

Ref. : TR-COV-006

INTENDED USE

COVID-VIRO® is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. **COVID-VIRO®** also detects SARS-CoV.

INTRODUCTION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

COVID-VIRO® is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

PRINCIPLE OF THE TEST

COVID-VIRO® is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal (NP) swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

MATERIAL PROVIDED

- 20 sealed pouches containing a test cassette and a desiccant
- 2 vials of buffer
- 20 nasopharyngeal sterile swabs
- 20 Extraction tubes and 20 nozzle with filter
- 1 workstation
- 1 instructions for use

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). Do not freeze any of the test kit components. Do not use test device and reagents after expiration date. Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.

MISES EN GARDE ET PRÉCAUTIONS

- For professional in vitro diagnostic use only.
- The test device should remain in the sealed pouch until use.
- Do not use kit past its expiration date.
- Swabs, tubes and test devices are for single use only.
- The extraction buffer contains a solution with a preservative (0.09% sodium azide). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
- Do not interchange or mix components from different kit lots.
- When collecting a nasopharyngeal swab sample, use the Nasopharyngeal Swab supplied in the kit.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

SPECIMEN COLLECTION

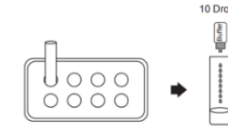
Use the nasopharyngeal swab supplied in the kit.

1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx. that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.

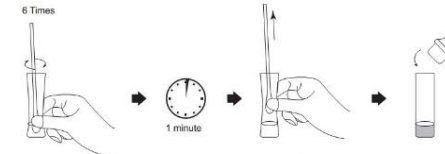


SAMPLE PREPARATION PROCEDURE

1. Insert the test extraction tube into the workstation in this product. Make sure that the tube is standing firm and reaches the bottom of the workstation.
2. Add 0.3 mL (about 10 drops) of the sample extraction buffer into the extraction tube.



3. Insert the swab into the extraction tube which contains 0.3 mL of the extraction buffer.
4. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
5. Leave the swab in the extraction tube for 1 minute.
6. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.



SPECIMEN TRANSPORT AND STORAGE

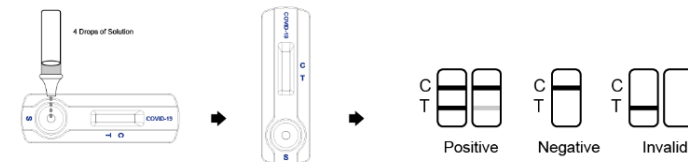
Nasopharyngeal swabs should be tested as soon as possible after collection.

If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasopharyngeal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to 1 hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

TEST PROCEDURE

Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing..

1. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
2. Insert a nozzle with filter into the sample extraction tube tightly.
3. Reverse the sample extraction tube, and add 4 drops (about 100µL) of test sample by squeezing the extracted solution tube into the sample window.
4. Wait for the colored band(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

Positive : the presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.
Negative : the presence of only control line (C) within the result window indicates a negative result.
Invalid : If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.
Note : the intensity of color in the test line region (T) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure..

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

- The etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test. The Coronavirus Ag Rapid Test Cassette (Swab) is capable of detecting both viable and non-viable SARS-CoV-2. The performance of the Coronavirus Ag Rapid Test Cassette (Swab) depends on antigen load and may not correlate with viral culture results performed on the same specimen.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of SARS-CoV-2 antigens in specimen, as they may be present below the minimum detection level of the test or if the sample was collected or transported improperly.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative results should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

COVID-VIRO® has been evaluated on patient samples coming from 2 sites. A commercialized molecular assay was used as the reference method. The results show that **COVID-VIRO®** has a high overall accuracy;

Table 1 : COVID-VIRO® vs PCR

Method	PCR		Total Results
	Positive	Negative	
COVID-VIRO®	Positive	71	71
	Negative	2	130
Total Results		73	203

Sensitivity : 97.3%

Specificity : 100%

Accuracy : 99%

Table 2 : Positive results broken down by days since symptom onset

Days since symptom onset	Cumulative PCR positive (+)	Cumulative COVID-VIRO positive (+)	PPA
1	7	7	100%
2	18	18	100%
3	30	30	100%
4	44	44	100%
5	59	58	98.3%
6	62	60	96.8%
7	70	68	97.1%
8	71	69	97.2%
9	72	70	97.2%
10	73	71	97.3%

Table 3: COVID-VIRO® performance against the Comparator Method – by Cycle Threshold Counts

COVID-VIRO®	PCR Results (Ct) of nucleoprotein(N) gene	
	Positive (Ct<30)	Positive (Ct≥30)
Positive	62	9
Negative	0	2
Total	62	11

COVID-VIRO®	PCR Results (Ct) of open reading frame(ORF) gene	
	Positive (Ct<30)	Positive (Ct≥30)
Positive	40	31
Negative	0	2
Total	40	33

Limit of detection (LOD)

The minimum detectable concentration of SARS-CoV-2 Ag is **1,15 x 10² TCID₅₀/ml**.

Interferences

The following substances have been tested : blood (EDTA), anti-viral drugs, antibiotics/anti-bacterial drugs, nasal sprays or nose drops, nasal corticoids. Results did not show any interference .

Precision

Intra-lot : 3 samples (negative, low positive (LOD) and high positive (4xLOD) have been tested in 10 replicates each. Results have been detected correctly.











Inter-lot : 3 samples (negative, low positive (LOD) and high positive (4xLOD) have been tested in 10 replicates with 3 different batches. Results have been detected correctly.


Cross-reactivity

COVID-VIRO® has been tested with samples containing the following pathogens. Results did not show any cross-reactivity.

Pathogen agents	Concentration	Pathogen agents	Concentration
Respiratory syncytial virus Type A	5.5x10 ⁷ PFU/ml	Human coronavirus OC43	1x10 ⁵ PFU/ml
Respiratory syncytial virus Type B	2.8x10 ⁵ TCID ₅₀ /ml	Human coronavirus NL63	1x10 ⁶ PFU/ml
Novel influenza A H1N1 virus (2019)	1x10 ⁶ PFU/ml	Human coronavirus HKU1	1x10 ⁶ PFU/ml
Seasonal influenza A H1N1 virus	1x10 ⁵ PFU/ml	Parainfluenza virus 1	7.3x10 ⁶ PFU/ml
Influenza A H3N2 virus	1x10 ⁶ PFU/ml	Parainfluenza virus 2	1x10 ⁶ PFU/ml
Influenza A H5N1 virus	1x10 ⁶ PFU/ml	Parainfluenza virus 3	5.8x10 ⁶ PFU/ml
Influenza B Yamagata	1x10 ⁵ PFU/ml	Parainfluenza virus 4	2.6x10 ⁶ PFU/ml
Influenza B Victoria	1x10 ⁶ PFU/ml	Haemophilus influenzae	5.2x10 ⁶ CFU/ml
Rhinovirus	1x10 ⁶ PFU/ml	Streptococcus pyogenes	3.6x10 ⁶ CFU/ml
Adenovirus 3	5x10 ⁷ .5TCID ₅₀ /ml	Streptococcus pneumoniae	4.2x10 ⁶ CFU/ml
Adenovirus 7	2.8x10 ⁶ TCID ₅₀ /ml	Candida albicans	1x10 ⁷ CFU/ml
EV-A71	1x10 ⁵ PFU/ml	Bordetella pertussis	1x10 ⁴ bacteria/ml
Mycobacterium tuberculosis	1x10 ³ bacteria/ml	Mycoplasma pneumoniae	1.2x10 ⁶ CFU/ml
Mumps virus	1x10 ⁵ PFU/ml	Chlamydia pneumoniae	2.3x10 ⁶ IFU/ml
Human coronavirus 229E	1x10 ⁵ PFU/ml	Legionella pneumophila	1x10 ⁴ bacteria/ml

INDEX OF SYMBOLS

	Consult instruction for use		Tests per kit		Manufacturer
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2 and 30°C		Lot Number		Catalog#
	CE mark				

 AAZ-LMB
43, rue de Bellevue
92100 – Boulogne-Billancourt France