COVID-VIRO®
COVID-19 Rapid Antigen Test
Ref.: TR-COV-006
User manual

CE

INDICATION FOR USE

COVID-VIRO® is an immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in nasopharyngeal swab samples.
COVID-VIRO® is a rapid test that helps in the diagnosis of SARS-CoV-2 infections.
COVID-VIRO® also detects SARS-CoV and new variants in which nucleoprotein N synthesis is not affected (alpha, beta, gamma, delta and delta plus variants).

INTRODUCTION

SARS-CoV-2 was identified in 2019 and belongs to the genus of β-coronaviruses. It is the pathogen that causes an emerging atypical pneumonia, coronavirus disease 2019 (Covid-19).
SARS-CoV-2 variants, called SARS-CoV-2 501YV.1 and 501YV.2 have been identified by viral genome sequencing. Their RNAs show multiple mutations and deletions resulting in deletions or changes of amino acids in the S protein (Spike) deletion 69-70, deletion 144, mutations N501Y, A570D, D614G, P681H, T716I, S982A and D1118H.
Currently, patients infected with SARS-CoV-2 are the main source of transmission: infected people, who are asymptomatic, can also be an infectious source. Based on the current epidemiological investigation, the incubation period can range from 1 to 14 days but is usually 3 to 7 days.
The main symptoms are fever or feeling feverish and coughing. The sudden loss of smell, without nasal obstruction and total disappearance of taste are also symptoms that have been observed in patients. In people who develop more severe forms, there are breathing difficulties, which can lead to hospitalisation in intensive care and death.
COVID-VIRO® was designed to detect the nucleocapsid (N) protein of SARS-CoV-2, so mutations affecting the synthesis of the spike protein do not affect the performance of the test.
COVID-VIRO® screens for the English "alpha", South African "beta", Brazilian "gamma" and Indian variants "delta" and "delta plus", with the same performance as it detects other known strains of the SARS-CoV-2 virus. This antigen is usually detectable in upper respiratory tract specimens during the acute phase of infection.

PRINCIPLE OF THE TEST

COVID-VIRO® is a lateral flow immunochromatographic assay that uses highly sensitive monoclonal antibodies to detect SARS-CoV-2 nucleocapsid antigen in a nasopharyngeal specimen.
The test uses monoclonal antibodies directed against the SARS-CoV-2 nucleocapsid protein attached to a nitrocellulose strip at the test area (T). A monoclonal antibody directed against the nucleocapsid protein of SARS-CoV-2 labeled with colloidal gold is used as a lyophilized conjugate.
In the test, the SARS-CoV-2 antigens in the sample interact with the monoclonal SARS-CoV-2 antibodies conjugated to the color particles to form a colored antibody-antigen complex.
This complex migrates by capillary action on the membrane to the test line (T) where it will be captured by the monoclonal anti-SARS-CoV-2 antibodies attached to the membrane.
A colored test line should appear in the results window (T) if SARS-CoV-2 antigens are present in the sample. The intensity of the colored test line will vary depending on the amount of SARS-CoV-2 antigens present in the sample. If no SARS-CoV-2 antigen is present in the sample, no color will appear on the test line (T). The control line is used as a procedural control and should always appear in the control box
(C) whether the test procedure is performed correctly.

EQUIPMENT PROVIDED

- 20 sealed pouches each containing a cassette and a moisture absorber
- 20 pre-filled buffer tubes
- 20 sterile nasopharyngeal swabs
- 20 dropper caps
- 1 tube holder
- 1 user manual

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). Do not freeze the components of the kit. REMOVE THE CASSETTE FROM THE SEALED POUCH ONLY JUST BEFORE DEPOSITING THE SAMPLE.

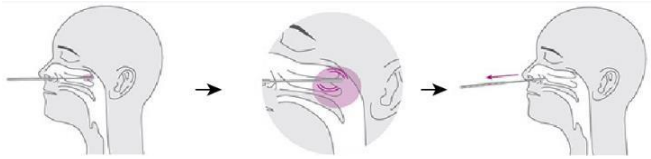
WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only.
- The test device should remain in the sealed pouch until it is used.
- Do not use the kit after the expiration date.
- The swabs, tubes and test cassettes are for single use. They should only be taken out of their bag or packaging individually before each test is carried out (to avoid cross-contamination).
- The extraction buffer contains a solution with a preservative (0.09% sodium azide). If the solution comes into contact with skin or eyes, rinse thoroughly with water.
- Solutions that contain sodium azide can react explosively with lead or copper pipes. Use large amounts of water to rinse the discharged solutions down a sink.
- Do not exchange or mix components from different batches.
- For nasopharyngeal swabs, use the flocked swab provided in this kit.
- To obtain accurate results, do not use samples that contain blood or are too viscous.
- Wear appropriate protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Humidity and temperature can affect the results.
- The equipment used must be disposed of in accordance with local regulations.

SAMPLE COLLECTION

Use of the nasopharyngeal swab provided in the kit.

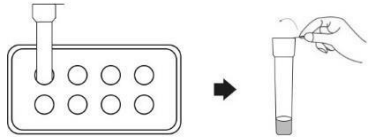
1. Carefully insert the swab into the patient's nostril, reaching the surface of the posterior nasopharynx.
2. Turn the swab several times.
3. Carefully remove the swab from the nasal cavity.



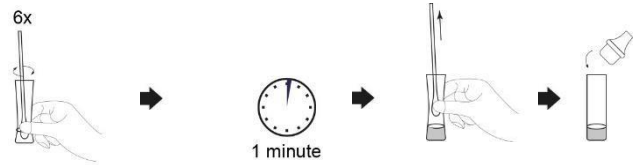
Note : in the case of a very crowded nose, suggest that the patient blow his nose.

SAMPLE PREPARATION

1. Insert the pre-filled tube of tampon into the holder and open it by removing its lid. Make sure the tube is securely in place and reaches the bottom of the bracket.



2. Immerse the swab in the pre-filled tube of buffer.
3. Turn the swab (at least 6 times) while pressing its head against the bottom and sides of the tube.
4. Let the swab rest in the tube for 1 minute. If the mucus appears thick at the time of collection, let the swab rest for an additional 1 minute.
5. Press the swab against the walls of the tube to extract the liquid from the swab.
6. Remove and discard the swab.
7. Insert a dropper cap onto the tube in a tight manner.



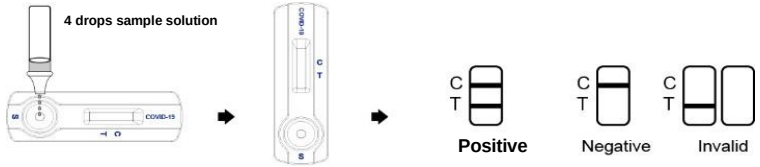
SAMPLE TRANSPORT AND STORAGE

Samples should be tested as soon as possible.
If this is not possible, in order to preserve the integrity of the sample, it is strongly recommended to place the swab in a clean, unused plastic tube, labeled with patient information, and hermetically sealed and then store it at room temperature (15-30°C) for up to 1 hour before the test is performed. Make sure that the swab fits firmly into the tube and that the cap is tightly closed. If the delay exceeds 1 hour, the sample must be disposed of. A new sample must be taken to perform the test.

PROCEDURE

Ensure that the sample and test components are at room temperature (15-30°C) before proceeding with the test.

1. Remove the cassette from the sealed pouch just before performing the test and place it on a flat surface.
2. Turn the tube upside down and place 4 drops (100µL) of sample, squeezing the tube, into the sample well (S) of the cassette. Hold the tube slightly above the cassette in order to visualize the drops falling one by one into the sample well (S).
3. Wait for the coloured stripe(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF THE RESULTS

Positive : 2 colored bands appear in the playback window: the control line (C) and the test line (T). This indicates a positive outcome.
Negative : Only the control line (C) appears in the result window. This indicates a negative result.
Invalid : If the control line (C) is not visible in the result window after performing the test, the result is considered invalid. Some causes of invalid results are due to not following the instructions correctly. It is recommended that the sample be retested using a new test.
Note : The intensity of the test line (T) color may vary depending on the concentration of antigens present in the sample. Therefore, any visible shade of color from the test line (T) should be considered positive.
Note that this is a qualitative test and cannot determine the concentration of antigen in the sample. Insufficient sample volume, incorrect operation, or outdated tests are the most likely reasons for missing the control tape.

QUALITY CONTROL

Internal quality control is included in the test. A red line appearing in the control region (C) is the internal procedure control. It confirms that a sufficient sample volume was used and that the test procedure was correctly followed. External quality checks are not provided in this kit.

BOUNDS

- The test is capable of detecting both viable and non-viable SARS-CoV-2. The performance of the test depends on the antigenic load and may not correlate with the results of the viral culture performed on the same sample. The etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test.
- Removing the cassette from the sealed pouch well before depositing the sample may lead to a false positive result.
- THIS TEST SHOULD NOT BE PERFORMED FROM A SWAB PREVIOUSLY PLACED IN A VIRAL TRANSPORT MEDIUM (VDM). Some MTVs contain chemicals that can interfere with the immunological reaction that underlies the test and can result in a false positive result.
- Failure to follow the test procedure may adversely affect the performance of the test and/or invalidate the test result.
- If the test result is negative and clinical symptoms persist, additional testing is recommended. A negative result does not exclude the presence of SARS-CoV-2 antigens in the sample at any time, as they may be present below the detection limit of the test or if the sample has been collected or transported incorrectly.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory results have been evaluated.
- Positive test results do not exclude co-infections with other pathogens and do not differentiate between SARS-CoV and SARS-CoV-2 and its variants.
- The test must be used according to the regulations in force.

PERFORMANCE

The performance of the **COVID-VIRO® test** was evaluated at the Orléans Regional Hospital (article published in JMV: https://onlinelibrary.wiley.com/doi/10.1002/jmv.26896) as part of a prospective comparative clinical study involving 226 individuals of unknown status with regard to SARS-CoV-2 infection, recruited consecutively or randomly.

Performance of COVID-VIRO® compared to RT-PCR from a nasopharyngeal swab

Reference method	PCR SARS-CoV-2 Positive
Number of positive samples	113
Total number of samples	117
Sensitivity Result	**96.6%***
95% CI	*93.3-99.8%*

Reference method	PCR SARS-CoV-2 Negative
Number of negative samples	109
Total number of samples	109
Specificity Result	**100%**
95% CI	*96.6-100%*

*The sensitivity of the test is **98.4%** for people with significant viral shedding (Ct ≤33), according to the criteria of the French Society of Microbiology (SFM).

Limit of Detection (LOD)
The minimum detectable concentration of SARS-CoV-2 is **1.15 x 102 TCID50/ml.**

Interference
The substances listed below were tested: blood (EDTA), antiviral drugs, antibiotics/antibacterial drugs, nasal sprays or nasal drops, nasal corticosteroids.
The results showed no interference.

Precision
Within: 3 samples (one negative, one weak positive (LOD) and one strong positive (LODx4)) were tested 10 times each. The results were all correct.
Inter-batch: 3 samples (one negative, one weak positive (LOD) and one strong positive (LODx4)) were tested 10 times on 3 different batches. The results were all correct.

Cross-reactions
Samples containing the pathogens listed below were tested. The results showed no cross-reaction.

Pathogen	Concentration
Respiratory syncytial virus Type A	5.5×107PFU/ml
Respiratory syncytial virus Type B	2.8×105TCID50/ml
Novel influenza A H1N1 virus (2019)	1×106PFU/mL
Seasonal influenza A H1N1 virus	1×105PFU/ml
Influenza A H3N2 virus	1×106PFU/mL
Influenza A H5N1 virus	1×106PFU/mL
Influenza B Yamagata	1×105PFU/ml
Influenza B Victoria	1×106PFU/mL
Rhinovirus	1×106PFU/mL
Adenovirus 3	5×107.5TCID50/ml
Adenovirus 7	2.8×106TCID50/ml
EV-A71	1×105PFU/ml
Mycobacterium tuberculosis	1×103bacteria/ml
Mumps virus	1×105PFU/ml
Human coronavirus 229E	1×105PFU/ml

Pathogen	Concentration
Human coronavirus OC43	1×105PFU/ml
Human coronavirus NL63	1×106PFU/mL
Human coronavirus HKU1	1×106PFU/mL
Parainfluenza virus 1	7.3×106PFU/mL
Parainfluenza virus 2	1×106PFU/mL
Parainfluenza virus 3	5.8×106PFU/ml
Parainfluenza virus 4	2.6×106PFU/ml
Haemophilus influenzae	5.2×106CFU/ml
Streptococcus pyogenes	3.6×106CFU/ml
Streptococcus pneumoniae	4.2×106CFU/ml
Candida albicans	1×107CFU/ml
Bordetella pertussis	1×104bacteria/ml
Mycoplasma pneumoniae	1.2×106CFU/ml
Chlamydia pneumoniae	2.3×106IFU/mL
Legionella pneumophila	1×104bacteria/ml

SYMBOL LEGEND

	Read the user manual	Σ	Number of tests per kit		Maker
IVD	For use in *in vitro diagnostics* only		Expiry date		Do not reuse
2°C 30°C	Store between 2 and 30°C	LOT	Lot number	REF	Reference
CE	CE marking				

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