COVID-VIRO ALL IN®
COVID-19 All-in-One Rapid Nasal Test
Ref : TR-COV-008
Instructions for use
Read the instructions for use completely before performing the test.
The instructions must be followed carefully.

INTENDED USE

COVID-VIRO ALL IN® is a rapid test**, specially designed and secured for use in children from the age of 1 month** or in adults, for the detection of SARS-CoV-2 N protein in nasal secretions.
COVID-VIRO ALL IN® is a rapid test that assists in the diagnosis of SARS-CoV-2 infections.
COVID-VIRO ALL IN® is a test for professional use only.
COVID-VIRO ALL IN® also detects SARS-CoV and the new variants in which the synthesis of nucleoprotein N is not affected (alpha, beta, gamma, delta and omicron variants).

INTRODUCTION

SARS-CoV-2 was identified in 2019, it belongs to the β-coronavirus genus. It is the pathogen behind an emerging atypical pneumonia, coronavirus disease 2019 (Covid-19).
Several SARS-CoV-2 variants, named alpha, beta, gamma, delta and omicron, 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 (Spike) protein.
Currently, patients infected with SARS-CoV-2 are the main source of transmission: infected persons, who are asymptomatic, can also be a source of infection. Based on the current epidemiological survey, the incubation period can range from 1 to 14 days but is usually 3 to 7 days.
The main symptoms are fever or the feeling of fever and cough. Sudden loss of smell, without nasal obstruction, and total loss of taste are also symptoms that have been observed in patients. In more severe forms, breathing difficulties are present, which can lead to hospitalisation in intensive care and death.
COVID-VIRO ALL IN® has been designed to detect the SARS-CoV-2 Nucleocapsid (N) protein. Mutations affecting the synthesis of the Spike protein do not affect the performance of the test.
COVID-VIRO ALL IN® detects the alpha, beta, gamma, delta and omicron variants with the same performance as other known SARS-CoV-2 strains.
The SARS-CoV-2 Nucleocapsid (N) protein is usually detectable in upper respiratory tract specimens during the acute phase of infection.

PRINCIPLE OF THE TEST

COVID-VIRO ALL IN® is a lateral flow immunochromatographic test that uses highly sensitive monoclonal antibodies to detect SARS-CoV-2 core antigen in a nasal sample.
The test uses monoclonal antibodies to the SARS-CoV-2 core protein attached to the test area (T) on a nitrocellulose strip.
A colloidal gold labelled monoclonal antibody to the SARS-CoV-2 core protein is used as a freeze-dried conjugate.
During the test, SARS-CoV-2 antigens in the sample interact with monoclonal anti-SARS-CoV-2 antibodies conjugated to the colour particles to form a coloured antibody-antigen complex.
This complex migrates by capillary action across the membrane to the test line (T) where it is captured by the monoclonal anti-SARS-CoV-2 antibodies bound to the membrane.
A coloured test line will appear in the results window (T) if SARS-CoV-2 antigens are present in the sample. The intensity of the coloured test line will vary depending on the amount of SARS-CoV-2 antigen present in the sample. If no SARS-CoV-2 antigen is present in the sample, no colour will appear on the test line (T). The control line is used as a procedural control and should always appear in the control area (C) if the test procedure is performed correctly.

MATERIAL PROVIDED

- 10 sealed bags containing an individual kit
- 1 instruction manual for professional use

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, timer, or stopwatch

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). Do not freeze the kit. The kit is stable until the expiry date indicated on the bag. DO NOT REMOVE THE KIT FROM THE SEALED POUCH UNTIL JUST BEFORE TESTING.

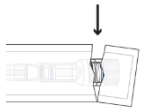
WARNINGS ET PRECAUTIONS

- The test device should remain in the sealed pouch until use.
- Do not use the kit after the expiry date, do not use the kit with a hole or damage in the bag.
- Incorrect results may be obtained if the kit is stored incorrectly.
- The kit is for single use only. It should not be removed from the bag until just before testing (to avoid cross-contamination).
- Avoid skin or eye contact with the swab in the dosette before, during or after the test. If the solution comes into contact with the skin or eyes, rinse thoroughly with water.
- For 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. The used kit should be disposed of in accordance with local regulations.

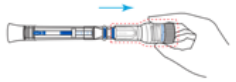
PROCEDURE

Ensure that the COVID-VIRO ALL IN® kit is at room temperature (15-30°C) before testing. Humidity and temperature may affect the resultsBring devices, reagents and specimens and/or controls to room temperature (15~30℃) before use.

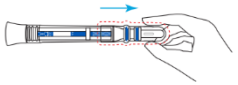
1. Ask the patient to blow their nose.
2. Remove the test from the sealed pouch just prior to performing the test.



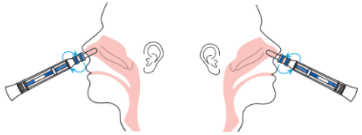
3. Remove the extraction tube from the test.



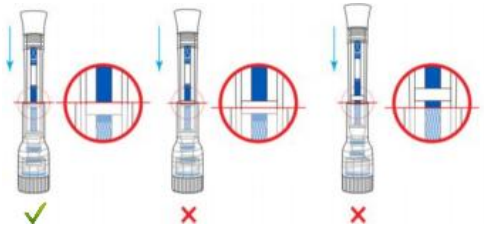
4. Remove the protective cap.



5. Gently insert the collection tube (foam) into the left nostril until there is resistance (approximately 1-2 cm into the nostril). Rotate in the nostril for 15 seconds while rubbing the collection area against the inner wall of the nostril. Repeat the same procedure in the right nostril. It is important to obtain as much secretion as possible



6. Insert the test point down into its holder on a table.
7. Press **hard** on the test to pierce the lid of the diluent pod and insert the test **to the bottom of the holder.**



8. Read the result at 15 minutes. Do not interpret the result after 20 minutes.

RESULT INTERPRETATION

Positive : the control line (C) and the test line (T) appear in the result window. This indicates a positive result.
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 colour intensity of the test line (T) may vary depending on the concentration of antigen present in the sample. Therefore, any shade of colour in 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 expired tests are the most likely reasons for the missing control strip.

QUALITY CONTROL

Internal Procedural Controls
An 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 volume of sample has been used and that the test procedure has been followed correctly.

LIMITATIONS

- The **COVID-VIRO ALL IN®** Test is intended for professional in vitro diagnostic use and should only be used for the qualitative detection of SARS-CoV-2 antigen. The colour intensity in a positive band should not be evaluated as "quantitative or semi-quantitative".
- The **COVID-VIRO ALL IN®** test is capable of detecting viable and non-viable SARS-CoV-2. The performance of the test is dependent on antigen load and may not correlate with the results of viral culture performed on the same sample.
- If the test result is negative and clinical symptoms persist, further testing is recommended. A negative result does not exclude the presence of SARS-CoV-2 antigens in the specimen at any time, as they may be present below the detection limit of the test or if the specimen has been collected or transported incorrectly.
- 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.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made after evaluation of all available clinical and laboratory findings.
- Failure to follow the test procedure may impair the performance of the test and/or invalidate the test result.
- The results obtained with this test should be used in conjunction with other clinical information.
- Negative results do not exclude infection with SARS-CoV-2.

PERFORMANCE CHARACTERISTICS

Test performance
The performance of the **COVID-VIRO ALL IN®** test was evaluated at the Orléans Regional Hospital in a prospective comparative clinical study involving 119 individuals of unknown SARS-CoV-2 infection status, recruited consecutively or randomly.

Performance of COVID-VIRO ALL IN® (nasal) vs RT-PCR (nasopharyngeal)

	PCR SARS-CoV-2 positive
Number of positive samples	40
Total number of samples	43
Sensitivity result	**93,02%**
IC95%	*81,4 – 97,6%*

	PCR SARS-CoV-2 negative
Number of negative samples	76
Total number of samples	76
Specificity result	**100%**
IC95%	*95,2-100%*

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

Adenovirus 1	MERS-coronavirus	*Bordetellaparapertussis*
Adenovirus 2	SARS-coronavirus	*Bordetella pertussis*
Adenovirus 3	Human metapneumovirus	*Candida albicans*
Adenovirus 4	Influenza A (H1N1) pdm09	*Chlamydia pneumoniae*
Adenovirus 5	Influenza A (H3N2)	*Group C Streptococcus*
Adenovirus 7	Influenza B Victoria lineage	*Haemophilusinfluenzae*
Adenovirus 55	Influenza B Yamagata lineage	*Legionella pneumophila*
Epstein-Barr virus	Norovirus	*Mycoplasma pneumoniae*
Enterovirus EV70	Parainfluenza virus 1	*Mycobacterium tuberculosis*
Enterovirus EV71	Parainfluenza virus 2	*Staphylococcus aureus*
Enterovirus A16	Parainfluenza virus 3	*Staphylococcus epidermidis*
Enterovirus A24	Parainfluenza virus 4	*Streptococcus agalactiae*
Enterovirus B1	Respiratory syncytial virus A	*Streptococcus pneumoniae*
Echovirus 6	Respiratory syncytial virus B	*Streptococcus pyogenes*
HCoV-229E	Rhinovirus A30	
HCoV-OC43	Rhinovirus B52	
HCoV-NL63		

Limit of Detection (LoD)
The minimum detectable concentration of SARS-CoV-2 is $1x10^{2.4}TCID_{50}$/mL.

Interferences
The following substances, which are naturally present in respiratory samples or can be artificially introduced into the respiratory tract, were evaluated at the concentrations indicated below. The results showed no interference.

Substance	Concentration	Substance	Concentration
4-acetamidophenol	10 mg/mL	Mupirocin	250 µg/mL
Acetylsalicylic acid	10 mg/mL	Oxymetazoline	25 µg/mL
Albuterol	10 mg/mL	Phenylephrine	10 mg/mL
Chlorpheniramine	5 mg/mL	Phenylpropanolamine	1 mg/mL
Dexamethasone	50 µg/mL	Zanamivir	10 mg/mL
Dextromethorphan	10 µg/mL	Adamantanamine	500 ng/mL
Diphenhydramine	5 mg/mL	Oseltamivir phosphate	10 mg/mL
Doxylamine succinate	1 mg/mL	Tobramycine	10 mg/mL
Flunisolide	25 µg/mL	Triamcinolone	14 mg/mL

INDEX OF SYMBOL

	Consult instruction for use		Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2 and 30°C	LOT	Lot Number	REF	Catalog number
CE	CE mark				

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