COV-S23

COVID-19 Antigen
Rapid Test Device
(Nasopharyngeal/oropharyngeal swab)

USE

The COVID-19 rapid antigen test device is an in vitro immunoassay. The test is for direct and qualitative detection of viral nucleoprotein antigens SARS-CoV-2 from nasopharyngeal secretions and oropharyngeal secretions. This test is for professional use only.

PRINCIPLE

The COVID-19 rapid antigen tester detects SARS-CoV-2 viral antigens through visual interpretation of color development. Anti-SARS-CoV-2 antibodies are innobilized on test areas of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to the colored particles are immobilized on a conjugated support. A sample is added to the extraction buffer that is optimized to release SARS-Cov-2 antigen from the specifics. During testing, the extracted antigens bind to anti-SARS-CoV-2 antibodies conjugated to the colored particles. As the sample migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by anti-SARS-CoV-2 antibodies in the test area.

The presence of a colored strip in the test area indicates a positive result for SARS-CoV-2 viral antigens, and its absence indicates a negative result. The colored strip in the control area serves as a procedure (control) indicating that the correct sample volume has been added and the membrane leakage is working.

MATERIALS

- Individually packaged test equipment
- Extraction tube
- Individually packaged tampons
- Leaflet
- Negative control (if required)
- Extraction buffer
- nozzle with filter
- test tube holder
- positive control (if required)

tools that are not included in the package

- clocks, watches, or stopwatches
- portable pipette

PRECAUTION

- For in vitro diagnostic use only.
- Read the leaflet before use. You should read the instructions and follow them carefully.
- Do not use expired kit or its parts.
- It currently contains material of Animal Origin and should be treated as a potential biological hazard. Do not use it if the package is damaged or opened.
- The test equipment is packed in foil bags that discharge moisture during storage. Before opening, check each foil bag. Do not use equipment that has holes in the foil or where the bag has not been completely closed. Improper storage of test reagents or components may result in wrong results.
- Do not use extraction buffer if it is discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.
- All patient specimens should be treated and disposed of as if they were biohazardous. All samples need to be thoroughly mixed prior to testing to ensure a representative sample prior to testing.

- If you fail to bring samples and reagents to room temperature prior to testing, it may reduce the test sensitivity. Inaccurate or improper collection, storage and transport of samples can lead to false negative test results.
- Avoid skin contact with the buffer.
- If SARS infection is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples should be taken with appropriate precautions to control the infection and sent to the state or local health department for testing.
- Isolation of viruses in cell culture and initial characterization of viral substances obtained in SARS-CoV-2 fungal cultures are NOT RECOMMENDED, with the exception of the BSI.3 laboratory using BSL3 working procedures.

STORAGE AND STABILITY

- If you do not use the COVID-19 Antigen Rapid Test, store it at 2 - 30 C.
- PROTECT FROM FROSTS.
- The contents of the kit are stable until the expiration date marked on their outer packaging and containers.

SAMPLE COLLECTION AND STORAGE

-Nasopharyngeal swab:

1) Remove the swab from the package
2) Insert the swab into the nostril parallel to the palate and gently push the stick into the back of the nasopharynx. Rotate against the nasal wall (so that the swab contains both cells and mucus).
3) Process the swab as soon as possible after sampling.

-Oropharyngeal swab:

1) Remove the swab from the package.
2) Insert the swab all the way into your mouth, centering on the red part of the throat wall and the maxillary tonsils, and wipe the tonsils and the throat wall on both sides. Do not touch the tongue and remove the swab.
3) Process the swab as soon as possible after sampling.

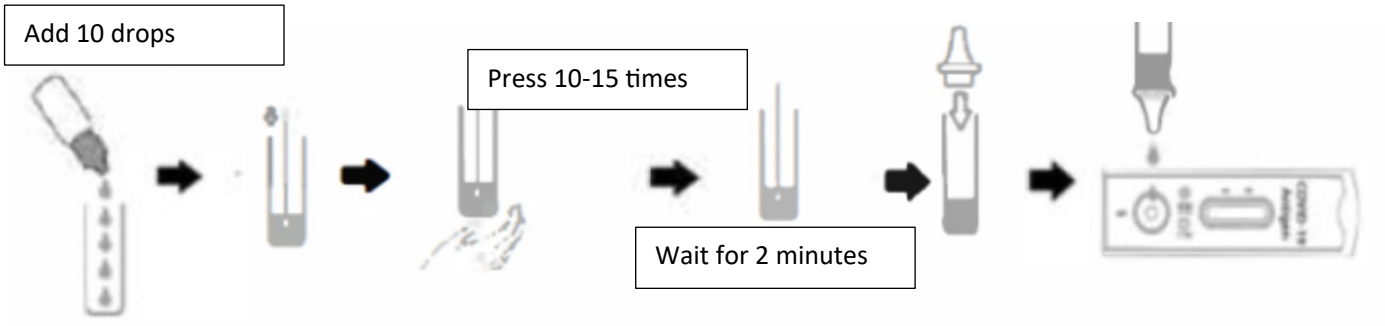
Note:

1. Use only synthetic fiber sticks with plastic stems. Do not use calcium alginate sticks or wooden stem swabs as they may contain substances that inactivate some viruses and inhibit further testing.
2. Swab samples should be tested as soon as possible after collection. Use freshly collected samples for the best test results.
3. If the test is not performed immediately, swab samples can be stored at 2-8 °C for 24 hours after collection.
4. Do not use samples that are obviously contaminated with blood, because it could affect sample flow when interpreting the results.

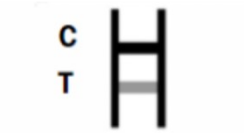
TESTING PROCEDURE

Before use, bring tests, reagents, and samples and/or control plates to room temperature (15-30 C) .

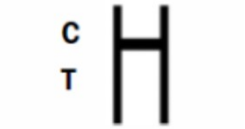
1. For each sample, before testing, open the foil pouch, remove the test device, and place it on a clean, flat surface. For the best results, label the tube with patient identification, the test should be performed within one hour.
2. Gently mix the extraction buffer. Add 10 drops to the extraction tube.
3. Insert the stick into the extraction tube. Mix well and press the swab 10-15 times by pressing the corners of the tube against the stick.
   Let is settle / wait for 2 minutes.
4. After removal, turn the stick's head against the inside of the tube. Try to release as much fluid as possible. Dispose of the used stick in accordance with the biological or hazardous waste disposal protocol.
5. Insert the nozzle into the sample extraction tube. Turn over the tube and gently squeeze the tube to add 2 drops of solution to the hollow of the test holder.
6. Read the results in 15 minutes.



INTERPRETATION OF RESULTS



POSITIVE: two colored stripes appear on the membrane. One strip appears in the control area **(C)** and the other strip appears in the test area **(T).**



NEGATIVE: Only one colored strip appears in the control area **(C).** No apparent color strip appears in the test area **(T).**

INVALID: The control strip does not appear. The results of any test that did not produce a control zone within the specified time must be discarded. Please check the procedure and repeat with a new test. If the problem is this there, stop using the kit immediately and contact your local distributor/seller.

Note:

1. The color intensity in the test area **(T)** may vary depending on the concentration of analytes present in the sample. Therefore, any color shade in the test area should be considered positive. Please note that this is only a qualitative test that cannot determine the concentration of analytes in the sample.
2. The most likely cause of a control zone failure is insufficient sample volume, incorrect work procedure, or expired tests.

QUALITY CONTROL

Internal procedural controls
The COVID-19 antigen rapid testing device has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should verify that the colored strip in area C is present before reading the result.
External positive and negative controls
Good laboratory practice suggests testing positive and negative external controls to ensure that test reagents are working and that the test is performed correctly.

TEST LIMITATIONS

1. The COVID-19 rapid antigen testing device is intended for professional in vitro diagnostic use and should only be used for the quantitative detection of SARS-CoV-2 antigen. The color intensity in the positive strip should not be evaluated as quantitative or semi-quantitative.
2. Viable and non-viable SARS-CoV-2 viruses are detectable by this device.
3. As with all diagnostic tests, the final clinical diagnosis should not be based on the result of a single test, but should be made by a doctor only after all clinical and laboratory findings have been evaluated.
4. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may affect the test result and/or invalidate the test result.
5. The results obtained by this test, especially in the case of weak test lines which are difficult to interpret, should be used in conjunction with other clinical information available to the doctor.
6. Negative results do not rule out SARS-CoV-2 infection and should be confirmed by molecular testing.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity (limit of detection):
The limit of detection was determined using a qualified SARS-CoV-2 virus and was evaluated at $2x10^{2.4}TCID_{50}/mL$.
The limit of detection was also determined with recombinant SARS-CoV-2 nucleoprotein and was evaluated for 0.4 ng/mL.

Clinical evaluation:
The clinical evaluation was performed to compare the results obtained with the COVID-19 antigen rapid assay and RT-PCR. The results were summarized below:

COVID-19 RAPID Test vs. RT-PCR

		RT-PCR		Celkem
		Pozitivní	Negativní	
COVID-19 Antigen Rapid Test	Pozitivní	50	9	59
	Negativní	3	1027	1030
Celkem		53	1036	1089

Total
Positive
Negative
Positive
Negative
Total

Relative sensitivity: 94.3% (84.6% - 98.1%) *
Relative specificity: 99.1% (98.4% - 99.5%) *
Overall accuracy: 98.9% (98.1% - 99.4%) *
* 95% confidence interval

Cross-reactivity:

Cross-reactivity was studied with the following organisms. Samples positive for the following organisms were found to be negative when tested using the COVID-19 rapid testing device (nasopharyngeal/oropharyngeal swab)

HCoV-HKU1	Flu A (H5N1)	Coxsackie virusA16
HCoV-OC43	Flu A (H7N9)	Norovirus
HCoV-NL63	Flu A (H7N7)	Mumps
HCoV-229E	Flu B Victoria linie	Legionella pneumophila
Measles	Flu B Y amagata linie	Mycoplasma pneumoniae
Streptococcus pneumoniae	Respiratory syncytial virus	Chlamydia pneumoniae
Epstein-Barr virus	Adenovirus	Streptococcus pyogenes
Bordetella parapertussis	Parainfluenza 1/2/3 virus	Streptococcus agalactiae
Flu A (H1N1) pdm09	Human metapneumovirus	Group C Streptococcus
Flu A (H3N2)	Rhinovirus	Staphylococcus aureus