x 10^5 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
Rhinovirus Type 1A Culture Fluid	7.05 x 10^4 $TCID_{50}$/ml	Negative (3X)	Negative (3X)
***Haemophilus influenzae* type b; Eagan**	2.81 x 10^8 CFU/ml	Negative (3X)	Negative (3X)
Steptococcus pneumoniae	5 x 10^{10} cells/ml	Negative (3X)	Negative (3X)
***Streptococcus pyogenes* Z018, Serotype M58**	2.39 x 10^9 CFU/ml	Negative (3X)	Negative (3X)
Candida albicans	5 x 10^9 cells/ml	Negative (3X)	Negative (3X)
Pooled human Nasal wash, representative of normal microbial flora	1X	Negative (3X)	Negative (3X)
Bordetella pertussis A639	1.68 x 10^9 CFU/ml	Negative (3X)	Negative (3X)
***Mycoplasma pneumoniae* M129**	1.35 x 10^8 CCU/ml	Negative (3X)	Negative (3X)
***Clamydia pneumoniae*, CWL-029**	12.35 Ct	Negative (3X)	Negative (3X)

***Legionella longbeachae* Long Beach 4**	7.5 x 10^7 CFU/ml	Negative (3X)	Negative (3X)
***Staphylococcus epidermidis* MRSE; RP62A**	1.24 x 10^9 CFU/ml	Negative (3X)	Negative (3X)
Staphylococcus aureus	5 x 10^{10} cells/ml	Negative (3X)	Negative (3X)
Staphylococcus epidermidis	5 x 10^{10} cells/ml	Negative (3X)	Negative (3X)
NATSARS(COV2)-NEG.	5.01 x 10^4 Cells/ml	Negative (3X)	Negative (3X)

Endogenous and Exogenous Substances	Concentration	Interference Result in Positive Contrived Samples	Interference Result in Negative Samples
Whole Blood.	4%	Negative (3X)	Negative (3X)
Mucin, recombinant human	0.50%	Negative (3X)	Negative (3X)
Mucin, Bovine submaxillary gland,	0.50%	Negative (3X)	Negative (3X)
Vicks VapoCOOL Sore throat (Menthol/Benzocaine)	1.5 mg/mL	Negative (3X)	Negative (3X)
Naso GEL (NeilMed)	5% v/v	Negative (3X)	Negative (3X)
CVS Nasal Drops (Phenylephrine)	15% v/v	Negative (3X)	Negative (3X)
Afrin (Oxymetazoline)	15% v/v	Negative (3X)	Negative (3X)
NasalCrom (5.2mg Cromolyn sodium/spray at RiteAid	15% v/v	Negative (3X)	Negative (3X)
Zicam Cold Remedy (Galphimia glauca 4x, Luffa operculata 4x, Sabalilla 4x)	5% v/v	Negative (3X)	Negative (3X)
Homeopathic (Alkalol)ALKALOL Mucus Solvent & Cleaner, 16 FL OZ, made by THE ALKALOL Company, Boston	1:10 dilution	Negative (3X)	Negative (3X)
Chloraseptic SORE THROAT (1.4% Phenol, Methanol)	15% v/v	Negative (3X)	Negative (3X)
Tobramycin	40 µg/mL	Negative (3X)	Negative (3X)
Mupirocin	1 mg/mL	Negative (3X)	Negative (3X)
Mupirocin	10 mg/mL	Negative (3X)	Negative (3X)
Fluticasone Propionate Aller-Flo by Kirkland, 50mcg Fluticasone Propionate (glucocorticoid)	10 mg/mL	Negative (3X)	Negative (3X)
Tamiflu (Oseltamivir Phosphate)	5% v/v	Negative (3X)	Negative (3X)
Autoimmune disease (Human Anti-mouse Antibody (HAMA)	5 mg/mL	Negative (3X)	Negative (3X)

Autoimmune disease (Rheumatoid factor)	50%	Negative (3X)	Negative (3X)
Serum protein (Whole Blood (human), EDTA anticoagulated, Human serum albumin)	50%	Negative (3X)	Negative (3X)
Whole Blood.	4% as whole blood	Negative (3X)	Negative (3X)

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. If the internet connection is not available or not stable, the test result can be invalid.
11. LooK SPOT 2 operation temperature: 0C to 45C, shipping and storage temperature: -25C to 60C
12. LooK SPOT 2 is for multiple uses and can conduct hundreds or thousands of tests.
13. Use only the AC/DC adaptor supplied with LooK SPOT 2 by Laipac. Using a different AC/DC adaptor will avoid the warranty of the product.

REFERENCES

1. "How to Protect Yourself & Others". Centers for Disease Control and Prevention (CDC). 8 April 2020. Archived from the original on 26 February 2020. Retrieved 9 April 2020.
2. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. US Department of Health and Human Services, CDC, N.I.H., Washington, DC (2007).
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).
4. C. B. F. Vogels et al., SalivaDirect: Simple and sensitive molecular diagnostic test for SARS-CoV-2 surveillance. medRxiv https://www.medrxiv.org/content/10.1101/2020.08.03.20167791v1 (4 August 2020).
5. Scohy et al., Low performance of rapid antigen detection test as frontline testing for COVID-19 diagnosis. J. Clin. Virol. 129, 104455 (2020).
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).

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)
	Serial Number
	Catalog Number
	Warning/Caution

	Ultraviolet Radiation
	Potential Biohazard

Safety Precautions for LooK SPOT 2

The LooK SPOT 2 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 2
- Do not attempt to look inside LooK SPOT 2 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 2 is cleaned by using the 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 2 should only be used by trained operators.
- Do not use if the LooK SPOT 2 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 2 damage:

- The LooK SPOT 2 is designed for countertop operation.
- The LooK SPOT 2 is not designed to withstand moisture, extreme humidity, or extreme temperatures for a longer period.
- The LooK SPOT 2 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 +1-905-604-3759 for a return or disposal of the LooK SPOT 2.
- Clean the LooK SPOT 2 per the Instruction of Use prior to return or disposal.
- The LooK SPOT 2 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 2 is not disposed of as municipal waste. If you are unsure of 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. 105C – LooK SPOT 2 (1)
2. 105B – LooK COVID-19 Antigen Rapid Test (10 tests)

LooK SPOT 2 Dimension and Weight:

Package: L 10” x W 8.5” x H 7.5”

Gross weight: 5.5 LB

Device: L 7.8” x W 5.0” x H 4.8”

Net weight: 3.5 LB

IVD

Laipac Technology Inc.

25 Valleywood Dr. Unit 11
Markham Ontario L3R 5L9 Canada
Tel: +1-905-604-3759
email: info@laipac.com
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Obelis s.a.

EC REP

CE

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Fax: +(32) 2 732-60-30
mail@obelis.net

Nasal Swabs

CE 2797

Puritan Medical Products Company LLC

31 School Street, Guilford, Maine
04443-0149 USA
Tel: +1-207-876-3311

LEGAL INFORMATION

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

The LooK SPOT 2 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

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.

Cet appareil est conforme aux normes RSS sans licence d'Industrie Canada. Son fonctionnement est soumis aux deux conditions suivantes:

1. Cet appareil ne doit pas provoquer d'interférences; et
2. Cet appareil doit accepter toute interférence, y compris les interférences susceptibles d'entraîner un fonctionnement indésirable de l'appareil.

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.

Déclaration de l'exposition aux radiations RF:

1. Pour se conformer aux exigences de conformité RF canadienne l'exposition, cet appareil et son antenne ne doivent pas être co-localisés ou fonctionnant en conjonction avec une autre antenne ou transmetteur.
2. Pour le fonctionnement du corps, cet appareil a été testé et répond aux directives d'exposition RF lorsqu'il est utilisé avec un accessoire qui ne contient pas de métal. Utilisation d'autres accessoires peut ne pas assurer le respect des directives d'exposition RF.

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.

Cet appareil numérique respecte les limites bruits radioélectriques applicables aux appareils numé- riques de classe B prescrites dans la norme sur le matériel brouilleur: «Appareils Numériques», NMB-003 édictée par le ministre canadien des Communications. Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exemptés de licence. L'exploitation est autorisée aux deux condi- tions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

EUROPE

CE / EU Declaration of conformity

Document dated 29/10/2021