LooK SPOT reader user's guide

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 smartphone-based reader to detect the COVID-19 antigen using LooK COVID-19 antigen cassette based on lateral flow immunoassay. LooK SPOT and LooK COVID-19 antigen cassettes use the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from patients suspected of COVID-19 within the first seven (7) days of symptom onset. The reagent is used to detect the SARS-CoV-2 nucleocapsid protein antigen, which is usually present in the respiratory tract specimens in the acute phase of infection. The test result is obtained by inserting the LooK COVID-19 antigen cassette into the smartphone-based LooK SPOT reader.

When a positive result is presented, it means that there are viral antigens in the specimen, but the patient's medical history must be combined with other clinical data to assess the infection status; a positive result cannot exclude bacterial infection or co-infection with other viruses, and the detected pathogen may not be the main reason of the disease.

Negative results cannot completely rule out SARS-CoV-2 infection, so this product should not be used as the only basis for treatment or management decisions (including infection control); negative results should be comprehensively evaluated based on the patient's contact history, medical history, signs and clinical symptoms, necessary at times, molecular diagnosis (RT-PCR) is used to confirm the diagnosis and serve as a basis for patient management. The LooK COVID-19 antigen cassette does not differentiate between SARS-CoV and SARS-CoV- 2.

LooK COVID-19 antigen rapid test is for use at the Point of Care (POC) settings by medical or trained professionals who perform rapid lateral flow tests. 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), 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. SARS-CoV-2 virus has spread globally.

LooK COVID-19 antigen rapid test 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 reagent is not only easy to execute, and the test result can be ready within five (5) minutes with the use of LooK SPOT reader and a smartphone with LooK SPOT app.

TEST PRINCIPLE

LooK COVID-19 antigen immunochromatographic detection reagent uses a rapid immunochromatographic detection method to detect whether the nucleocapsid protein antigen 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 SARS-CoV-2 virus have the SARS-CoV-2 antigen in their nasal swabs.

Before performing 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. Each LooK COVID-19 antigen cassette has an embedded microchip for security, quality control, and identification purposes.

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 reader attached to a smartphone. LooK SPOT reader sends the images of the fluorescent signal in the test window of the cassette to LocationNow AI Cloud for analysis. LocationNow AI Cloud analyzes the images using proprietary AI algorithms and sends the test results to LooK SPOT app at 5 minutes. The test result can be Positive, Negative, or Invalid. The same test result is also sent to the patient's LooK PASS app. If the test result is negative, LooK PASS app will generate a QR code as Day Pass with a timestamp of the test for the patient.

LocationNow AI algorithm provides high repeatability of detection vs. visual interpretation traditional methods in which human errors can occur from time to time.

MATERIALS SUPPLIED

1. LooK SPOT Reader
2. Calibration Cassette
3. Double Side Adhesive Strip

MATERIALS REQUIRED BUT NOT SUPPLIED

1. LooK COVID-19 Antigen Cassettes
2. Droppers
3. Extraction Buffer Tubes
4. Nasal swabs
5. AAA x 2 Batteries
6. Personal Protective Equipment

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Do not use the kit 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. Do not reuse the used LooK COVID-19 Antigen Cassette, Extraction Buffer Tube, Nasal Swabs, and dropper.

7. 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.
8. When collecting nasal specimens, please use the nasal swab provided in the kit. Do not use other swabs, which may result in false-negative results.
9. 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.
10. Discard any suspected used or damaged cassette.
11. 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.
12. 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.
13. Do not write on the barcode of the cassette or peel off the barcode sticker.
14. Testing should be performed in an area with adequate ventilation.
15. The Instruction of Use must be followed for a good result.
16. LooK SPOT reader must be used to obtain good results for the test.
17. Use the calibration cassette first when setup the LooK SPOT reader before the test.
18. Do not use other types or brands of antigen cassette for LooK SPOT.
19. Use the LooK SPOT on a flat surface so the antigen cassette will not move out of focus from the camera.
20. Dispose of unused contents in accordance with Federal, State, Province, and Local regulatory requirements.
21. Wash hands thoroughly after completing the test.
22. If you have no previous experience collecting samples and handling the test reagents, please seek training or refer to relevant operating instructions.
23. 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 reader and LooK COVID-19 antigen cassette:

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

Look SPOT Reader Calibration Check Procedure

This procedure should be performed every time when the LooK SPOT reader is attached to a smartphone for the COVID-19 antigen test. This Calibration Check is important to check the alignment of LooK SPOT reader's lens with the smartphone's camera, focal point, and angle. LooK SPOT reader uses a specific calibration cassette that comes with the LooK SPOT reader.

First, download the LooK SPOT app from the app stores to your smartphone and register online. Clamp the Look SPOT reader to your smartphone by aligning the lens of LooK SPOT reader with the camera of the smartphone. Adjust the wheel and slide the guide rail to find the optimal position for the alignment.

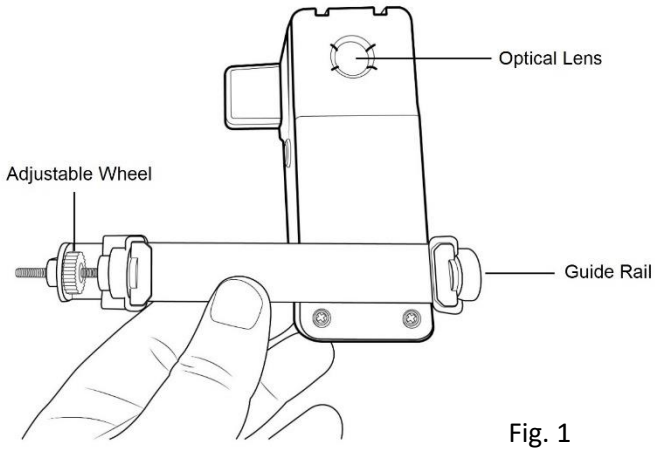

Fig. 1

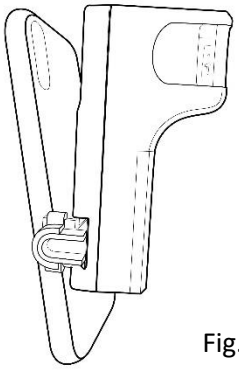

Fig. 2

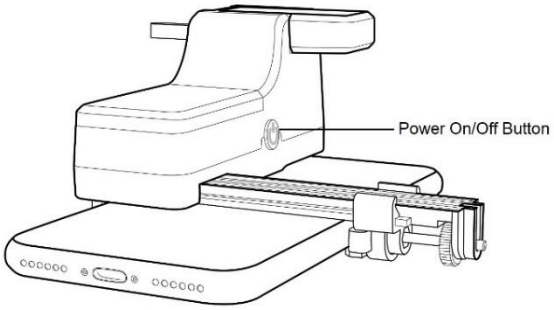

Fig. 3

If the size of your 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 reader with the smartphone. This method can also be applied to smartphones using protective cases.

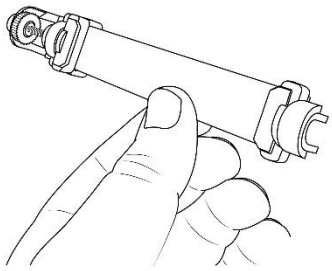

Fig. 4

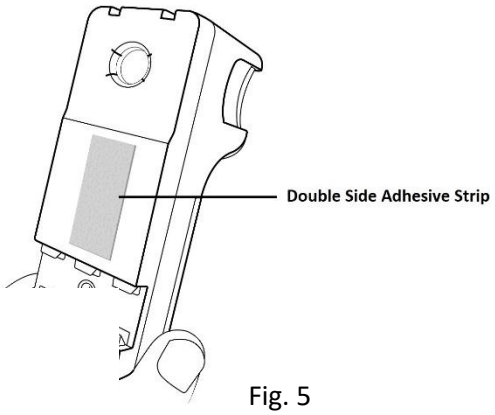

Fig. 5

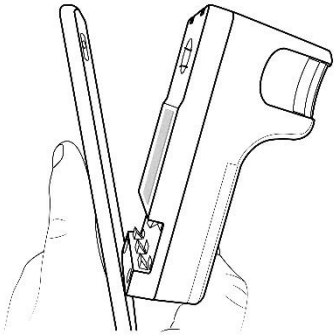

Fig. 6

1. With the LooK SPOT reader attached to the smartphone, 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 reader.

Fig. 7

2. Open LooK SPOT app. Press the X mark of "LooK SPOT reader connected" to see the available LooK SPOT within the Bluetooth signal range. Select the correct LooK SPOT based on the MAC address provided in the package to connect with the smartphone.

Fig. 8

Fig. 9

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

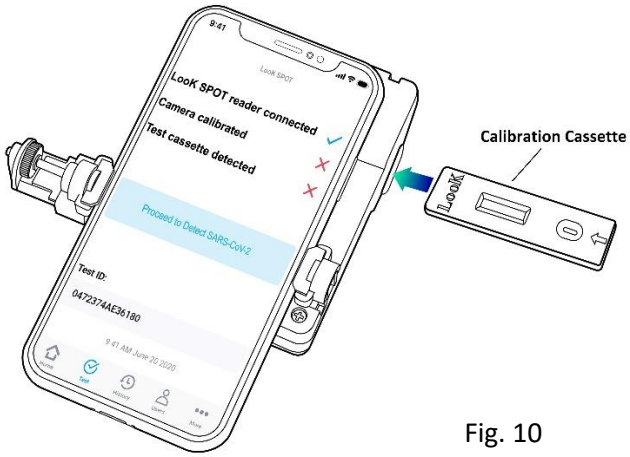

Fig. 10

4. The screen will show the view of the calibration cassette and a rectangle box. Use your index finger to move the rectangle box to cover the test window of the calibration cassette. Press Confirm to finish this calibration process.

Fig. 11

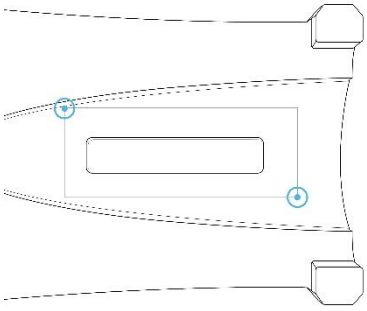

Fig. 12

5. The screen now shows "Camera Calibrated" checked. Remove the calibration cassette and be ready for the COVID-19 antigen test.

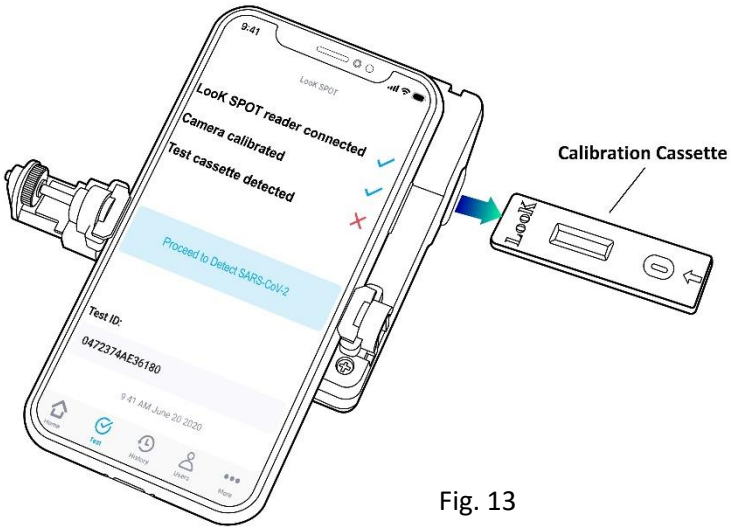

Fig. 13

The above process is important to obtain the correct test result for Look COVID-19 antigen test. Without completing the Look SPOT Reader Calibration Check Procedure, the test result can be invalid.

NOTE: If the Look SPOT Reader 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 with LooK SPOT reader are sent to LocationNow AI cloud for analysis and diagnosis. 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 initiating the COVID-19 antigen test. This unique flow control of the test results ensures the correct test result to the patient in the shortest time as possible. The patient with the negative test result will receive a QR Pass automatically.

Fig. 14a

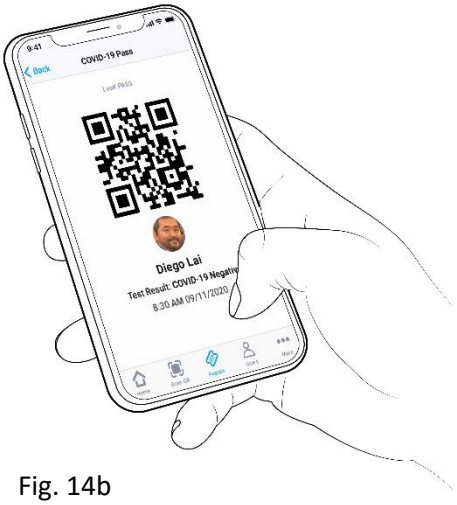

Fig. 14b

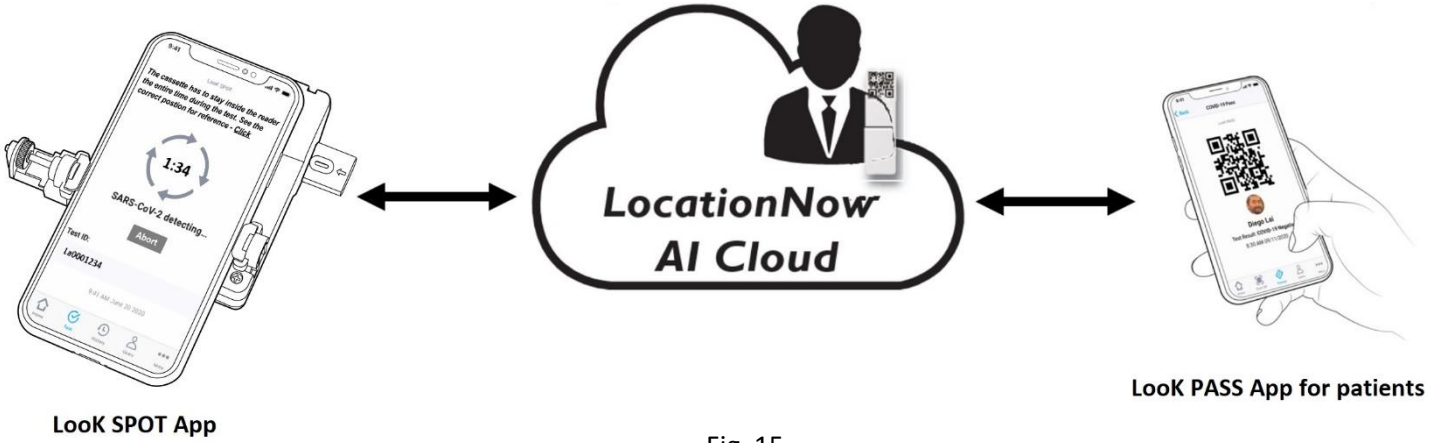

Fig. 15

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 with LooK SPOT.

For example:
Using an unknown third party or used antigen cassette.
LocationNow AI Cloud will alert immediately as an unknown antigen cassette.

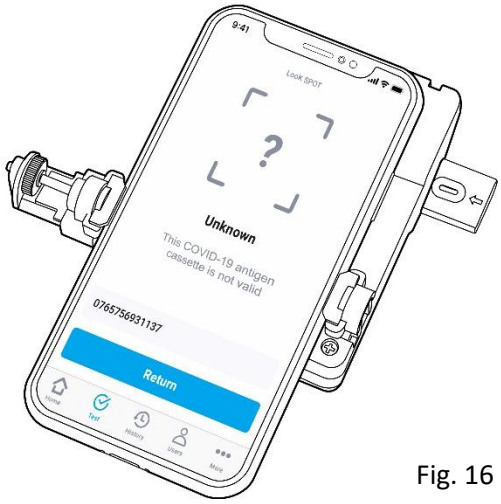

Fig. 16

The test results are documented automatically in the History section of LooK SPOT app with the Test ID, location, city, country, and timestamp of the tests. If the test did not flow correctly, the test result would show Invalid. The operator can also request the cause for the invalid test result to be delivered by email.
Shall the invalid test result occur, please initiate a new test using an original Look COVID-19 antigen cassette and a new nasal swab.

Fig. 17

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 seven (7) 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 in the test kit to collect the nasal sample. During the collection process, in order to obtain as much secretion as possible, the nasal swab must be inserted into the nostril where there are more secretion and visible drainage, or the nostril that is most congested if drainage is not visible. Push the swab until stopping at the level of the turbinates (one inch into the nostril). Rotate the swab five (5) times or more against the nasal wall then slowly remove 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 reader (The Steps 1-3 must be done before Nasal Swab Test Procedure)

1. Download 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.

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.

Fig. 18

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

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

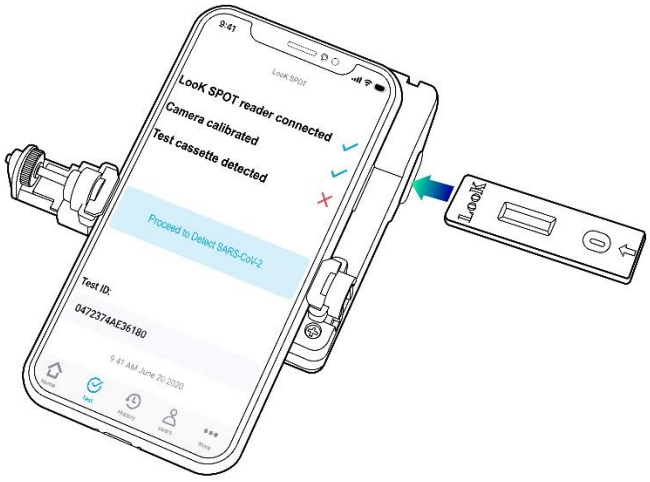

Fig. 19

Fig. 20

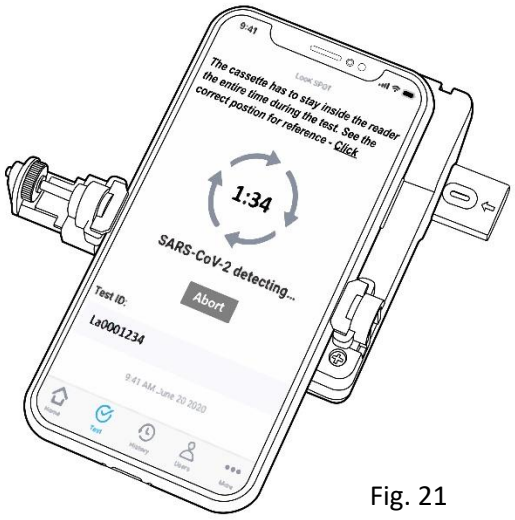

Fig. 21

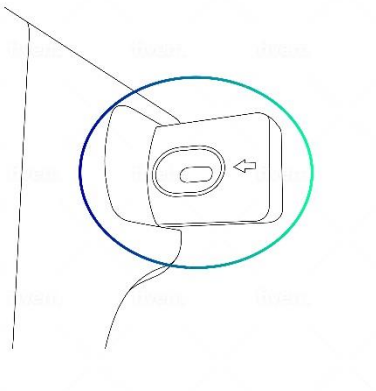

Fig. 22

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

Fig. 23

Fig. 24

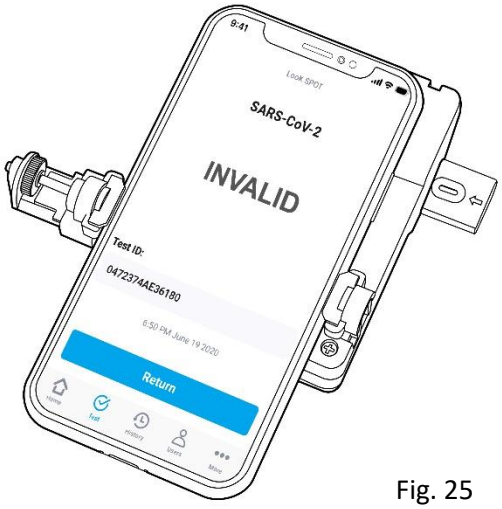

Fig. 25

5. Remove the test cassette and dispose of it in biohazard waste. LooK SPOT reader will sterilize automatically with an internal UV light of 260nm wavelength for 10 seconds and ready for the next test.

Fig. 26

LIMITATIONS

1. This product qualitatively detects whether the nasopharyngeal swab sample has the SARS-CoV-2 virus antigen.
2. Failure to use this product in accordance with 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 7th 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 LooK SPOT reader. If the internet connection is not available or not stable, the test result can be invalid.

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

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.

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

We declare that this equipment complies with:
- R&TTE Directive 1999/5/EC;
- Low Voltage Directives 2006/95/EC and 2014/35/EU;

- EMC Directive 2004/108/EC;
- RoHS II Directive 2011/65/EU.

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