COVID-19 Antigen Saliva Test Kit

COV-S35H1

Scan for instruction video

1. INTENDED USE

The COVID-19 Antigen Saliva Test Kit is an in vitro immunoassay. The assay is for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens form saliva samples. The test is an in vitro diagnostic device intended for use as an aid in the diagnosis of SARS-CoV-2 viral infection. The test is designed for self-testing use. Children aged between 2 and 18 years old, must be supervised or aided by an adult when carrying out the test. Negative results do not preclude SARS-CoV-2 viral infection. Testing results should not be the sole basis for treatment or other management decisions.

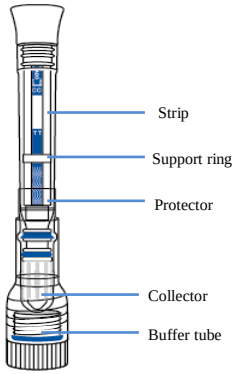
2. PRINCIPLE

The COVID-19 Antigen Saliva Test Kit detects SARS-CoV-2 viral antigens by means of visual interpretation (evaluation by eye) of color development. When the collector is placed into the extraction buffer, the mixed sample flows in the test device. The test reaction will take 15 minutes. If the test detects the relevant Coronavirus protein, a line will appear in the test line region (T), indicating a positive test result. Absence of the test line (T) suggests a negative test result. A line will always appear in the control region (C) if the test has been perfomed correctly.

3. MATERIALS

Materials provided

- Package insert
- Waste bag
- Individual packaged test kit



Materials required but not provided

- Clock, timer, or stopwatch

4. TEST PROCEDURE

Prepare for the test

• The test should be used at room temperature.

• Make sure that the entire package is intact. Do not use the test if the foil package is visibly damaged.

• Do not open the foil package until you are ready to perform the test. Use the test within 1 hour after opening.

• Do not eat, drink, smoke, brush your teeth or chew gum for 30 minutes before collecting saliva.

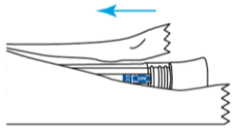
• Do not bite the collector when sampling.

• Children under age of 12 should be supervised and/or helped by an adult when performing the test for the duration of collecting the sample (Step 7).

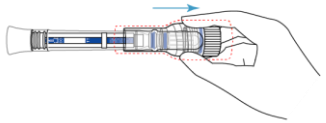
1. Clean the operation surface before starting the test.

2. Wash your hands thoroughly with soap and warm water or hand sanitizer for 20 seconds. If you do more than one test, clean the surface and wash your hands again between each test.

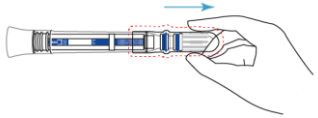
3. Remove the test device from its package. For the best results, the assay should be performed within one hour.



4. Take the test device out of the tube with extraction buffer.

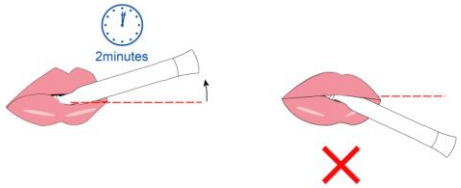


5. Remove the protector.



6. Take a deep breath, and cough hard (about 3-5 times).

7. Place the saliva collector into the mouth. Keep the top of the device facing upward at an angle to the horizontal line and hold for 2 minutes.



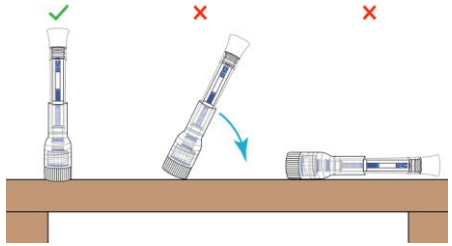
Note:

1. Discard the test and make a new test if you don't keep the saliva collector lifted up, which will lead to incorrect testing results,

2. Do not bite the device with teeth, as this will lead to incorrect testing results or injury. If you do so, please discard the test kit, and perform the test with another one.

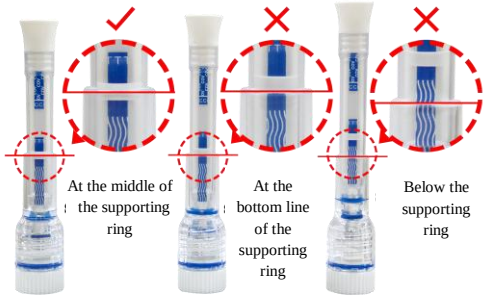
8. Take out the saliva collector from the mouth.

9. Place the test device **vertically** into the extraction tube until the edge of the extraction tube reaches the middle of the supporting ring. Keep the test kit vertically on the table, do not tilt or tip it over, otherwise **the test should be discarded.**



Note:

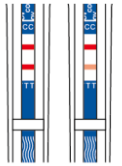
When placing the test device vertically into the extraction tube, the edge of the extraction tube (the red line) must reach the middle of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect or invalid result. **(Discard the test and perform a new test if the edge does not reach the middle of the supporting ring.)**



10. Read the results at 15 minutes. After more than 30 minutes, the result is no longer valid.

11. When your test is finished, put the tested kit into the waste bag provided. Dispose of the closed waste bag with household waste.

5. RESULT INTERPRETATION



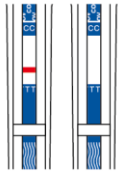
POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C), and another band appears in the test region (T).

The intensity of the color in the test area (T) varies. However, any shade in the test area should be considered positive. Note that this is a qualitative test only and the virus concentration in the sample cannot be determined.

If you get a positive result, it indicates a possible SARS-CoV-2 infection. A positive result also means that you are at risk of infecting others, please contact a doctor, a family doctor or the local health department immediately for a confirmatory PCR test.

NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

Negative results do not completely rule out SARS-CoV-2 infection. Please continue to comply with all applicable rules regarding contact with others and protective measures. An infection can also be present if the test is negative. In case of suspicion, repeat the test after 1-2 days, as the coronavirus cannot be accurately detected in all phases of an infection.



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the test results remain invalid, contact a doctor or a COVID-19 test center.

NOTE:

Insufficient sample size, incorrect application procedure, or expired tests are the most likely reasons for the missing control strip.

6. PRECAUTIONS

- **DO NOT eat, drink, smoke, brush teeth, or chew gum for 30 minutes before collecting saliva.**
- **To avoid choking, caution is advised when inserting the collector in the mouth. Children aged between 2 and 18 years old, must be supervised or aided by an adult when carrying out the test.**
- **DO not swallow.**
- **DO not bite the test kit when sampling.**
- **Keep out of the reach of children.**
- **Solely for in vitro use.**
- **Only use the test kit one (1) time.**
- Do not use this test on anyone under 2 years of age.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Avoid skin or eyes in contact with buffer.
- Use a separate test for each person.
- This test is for human use only.
- Do not use any expired test or component.
- The test kit is packaged in foil sachets to eliminate moisture during storage. Inspect each foil sachet before opening. Do not use a test kit if there are any holes in the foil or the sachet is not completely sealed. A false result may be produced if the test kit or any component has been incorrectly stored.
- Do not use the kit when any component including test device, protector, extraction buffer and package insert is missing.
- Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use. Place the collector into the buffer immediately after collecting the sample.
- Inaccurate or incorrect sampling can produce wrong test results.
- Do not bite the device, buffer, or any other kit component.

7. STORAGE AND STABILITY

- Store the COVID-19 Antigen Saliva Test Kit at 2 - 30℃ when not in use.
- **DO NOT FREEZE**.
- The content of the kit is stable until the expiration date indicated on the outer package.

8. QUALITY CONTROL

Internal Procedural Controls

The COVID-19 Antigen Saliva Test Kit has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the colored band located at the "C" region is present before reading the result.

9. LIMITATIONS OF THE TEST

- The COVID-19 Antigen Saliva Test Kit is solely for in vitro diagnostic use and may only be used for the qualitative detection of SARS-CoV-2 antigens. The color intensity in a positive band does not represent virus concentration.
- Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION can have a negative impact on test performances and/or render the test result invalid.
- This test cannot be used to evaluate the immune response (antibodies); the immune response requires different test methods.
- Positive results indicate the presence of viral antigens, but the clinical results, the medical history and other diagnostic information are necessary for determining the infection status.
- Positive results do not eliminate the possibility of a bacterial infection or co-infection with other viruses.
- Negative results should be seen as provisional results and, if necessary, a PCR confirmation test should be carried out.
- Even if the result is negative, you still need to continue observing all protective and hygienic measures.
- Carefully follow the instructions given by the government.

10. PERFORMANCE

Analytical Sensitivity (Limit of Detection):

The limit of detection was determined with quantified SARS-CoV-2 virus and has been evaluated at $1.25x10^{1.4}$ $TCID_{50}$/mL.

Clinical Evaluation:

A clinical evaluation was carried out in America to compare the results obtained with a COVID-19 Antigen Saliva Test Kit with the results of an RT-PCR. The results are shown in the table below.

Table: COVID-19 Antigen Saliva Test Kit vs. RT-PCR

		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen Saliva Test Kit	Positive	184	2	186
	Negative	29	314	343
Total		213	316	529

Relative Sensitivity: 86.4 % (81.1% ~ 90.4%)*

Relative Specificity: 99.4 % (97.7% ~ 99.8%)*

Overall Agreement: 94.1 % (91.8% ~ 95.8%)*

*95% Confidence Interval

Cross Reactivity:

One study investigated whether the test would give a false-positive result in the presence of other pathogens (cross-reactivity). The following pathogens were examined: Adenoviruses, Epstein-Barr virus, Enteroviruses, Echovirus 6, HCoV-229E, HCoV-OC43, HCoV-NL63, MERS-coronavirus, SARS-coronavirus, Human metapneumovirus, Influenza A (H1N1)pdm09, Influenza A (H3N2), Influenza B Victoria lineage, Influenza B Yamagata lineage, Norovirus, Parainfluenza viruses, Respiratory syncytial viruses, Rhinovirus A30, *Bordetella parapertussis*, *Bordetella pertussis*, *Candida albicans*, *Chlamydia pneumoniae*, *Group C Streptococcus*, *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, *Mycobacterium*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*.

All results were negative. This means a positive result represents a high probability of SARS-CoV-2, which is not due to another pathogen.

Interfering Substances:

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect the test performance of the COVID-19 Antigen Saliva Test Kit.

3 OTC nasal sprays, 3 OTC mouthwashes, 3 OTC throat drops, 4-acetamidophenol, Adamantanamine, Acetylsalicylic acid, Albuterol, Chlorpheniramine, Dexamethasone, Dextromethorphan, Diphenhydramine, Doxylamine succinate, Flunisolide, Guaiacol glyceryl ether, Mucin, Mupirocin, Oxymetazoline, Phenylephrine, Phenylpropanolamine, Oseltamivir phosphate, Tobramycin, Triamcinolone, and Zanamivir.

11. LITERATURE REFERENCES

1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).
2. Ithete, N. L. et al. Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).

12. GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by date
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

IVD

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