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# 🌐 Look SPOT Antigen Rapid Test System V.1

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Coronavirus Method De...

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**Protocol status:** Working

**We use this protocol and it's working**

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## Disclaimer

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## Abstract

**Look SPOT COVID-19 antigen rapid test** uses a smartphone-based Look SPOT reader, antigen cassette, and LocationNow AI Cloud to qualitatively detect the SARS-CoV-2 Nucleocapsid protein antigen **within 5 minutes**. The reagent is used to detect the SARS-CoV-2 nucleocapsid protein antigen, which is usually present in the upper respiratory tract sample in the acute phase of infection. When a positive result is presented, it means that there are viral antigens in the sample.

The **Look SPOT system** consists of **5 key components**:

1. Look SPOT reader
2. Look SPOT app
3. Look COVID-19 antigen cassette
4. Look PASS app
5. LocationNow AI Cloud

To start the test, the patient has to download and register the Look PASS app from the app stores. 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. Then place the nasopharyngeal swab with the sample of the patient into the Extraction Buffer Tube. Stir the nasopharyngeal swab in the Extraction Buffer Tube and wait for one (1) minute. The virus particles in the sample are disrupted and exposing the internal viral nucleoproteins. Use the liquid dropper to extract the liquid inside the tube and apply three drops in the sample window of the antigen cassette. Insert the antigen cassette into Look SPOT reader attached to a smartphone by using the camera of the smartphone to take pictures from the sample. Look SPOT reader detects the ID of the Look antigen cassette and sends these images of the sample reading to LocationNow AI cloud for analysis. LocationNow AI cloud analyzes the images of the fluorescent signal of the sample by using proprietary AI algorithms and returns results of Positive, Negative, or Invalid to the Look SPOT reader **within 5 minutes**. The same result is also sent to the patient's smartphone's Look PASS app. This test procedure is secured with full privacy. LocationNow AI algorithms have reduced the false-negative cases caused by human visual check errors.

Look COVID-19 antigen rapid test is designed for use at the Point of Entry for the revival of the economy.

## Attachments



Look SPOT v3.23.png

4.6MB

## 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

### MATERIALS SUPPLIED

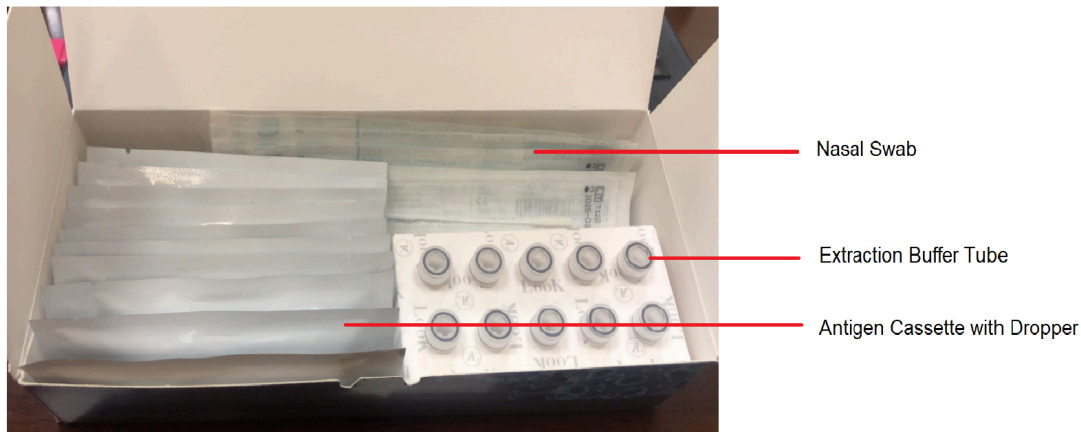
Look COVID-19 Rapid Test Kit - 10

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

### Sensitivity (Detection Limit)

The detection limit test is performed through the negative clinical nasopharyngeal matrix of healthy donors, followed by the addition of a virus at a specified concentration for determination. The initial inclusive analysis used a 10-fold serial dilution, and each concentration was repeated 3 times; for each test, about 50  $\mu$ L of the sample was stained through the swab, and then followed the determination steps of the Look COVID-19 Antigen Rapid Test Reagent get on.

Then select the lowest 2 positive result concentration and the highest 2 negative result concentration; test each concentration 20 times in the same way, and prove that the concentration has a detection rate of at least 95%, which is the detection limit of the product. The detection limit of this product is

- SARS-CoV-2, Virus:  $7.90 \times 10^1$  TICD50/ml
- SARS-CoV-2, Nucleocapsid protein: 18.125 ng/ml

No.	Item	Source	Limit of Detection
1	SARS-CoV-2, Virus	RCEVI, CMUH, Taiwan	$1.57 \times 10^3$ TICD50/ml

### 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 TCID<sub>50</sub>/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	
Adenovirus type 7	Influenza A virus (A/TW/344/19 (H1N1))
Coronavirus (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 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 certifications are pending



Look SPOT Reader uses 2 x AAA alkaline battery

## 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.

## Before start

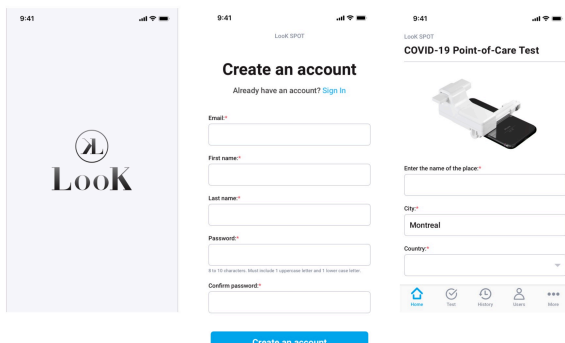
- Use proper personal protective equipment (PPE) for the handling of patient samples.
- Testing should be performed in an area with adequate ventilation
- Look SPOT reader must be used to obtain good results for the test.
- Look SPOT reader uses 2 AAA batteries
- Have a smartphone ready and fully charged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

- 1 At the point of entry, the operator attaches the Look SPOT reader on a smartphone. It can be any Android phone or an iPhone with a video camera of more than 3MP. Align the camera with the lens of Look SPOT. Fix the rail with the wheel until the Look SPOT reader is fixed on the phone tightly.



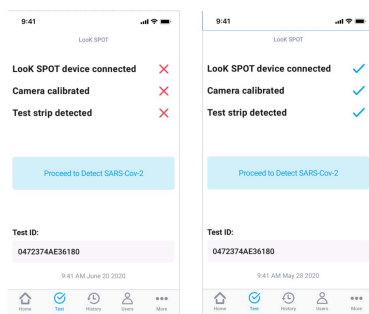
Look SPOT Reader clamps on an iPhone

- 1.1 The operator downloads the Look SPOT app from the app stores and installs it. Register the app and the location (SPOT) of the test. The signup process is simple with contact info.



Look SPOT app screen shots

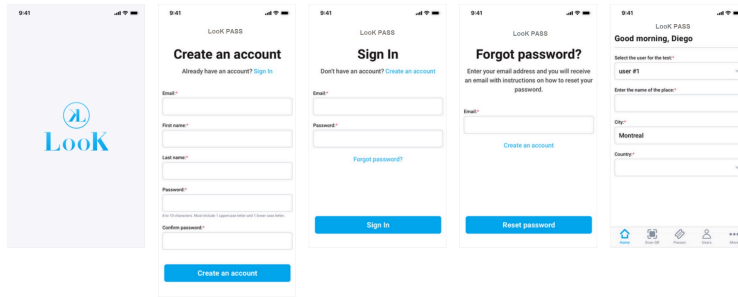
- 2 The operator runs the Look SPOT app and connects with the Look SPOT reader via Bluetooth.  
Initiate the self-calibration process with indications of ok or not ok.



Look SPOT app screen shots for calibration

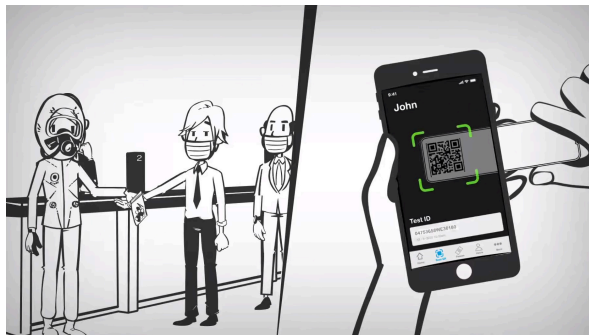
- 3 The patient in the waiting line at the point of entry has downloaded and registered for the Look PASS app. The signup process is simple with contact info.





Look PASS app screen shots for registration

- 4 The patient scans the QR code of the Look COVID-19 antigen cassette given by the operator and associate the antigen cassette's ID with the patient's ID at the point of entry.




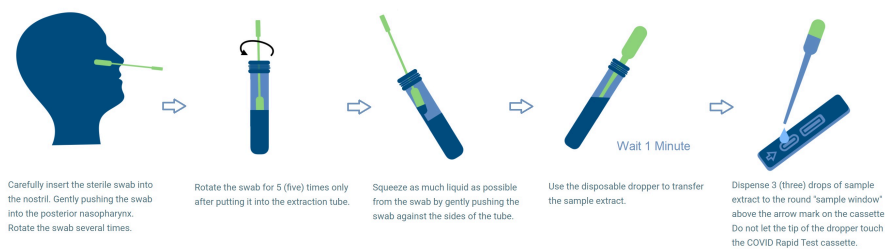
Scanning the QR code of the Look COVID-19 antigen cassette using Look PASS app

- 4.1 The patient's information is uploaded instantaneously to the LocationNow AI cloud with the Look antigen cassette's info. It validates the legitimacy of the antigen cassette and the patient's contact info.



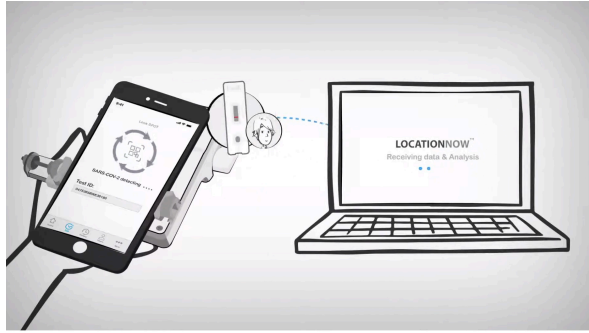
Illustration of uploading information to LocationNow AI Cloud

- 5 The operator takes a nasal sample from the patient using the nasal swab from the kit. Then place the nasal swab into the tube that contains the extraction buffer. Stir few times and wait  00:01:00 . Now the operator uses the dropper to extract the liquid inside the tube and applies three drops in the sample window of the LookK antigen cassette.



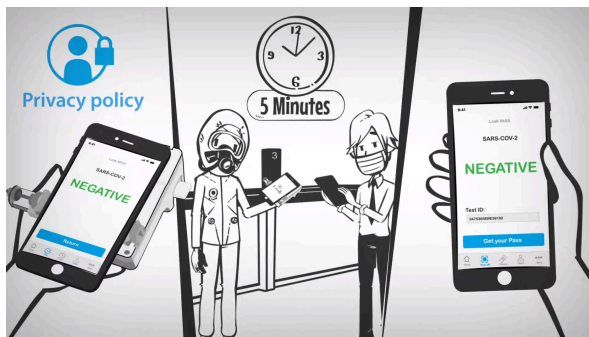
Steps for collecting the nasal sample

- 6 The operator inserts the antigen cassette into the Look SPOT reader. Look SPOT reader detects the ID of the Antigen cassette assigned to the patient. Look SPOT app begins to send images of the sample reading to the LocationNow AI Cloud for analysis.



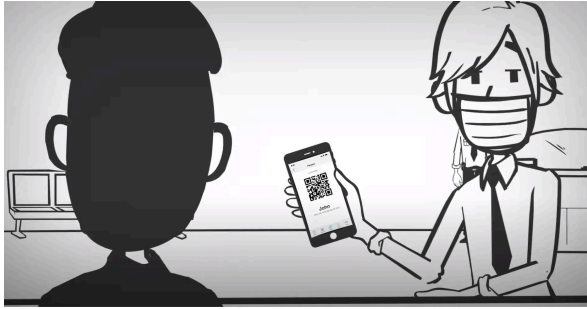
Look SPOT taking pictures of the sample reaction of the antigen cassette and uploading to the LocationNow AI Cloud for analysis

- 7 LocationNow AI cloud analyzes the color intensity of the samples and returns the result to the operator and the patient **within** 🕒 00:05:00



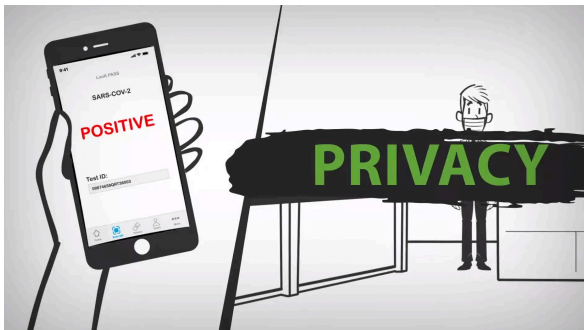
Showing Look SPOT only receives the test result but does not know the patient's info with privacy protection

- 8 A Day Pass QR code is generated for the patient because the test result is negative. The patient is permitted to enter the venue.




Showing the Day Pass with a time stamp and location info

- 8.1 If the test result is positive, it will follow the privacy protocol for the person and alert to CDC and health agencies via API in real-time when it is required.



Full privacy for positive test result

## Discard the antigen cassette safely and auto-sterialization

- 9 The operator removes the antigen cassette and discards it safely. Look SPOT reader sterilizes with the interior UV light for  00:00:10 and ready for the next test.



Innovated safety protocol for self-sterilization to avoid contamination