FORA® COVID-19 Antigen Rapid Test

ver 1.0 202103
312-4531100-033

INTENDED USE

The FORA COVID-19 Antigen Rapid Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in fresh nasopharyngeal swab or fresh nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider.

The FORA COVID-19 Antigen Rapid Test is intended for use by trained clinical laboratory personnel specifically instructed and trained in *in vitro* diagnostic procedures and individuals trained in point of care settings.

The test also provides individuals with the option to self-collect with nasal sample under the healthcare professional. It also could be used without healthcare professional depend on local regulatory requirements.

Self-collected is suitable for the following people:
Adults ages 18+, self-collect, with assistance if needed.
Adolescents aged 12 – 17, Self-collect with adult supervision. The adult may conduct the test as necessary.
Children under 12. Children under 12 years of age should be tested by an adult. Do not conduct this test if you do not feel confident testing a child. Do not continue the test if the child feels any pain.

The FORA COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in upper repiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine the status of the infection. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease.

Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay if necessary for patient management.

SUMMARY AND EXPLANATION

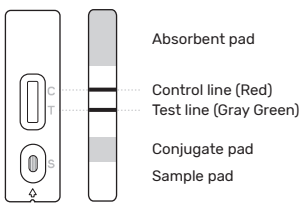
The coronavirus disease 2019 (COVID-19) is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 is a coronavirus identified as the cause of an outbreak of respiratory illnesses first detected in Wuhan, China. The WHO declared on March 11, 2020 that COVID-19 was a pandemic.[1] COVID-19 has caused millions of confirmed cases worldwide, including hundreds of thousands of deaths, and statistics are increasing.[2] It has been reported that symptoms ranging from mild to severe may appear 2-14 days after exposure to SARS-CoV-2. People with these symptoms may suffer from COVID-19: fever, cough, and shortness of breath.[3]

There are three main categories of COVID-19 tests: (1) The antibody test results (such as IgM and IgG) can show whether a person has been infected before. Human immune system may take 15 days in most patients to produce antibodies after infection.[4] (2) The antigen test results can show whether there is currently a virus infection. According to CLSI standard of viral culture, the median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.[5] FORA COVID-19 Antigen Rapid Test uses the monoclonal antibody that specifically binds to the nucleocapsid (N) protein to determine the presence of the SARS-CoV-2 antigen. (3) Real-Time RT-PCR (Reverse-Transcription Polymerase Chain Reaction) is a molecular method intended for the qualitative detection of nucleic acid from SARS-CoV-2. SARS-CoV-2 RNA is converted into complementary DNA by using a reverse transcriptase. The PCR amplification process of complementary DNA can be monitored by fluorescent dyes. By detecting the total fluorescence of the product after PCR cycles, it can show whether the suspected specimen contains SARS-CoV-2 nucleic acid.

[1] WHO Timeline - COVID-19
https://www.who.int/news-room/detail/27-04-2020-who-timeline---covid-19
[2] COVID-19 Coronavirus Cases and Deaths https://www.worldometers.info/coronavirus/?utm_cam-paign=homeAdvegas1?%22%20%5Cl%20%22countries%3Ca%20href=
[3] CDC Symptoms of COVID-19
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
[4] Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa344/5812996
[5] CLSI M41-A, Viral Culture; Approved Guideline
https://clsi.org/standards/products/microbiology/documents/m41/

TEST PRINCIPLE

FORA COVID-19 Antigen Rapid Test is a lateral flow chromatographic immunoassay in a sandwich design with colloidal gold as an indicator. The FORA COVID-19 Antigen Rapid Test is designed to detect antigen from the SARS-CoV-2 in fresh nasopharyngeal swabs and fresh nasal swabs directly from patients who are suspected of COVID-19 by their healthcare provider. This test allows for the detection of SARS-CoV and SARS-CoV-2. The test detects, but does not differentiate, between the two viruses.



The test cassette consist of a test strip containing:
1) Conjugate pad : **Anti SARS-CoV-2 N protein IgG CGC**
2) Test line (T Line) : **Anti-SARS-CoV-2 N protein IgG**
3) Control line (C Line) : **Control line antibody**
***** CGC: colloidal gold conjugation

Place a fresh nasopharyngeal swab or fresh nasal swab specimen in an extraction buffer tube. During this time, the virus particles in the swab will be destroyed, and the internal viral nucleoprotein will be exposed. When a correct volume of extraction buffer with exposed viral nucleoprotein is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the test strip.

If present in the sample, SARS-CoV-2 nucleoprotein will bind **Anti SARS-CoV-2 N protein IgG CGC** and the complex will migrate to the T line.

The T line has Anti-SARS-CoV-2 N protein IgG fixed on the surface of the test strip. When the antibody and SARS-CoV-2 nucleocapsid protein association complex move to the T line, sandwich immune complexes are formed. Two antibodies sandwich SARS-CoV-2 nucleocapsid protein in the middle, and the colloidal gold particles are fixed on the T line. Aggregation occurs and produces a colored line, indicating a positive test result for SARS-CoV-2 nucleocapsid protein.

The C line has **Control line antibody** fixed on the surface of the test strip. The C Line is an internal control which should exhibit a colored line by immune complexes regardless of the color development on the T line. If no C Line is observed, the test result is invalid and the specimen must be re-collected and tested with a new cassette.

1) Accessories Included with the Test:
- Individually Foil Packaged Test Cassette
  The cassette includes:
  1) Conjugate pad : **Anti SARS-CoV-2 N protein IgG CGC**
  2) Test line (T Line) : **Anti-SARS-CoV-2 N protein IgG**
  3) Control line (C Line) : **Control line antibody**
- Extraction Buffer Tube (0.5 ml per bottle): Detergent, salts and non-reactive ingredients
- Sterile Swab
- User Manual
- Quick Reference Guide

2) Accessories Required But Not Included with the Test:
- Timer or watch.
- Any necessary personal protective equipment.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This test is intended for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
3. Sample collection and handling procedures should be followed with this instruction of use.
4. When collecting a fresh nasopharyngeal swab and fresh nasal swab specimens, use the sterile swabs supplied in the kit.
5. Do not use the kit contents beyond the expiration date printed on the label.
6. Please check the package before use. Do not use if the package is damaged or the seal is broken.
7. Discard and do not use any damaged or dropped Test Cassette or material.
8. Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit by trained clinical laboratory personnel or healthcare professional.
9. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
10. Always wear gloves to handle patient samples.
11. Avoid splashing and formation of droplets.
12. The user should never open the foil package of the Test Cassette exposing it to the ambient environment until the Test Cassette is ready for immediate use.
13. Start the assay procedure immediately after removing the cassette from the foil package.
14. Do not reuse the used test cassettes, extraction buffer tubes or the sterile swabs.
15. The Extraction Buffer contains a salt solution (saline). If the solution is in contact with the skin or eye, flush with copious amounts of water.
16. To obtain accurate results, the User Manual instructions must be followed. Incorrect sampling or procedure may result in inaccurate test results.
17. To obtain accurate results, do not use visually bloody or overly viscous samples.
18. Dispose of containers and unused contents in accordance with Local regulatory requirements.
19. Use appropriate disinfectants to thoroughly remove spills.
20. The possibility of infection cannot be totally ruled out. Therefore, all materials should be handled with care and treated like specimens. In the event of exposure, follow the instructions of local regulations.
21. Specimens, reagent kits and materials that may be contaminated during inspection are considered infectious waste, and must be discarded in accordance with local biological infectious regulations.
22. Do not interchange or mix different specimens.
23. Wash hands thoroughly after handling.
24. Use certified sterile rayon, foam, polyester or flocked flexible-shaft NP swabs to collect a nasopharyngeal swab sample or nasal swab sample.
25. If you've had a nosebleed within the last 24 hours, swab the other nostril or wait 24 hours.

STORAGE

1. Store at 2-30°C. Avoid direct sunlight.
2. Kit contents are stable until the expiration date printed on the label.
3. The test cassette must be kept in the sealed foil package. After unpacking, use the test cassette immediately.
4. Avoid freezing or heating test cassettes or kit contents.

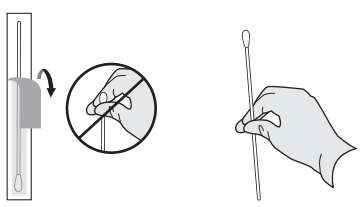
WHAT YOU NEED TO DO BEFORE SELF-COLLECTION

1. Prepare your test area and check your test kit contents.
2. Read this instruction of use carefully.
3. Clean and dry a flat surface immediately before starting the test.
4. Wash your hands thoroughly, using soap and water, or hand sanitiser. Dry your hands before performing the test.
   If you do more than one test, clean the surface and wash your hands again for each test.

SET UP YOUR TEST

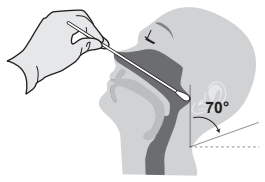
1. Take the test strip out from the sealed packaging and place it on a flat and clean surface. Once opened, start the test within 20 minutes.
2. **Gently blow your nose into a tissue and throw the tissue away in a closed bin. If you are testing a child help them to blow their nose.** This is so that you get rid of excess mucus.
3. Wash your hands thoroughly, using soap and water, or hand sanitiser. Final, dry your hands.
4. Open swab package
5. Take swab out.

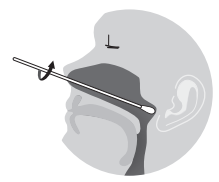
⚠ Never touch the soft, fabric tip of the swab with your hands.



SAMPLE COLLECTION AND HANDLING

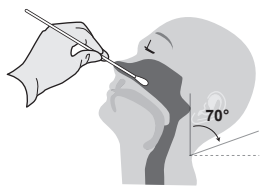
Nasopharyngeal Swab Sample

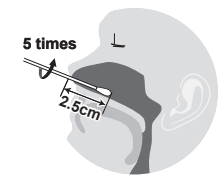




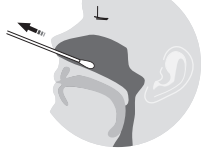
1. Use the sterile swab supplied in the kit. Tilt the patient's head back about 70 degrees.
   To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, insert the swab to the palate (not upwards) until resistance is encountered.
2. Gently rub and roll the swab over the surface of the posterior nasopharynx.
3. Slowly remove the swab while rotating it.

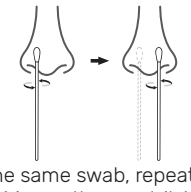
Mid-turbinate or Anterior nasal Sample





1. Use the sterile swab supplied in the kit to collect a nasal swab sample.
2. Tilt the head back about 70 degrees.
3. Gently insert the entire absorbent tip of the swab into one nostril. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 5 times. **Make sure the swab tip is touching the nostril walls as you rotate.** Take approximately 15 seconds to collect the sample.





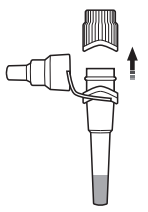
4. Remove the swab from the nostril.
5. Using the same swab, repeat Step 3 to Step 4 in another nostril. **It is important to collect samples from BOTH nostrils using the same swab.**
6. After the sample collection is complete, proceed to the assay procedure as soon as possible. Do NOT place the swab back into the packaging after sample collection is complete.

- It is recommended that the collection of specimens be done by physicians or healthcare providers, and/or could be self-collected without healthcare professional depend on local regulatory requirements.
- The instruction in specimen collection is highly recommended because of the importance of specimen quality. If the correct procedure in handling specimens is not followed, the value of the test results may be compromised or even negated.
- The test should be conducted as soon as possible after the sample is collected.
- For optimal test performance, use the swabs supplied in the kit.
- Please follow the local regulations for the collection, storage and transport of the specimens.

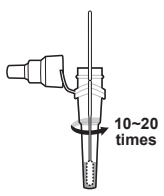
ASSAY PROCEDURE

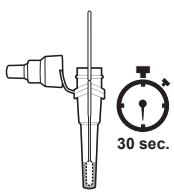
- Bring the extraction buffer tube and individually foil packaged test cassette to room temperature approximately 30 minutes before performing the assay.
- All specimens, assay materials and procedures must be handled at room temperature.
- Check the expiration date printed on each kit contents before use. Do not use any accessory past the expiration date.
- Remove the cassette from the foil package before use and place it on a flat and dry surface.

1. Identify the Cassette for each sample with the individual's name and/or number.
2. Remove and discard the cap from the extraction buffer tube.

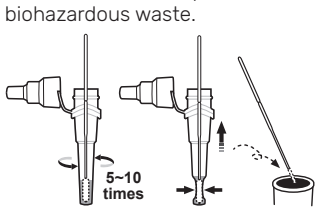


3. Immerse the patient nasopharyngeal or nasal swab sample into the extraction buffer tube. Roll the swab at least ten-twenty (10-20) times while pressing the head against the bottom and side of the extraction buffer tube. Try to dissolve the sample in the extract as much as possible. Leave the swab in the extraction buffer for 30 seconds.

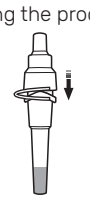




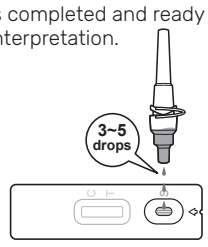
4. When removing, roll the swab head toward the inside of the extraction buffer tube at least five-ten (5-10) times and squeeze the sides of the tube to extract the liquid from the swab. Dispose of the used swab in your biohazardous waste.



5. Press the attached cap tightly onto the extraction buffer tube containing the processed sample.



6. Add 3~5 drops about 100 µL of the processed sample into the sample (S) well. Do not handle or move the cassette until the test is completed and ready for interpretation.



7. An interpretation is available within 15-20 minutes. Some positive results may appear sooner.

CAUTION:

1. Do not read the results after 20 minutes. It may provide false results.

2. Make sure you place the test strip on a flat table. Do not move the strip during the test.

INTERPRETATION OF RESULTS

Valid Assay:

Positive:

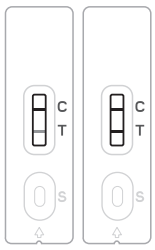
In addition to the presence of the colored C line, if the colored T line appears, the test result indicates the presence of SARS-CoV-2 virus in the nasopharyngeal or nasal swab sample. The result is COVID-19 positive or COVID-19 reactive. Within the specified observation time, a very weak colored line should be judged as a positive result.

False positive results may occur due to cross-reacting antigens from previous infections, such as other coronaviruses, or from other causes.

Positive results should be confirmed with a molecular diagnostic test (e.g. RT-PCR) and clinical findings before a diagnostic determination is made.

For self-user, you need to contact with your healthcare provider to determine how best to care for you based on your test result(s).

Positive



Negative:

If only the colored C line appears, the test result indicates that SARS-CoV-2 virus is not detected at the time when the nasopharyngeal or nasal swab sample was collected. The result is COVID-19 negative or COVID-19 non-reactive.

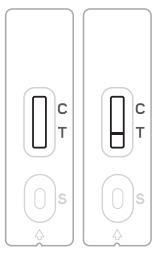
Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test (e.g. RT-PCR) is necessary to rule out infection in these individuals.

Negative

Invalid Assay:

There should always be a colored control line in the control region regardless of the test result. If the control line is not seen, repeat the assay with a new test cassette.

Invalid Assay



Negative / High CT value :

Within a specified observation time a very weak and faded colored on T line should be judged as negative high CT value, please refer to RT-PCR result.

⚠ It is important that you work with your healthcare provider to help you understand further information on the next steps to take after testing.

Negative / High CT value

QUALITY CONTROL

FORA COVID-19 Antigen Rapid Test uses the Internal Control as the mechanism for quality control. A colored Control (C) line is an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique.

External positive and negative controls are not supplied with this kit; however, external positive and negative controls should be tested in consistent with good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE PROCEDURE

1. The contents in this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from fresh nasopharyngeal swab and fresh nasal swab specimens.
2. Failure to follow the test procedure or incorrect interpretation of results may adversely affect test performance and result in invalid interpretation.
3. This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
4. A negative test result may occur if the amount of virus (antigen) in a sample is below the limit of the assay or if the sample was not collected properly.
5. Test results must be evaluated in conjunction with other clinical data available to the physician.
6. The color of the test line has no correlation with clinical symptoms and severity. The interpretation of the test results must be evaluated together with epidemiology, clinical symptoms, and other diagnostic methods.
7. Positive test results do not rule out co-infections with other viruses.
8. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
9. Negative results cannot completely rule out the possibility of COVID-19 infection. The possible cause is that the amount of virus (antigen) in the sample is too low to be detected or the sample is not collected properly. Negative results must be determined with an WHO authorized molecular assay.
10. Users should test samples as quickly as possible after sample collection.
11. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with local public health departments, is required.

ANALYTICAL PERFORMANCE

Limit of Detection(LoD)

The Limit of Detection (LoD) of FORA COVID-19 Antigen Rapid Test was determined using limiting dilutions of live SARS-CoV-2, isolate TWN/CG-MH-CGU-01. The material was supplied frozen at a concentration of $10^{5.4}$ $TCID_{50}$ per mL. The study to determine the FORA COVID-19 Antigen Rapid Test LoD was designed to reflect the assay when using direct nasopharyngeal or nasal swab.

In this study, all the SARS-CoV-2 serial dilutions were made in the SARS-CoV-2 negative nasopharyngeal swab pool.

The LoD was determined in three steps:

1. LoD Screening
   10-fold dilutions of the live SARS-CoV-2 were made as described above. These dilutions were tested in triplicate. The concentration demonstrating 3 of 3 positives was chosen for LoD range finding.
   Based on this testing, the concentration chosen for LoD Range Finding was $10^{2.4}$ $TCID_{50}$ per mL.
2. LoD Range Finding
   Five (5) 2-fold dilutions of the $10^{2.4}$ $TCID_{50}$ per mL concentration were made as described above. These dilutions were tested in triplicate. The concentration demonstrating 3 of 3 positives was chosen for LoD confirmation.
   Based on this test the concentration chosen was 1.26 x 10^2 $TCID_{50}$ per mL.
3. LoD Confirmation
   The concentration 1.26x10^2 $TCID_{50}$ per mL dilution was tested for a total of twenty (20) results. Twenty (20) of twenty (20) results were positive.
   Based on this test the concentration of LoD was confirmed as 1.26 x 10^2 $TCID_{50}$ per mL.

Cross-Reactivity

Cross-reactivity of the FORA COVID-19 Antigen Rapid Test was evaluated by testing various viruses (17) and bacteria (19). Each virus or bacteria was tested in triplicate in the absence or presence of **3.78 x 10^2 $TCID_{50}$/mL (3 LoD)** of live SARS-CoV-2. The final concentration of each virus or bacteria was listed in the Table below. Testing was performed in triplicate.

Based on the data generated by this study, each virus or bacteria tested with FORA COVID-19 Antigen Rapid Test does not cross-react or interfere.

Clinical Performance

Clinical performance of FORA COVID-19 Antigen Rapid Test was determined by testing 103 positive and 268 negative specimens for SARS CoV-2 antigen (Ag) to have a sensitivity of 94.2% (95%CI: 87.9%-97.3%) and specificity of 99.6% (95%CI: 97.9%-99.9%).

		PCR Test Result		
		Positive	**Negative**	**Subtotal**
FORA COVID-19 Antigen Rapid Test (TD-4531)	**Positive**	97	1	98
	Negative	6	267	273
	Subtotal	103	268	371
Sensitivity		94.2% (95%CI: 87.9%-97.3%)		
Specificity		99.6% (95%CI: 97.9%-99.9%)		

Cross-Reactivity: FORA COVID-19 Antigen Rapid Test - Wet Testing

Virus/Bacteria	Concentration	Cross-Reactive Results	SARS-CoV-2 Concentration (3 LoD)	Interference Results
Human Coronavirus OC43	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Human Coronavirus 229E	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Influenza A，H1N1	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Influenza A，H3N2	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Influenza B，Victoria	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Influenza B，Yamagata	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Respiratory syncytial virus	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Rhinovirus	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Adenovirus type 1 (Adenoid 71)	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Adenovirus type 7	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Enterovirus 68	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Human parainfluenza type 1	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Human parainfluenza type 2	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Human parainfluenza type 3	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Human parainfluenza type 4	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Respiratory syncytial virus type A	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Respiratory syncytial virus type B	2.5 x 10^5 pfu/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Bordetella pertussis	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Chlamydia pneumoniae	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Corynebacterium sp.	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Escherichia coli	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Hemophilus influenzae	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Lactobacillus sp.	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Moraxella catarrhalis	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Mycobacterium tuberculosis (avirulent)	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Neisseria meningitidis	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Neisseria sp.	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Pseudomonas aeruginosa	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Staphylococcus aureus (Protein A producer)	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Staphylococcus epidermidis	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Streptococcus pneumoniae	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Streptococcus pyogenes	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Streptococcus salivarius	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Pooled human nasal wash – representative of normal respiratory microbial flora	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Mycoplasma pneumoniae	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Legionella Pneumophila	2 x 10^6 CFU/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive

Interference Substances Studies

A study was performed demonstrate that twenty (20) potentially interfering substances that may be found in the upper respiratory tract do not cross-react or interfere with the detection of SARS-CoV-2 in FORA COVID-19 Antigen Rapid Test. Each substance was tested in triplicate in the absence or presence of **3.78 x 10^2 $TCID_{50}$/mL (3 LoD)** of live SARS-CoV-2.

Based on the data generated by this study, the substances tested FORA COVID-19 Antigen Rapid Test do not cross-react or interfere.

Interfering Substance	Active Ingredient	Concentration	Cross-Reactive Results	SARS-CoV-2 Concentration (3 LoD)	Interference Results
Ephrine Nasal Spray "GCPC"	Oxymetazoline	5% v/v	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Chloraseptic, Regular strength	Benzocaine / Menthol	1.5 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Tamiflu	Oseltamivir	2.5 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Physiomer Saline nasal spray	Saline	15% v/v	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Tobrex Eye Ointment	Tobramycin	51.4 µmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Sucrets	Dyclonine / Menthol	1.5 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
NeilMed NasoGEL Spray	sodium hyaluronate / Saline	5% v/v	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Acetaminophen	Acetaminophen	1324 µmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Acetylsalicylic acid	Acetylsalicylic acid	3.62 mmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Ibuprofen	Ibuprofen	2.425 mmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Erythromycin	Erythromycin	81.6 µmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Fisherman's Friend	Menthol	1.5 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Plaquenil	Hydroxychloroquine sulphate	150 µmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
SUPEROCIN	Ciprofloxacin	30.2 µmol/L	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Zeffix	Lamivudine	1 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Blood (human)	Blood (human)	2.5% v/v	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Ricola	Menthol	1.5 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Mupirocin	Mupirocin	10 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Flonase	Fluticasone	5% v/v	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive
Purified mucin protein	Mucin protein	2.5 mg/mL	Negative	3.78 x 10^2 $TCID_{50}$/mL	Positive

SYMBOL INFORMAION

SYMBOL	REFERENT	SYMBOL	REFERENT
IVD	*In vitro* diagnostic medical device		Do not re-use
	Use-by date		Consult instructions for use
LOT	Batch code		Manufacturer
	Temperature limit	EC REP	Authorized representative in the European Community
CE	CE mark	REF	Model number
	Do not use if package is damaged	Σ	Contains sufficient for <n> tests

EC REP **MedNet EC-REP GmbH**
Borkstraβe 10, 48163
Münster, Germany

TaiDoc Technology Corporation
B1-7F, No.127, Wugong 2nd Rd.,Wugu Dist., 24888 New Taipei City, Taiwan

For Professional Use and for Self-collection

CE REF TD-4531 IVD