SARS-CoV-2 Antigen Rapid Qualitative Test

Instructions for Use

Catalog No.BT1309

Please read these instructions completely before beginning testing of specimens.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Qualitative Test is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human nasal swabs, throat swabs, and sputum samples from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in upper respiratory samples or lower respiratory samples 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 infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of 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.

The SARS-CoV-2 Antigen Rapid Qualitative Test is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures, and proper infection control procedures and individuals similarly trained in point of care settings.

SUMMARY

SARS-CoV-2 belongs to the broad family of viruses known as coronaviruses. It is a positive-sense single-stranded RNA (+ssRNA) virus. Other coronaviruses are capable of causing illnesses ranging from the common cold to more severe diseases such as Middle East respiratory syndrome (MERS). It is the seventh known coronavirus to infect people, after 229E, NL63, OC43, HKU1, MERS-CoV, and the original SARS-CoV. Protein modeling experiments on the spike (S) protein of the virus suggest that it has sufficient affinity to the angiotensin converting enzyme 2 (ACE2) receptors of human cells to use them as a mechanism of cell entry. Studies have shown that SARS-CoV-2 has a higher affinity to human ACE2 than the original SARS virus strain.

SARS-CoV-2 infections cause COVID-19 disease. People who have confirmed COVID-19 have a range of symptoms, from people with little to no symptoms to people being severely sick and dying. Symptoms can include: fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention.

Human-to-human transmission of the virus has been confirmed and occurs primarily via respiratory droplets from coughs and sneezes within a range of about 6 feet (1.8m). Viral RNA has also been found in stool specimens from infected patients. It is possible that the virus can be infectious even during the incubation period, but this has not been proven, and the WHO stated on 1 February 2020 that "transmission from asymptomatic cases is likely not a major driver of transmission" at this time.

The median incubation time is estimated to be approximately 5 days with symptoms estimated to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough, shortness of breath.

PRINCIPLES OF THE PROCEDURE

This reagent is based on colloidal gold immunochromatography assay.

During the test, sample extracts are applied to the test cartridges. If there were SARS-CoV-2 antigen in the extract, the antigen will bind to the SARS-CoV-2 monoclonal antibody. During lateral flow, the complex will move along the nitrocellulose membrane toward the end of the absorbent paper. When passing the test line (line T, coated with another SARS-CoV-2 monoclonal antibody) the complex is captured by SARS-CoV-2 antibody on test line resulting in coloring on line T; when passing the line C, colloidal gold-labeled goat anti-rabbit IgG is captured by control line (line C, coated with rabbit IgG) resulting in coloring on line C.

REAGENTS

The following components are included in the SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2.

Specification and Component

Specification / Component	10Tests/Kit	25Tests/Kit	Note
SARS-CoV-2 Antigen Test Cartridge	10	25	Materials Provided
Extraction Tube	10	25	Materials Provided
Extraction Solution	1 bottle/kit	2 bottles/kit	Materials Provided
Instructions for Use	1 copy/kit	1 copy/kit	Materials Provided
Qualification Certificate	1 copy/kit	1 copy/kit	Materials Provided
Throat Swab	10	25	Optional Materials (Scheme A)
Nasal Swab	10	25	Optional Materials (Scheme B)
Screw-cap Collection Cup	10	25	Optional Materials (Scheme C)
Transfer Pipette	10	25	

Note: Our customers and agents can choose one of the three schemes mentioned-above respectively.

Materials required but not provided:

1. Timer
2. Tube rack for specimens
3. Any necessary personal protective equipment
4. External control set

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
3. Do not use this kit beyond the expiration date printed on the outside carton.
4. Do not use the kit to evaluate patient specimens if either the positive control or negative control fail to give expected results.
5. Test results are meant to be visually determined.
6. To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
7. Do not reuse any kit components.
8. When collecting a nasal swab sample, use the nasal swab supplied in the kit. Use of alternative swabs may result in false negative results.
9. Proper sample collection, storage and transport are critical to the performance of this test.
10. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.
11. The SARS-CoV-2 external positive control have been prepared from recombinant viral proteins and do not contain infectious material.
12. Dispose of used test kits as biohazardous waste in accordance with local requirements.
13. Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.

STORAGE CONDITIONS & PERIOD OF VALIDITY

1. Store extraction solution at 2-30℃, the shelf life is 24 months tentatively.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months tentatively.
3. Test Cartridge should be used rightly after opening the pouch.

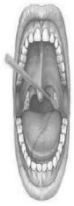
Reagents and devices must be at room temperature (15–30 °C) when used for testing.

SPECIMEN COLLECTION AND HANDING

Specimen Collection and Preparation

Throat Swab Specimen Collection:

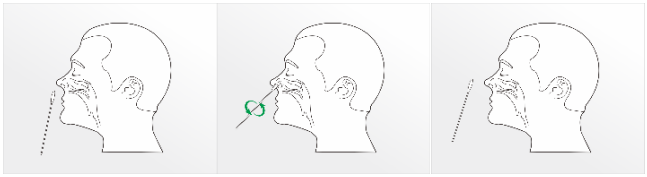
Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with moderate force back and forth for at least 3 times.



Nasal Swab Specimen Collection:

1. Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril.
2. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected
3. Using the same swab, repeat this process for the other nostril to ensure that an

adequate sample is collected from both nasal cavities. Withdraw the swab from the nasal cavity.



Sputum Specimen Collection:

1. Rinse the mouth with water.
2. Expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap collection cup.

Specimen Transport and Storage:

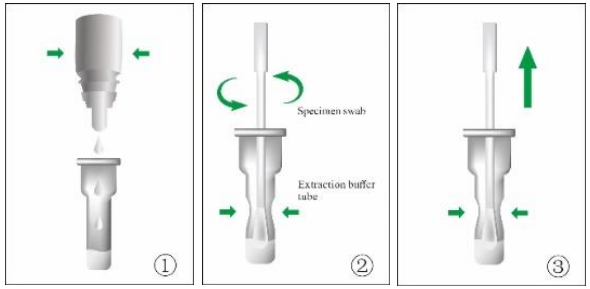
Samples should be tested as soon as possible after collection. Specimens are stable for up to 24 hours at room temperature or 2°C to 8°C.

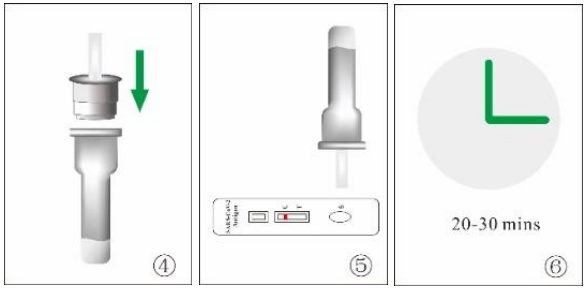
TEST METHODS

The test should be operated at room temperature（15-30℃）.

For Nasal Swab Specimen/ Throat Swab Specimen

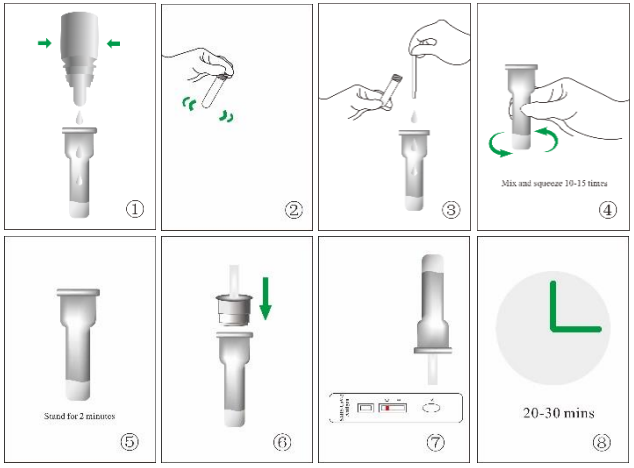
1. Place the extraction tube with opening facing up. Press the extraction solution bottle to drip 6 drops of extraction solution into the extraction tube without touching the edge of the tube.
2. The extraction of specimen: Put the swab that had collected specimen into the extraction tube, hold and press the swab head against the wall of tube with force while rotating the swab for about 10 seconds to release the antigen into the extraction solution from the swab head.
3. Removing swab: Squeeze the swab head while removing the swab in order to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal regulations.
4. Install the nozzle cap onto the extraction tube.
5. Loading: drip 2 drops of extraction solution into the sample well of the test cartridge, and start the timer.
6. Read the results at 20~30 minutes. If positive signal appears after 30 minutes, it should not be reported as positive.





For Sputum Specimen

1. Place the extraction tube with opening facing up. Press the extraction solution bottle to drip 10 drops of extraction solution into the extraction tube without touching the edge of the tube.
2. Vortex or thoroughly mix sputum specimen. Do not centrifuge.
3. Transfer 300μL of specimen into the extraction tube using transfer pipette.
4. Mix well and squeeze 10-15 times. Stand for 2 minutes. Install the nozzle cap onto the extraction tube.
5. Loading: drip 2 drops of extraction solution into the sample well of the test cartridge, and start the timer.
6. Read the results at 20~30 minutes. If positive signal appears after 30 minutes, it should not be reported as positive.



INTERPRETATION OF TEST RESULTS

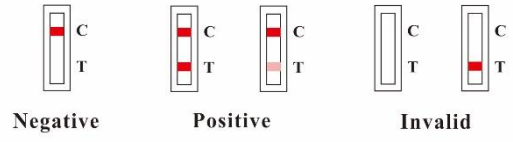
Line C must be colored to have a valid test result.

Valid results:
Negative result: There is coloration on line C only showing as following picture, suggesting that there is no SARS-CoV-2 antigen in the specimen.

Positive result: There are coloration on both line C and line T showing as follow pictures, suggesting that there is SARS-CoV-2 antigen in the specimen.

Invalid result:

There is no coloration on line C, as shown in the following pictures. The test is invalid or an error in operation occurred. Repeat the assay with a new cartridge.



REPORTING OF RESULTS

Positive Test:

Positive for the presence of SARS-CoV-2 antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative Test :

Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management Control.

Invalid:

Do not report results. Repeat the test.

QUALITY CONTROL

The SARS CoV-2 Antigen Control Set (catalog number: 1339) is available to purchase separately from Innova Medical Group, Inc. as external controls. The control set can be ordered through website (www.innovamedgroup.com), telephone(+1-(626)239-0025) and email (info@innovamedgroup.com). One negative and one positive control are included in the control set. Returning expected test results for each control in the control set indicates appropriate performance of SARS-CoV-2 Antigen Rapid Qualitative Test. If any control of the control set fail to provide the expected result, reasons that have led to failure including the test kit, the operator, the environment, the test procedure and any other causes which may affect the test result should be analyzed and corrective action taken. Clinical specimens can be run in the Innova SARS-CoV-2 Antigen Rapid Qualitative Test. If all the control set results observed are the expected results. Please refer to the Instructions For Use of Innova SARS-CoV-2 Antigen Control Set for expected test results as well as other information. It is recommended that the controls are tested when:

A. A new operator uses the kit;

B. A new lot of test kits is used;

C. A new shipment of kits is used;

D. The temperature used during storage of the kit falls outside of the recommended conditions;

E. The temperature of the test area falls outside of 15-30°C;

F. To verify a higher than expected frequency of positive or negative results;

G. To investigate the cause of repeated invalid results.

H. A new test environment is used (e.g., natural light vs. artificial light).

I. As required by external quality control procedures and in accordance with local regulations or accreditation requirements.

NOTE: Prepare kit control and test using the same procedure as used for patient specimens. Failure of the external/procedural controls will generate an invalid test result.

If the kit controls do not perform as expected, do not report patient results. Contact Innova Medical Group, Inc. Technical Services at +1-(626)239-0025 or email(info@innovamedgroup.com).

LIMITATIONS OF THE PROCEDURE

1. Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.
2. Users should test specimens as quickly as possible after specimen collection.
3. Positive test results do not rule out co-infections with other pathogens.
4. Results from SARS-CoV-2 Antigen Rapid Qualitative Test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
5. A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
6. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.
7. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
8. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swabs, throat swabs or sputum samples only.
9. The kits for rapid detection of SARS-CoV-2 can detect both viable and non-viable SARS-CoV-2 material. The SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2 performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
10. Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
11. Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
12. This device has been evaluated for use with human specimen material only.
13. Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
14. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
15. The kit was validated with the assorted swabs. Use of alternative swabs may result in false negative results.
16. The validity of SARS-CoV-2 Antigen Rapid Qualitative Test has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.

CLINICAL PERFORMANCE

The performance of the Innova SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2 was established with 295 direct nasal swab or throat swab prospectively collected and enrolled from individual symptomatic patients (within 5 days of onset) who were selected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increases. For each type, four kinds of samples from the same person were tested by Company's Kit. We selected 25 positive and 25 negative sample. P1-P25 of samples are from infected people, and NI-N25 are from uninfected people. P21-P25 are weak positive.

Method		PCR Test		Total Results
	Results	Positive	Negative	
Innova Results	Positive	72	0	72
	Negative	3	220	223
Total Results		75	220	295

*** 95% Confidence Interval**

Relative Sensitivity:	72/75	96.00% (88.75%～99.17%)
Relative Specificity:	220/220	100.00% (98.34%～100.00%)
Accuracy:	292/295	98.98% (97.06%～99.79%)

ANALYTICAL PERFORMANCE

CROSS REACTIVITY (ANALYTICAL SPECIFICITY)

Human sputum matrix

Cross-reactivity of the SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2 was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2. Each organism and virus spiked into negative sputum specimen was wet-tested in triplicate. The final concentration of each organism is documented in the following table.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
1	Human coronavirus 229E	2.0 x 10^6 TCID50/mL	NO
2	Human coronavirus OC43	2.0 x 10^6 TCID50/mL	NO
3	Human coronavirus NL63	2.0 x 10^6 TCID50/mL	NO
4	SARS-coronavirus	2.0 x 10^6 TCID50/mL	NO
5	MERS-coronavirus	2.0 x 10^6 TCID50/mL	NO
6	Human Metapneumovirus (hMPV)	2.0 x 10^6 TCID50/mL	NO
7	Parainfluenza virus 1	2.0 x 10^6 TCID50/mL	NO
8	Parainfluenza virus 2	2.0 x 10^6 TCID50/mL	NO
9	Parainfluenza virus 3	2.0 x 10^6 TCID50/mL	NO
10	Parainfluenza virus 4	2.0 x 10^6 TCID50/mL	NO
11	Influenza A	2.0 x 10^6 TCID50/mL	NO
12	Influenza B	2.0 x 10^6 TCID50/mL	NO
13	Enterovirus EV71	2.0 x 10^6 TCID50/mL	NO
14	Enterovirus CA16	2.0 x 10^6 TCID50/mL	NO
15	Respiratory syncytial virus	2.0 x 10^6 TCID50/mL	NO
16	Rhinovirus	2.0 x 10^6 TCID50/mL	NO
17	Haemophilus influenzae	2.0 x 10^7 TCID50/mL	NO
18	Streptococcus pneumoniae	2.0 x 10^7 TCID50/mL	NO
19	Streptococcus pyogenes	2.0 x 10^7 TCID50/mL	NO
20	Bordetella pertussis	2.0 x 10^7 TCID50/mL	NO
21	Mycoplasma pneumoniae	2.0 x 10^7 TCID50/mL	NO
22	Chlamydia pneumoniae	2.0 x 10^7 TCID50/mL	NO
23	Legionella pneumophila	2.0 x 10^7 TCID50/mL	NO
24	Mycobacterium tuberculosis	2.0 x 10^7 TCID50/mL	NO
25	Pneumocystis jirovecii (PJP)	2.0 x 10^7 TCID50/mL	NO
26	Normal nasal flush fluid	/	NO

Note : 1 TCID50/mL≈0.7CFU/mL
Based on the data generated by this study, the substances tested SARS-CoV-2 Antigen Rapid Qualitative Test do not cross-react.

Human NP swabs samples without VTM matrix

Cross-reactivity of the SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2 was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the SARS-CoV-2 Antigen Rapid Qualitative Test for rapid detection of SARS-CoV-2. Each organism and virus spiked into negative NP swabs samples without VTM was wet-tested in triplicate. The final concentration of each organism is documented in the following table.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
1	Human coronavirus 229E	2.0 x 10^6 TCID50/mL	NO
2	Human coronavirus OC43	2.0 x 10^6 TCID50/mL	NO
3	Human coronavirus NL63	2.0 x 10^6 TCID50/mL	NO
4	SARS-coronavirus	2.0 x 10^6 TCID50/mL	NO
5	MERS-coronavirus	2.0 x 10^6 TCID50/mL	NO
6	Human Metapneumovirus (hMPV)	2.0 x 10^6 TCID50/mL	NO
7	Parainfluenza virus 1	2.0 x 10^6 TCID50/mL	NO
8	Parainfluenza virus 2	2.0 x 10^6 TCID50/mL	NO
9	Parainfluenza virus 3	2.0 x 10^6 TCID50/mL	NO
10	Parainfluenza virus 4	2.0 x 10^6 TCID50/mL	NO
11	Influenza A	2.0 x 10^6 TCID50/mL	NO
12	Influenza B	2.0 x 10^6 TCID50/mL	NO
13	Enterovirus EV71	2.0 x 10^6 TCID50/mL	NO
14	Enterovirus CA16	2.0 x 10^6 TCID50/mL	NO
15	Respiratory syncytial virus	2.0 x 10^6 TCID50/mL	NO
16	Rhinovirus	2.0 x 10^6 TCID50/mL	NO
17	Haemophilus influenzae	2.0 x 10^7 TCID50/mL	NO
18	Streptococcus pneumoniae	2.0 x 10^7 TCID50/mL	NO
19	Streptococcus pyogenes	2.0 x 10^7 TCID50/mL	NO
20	Bordetella pertussis	2.0 x 10^7 TCID50/mL	NO
21	Mycoplasma pneumoniae	2.0 x 10^7 TCID50/mL	NO
22	Chlamydia pneumoniae	2.0 x 10^7 TCID50/mL	NO
23	Legionella pneumophila	2.0 x 10^7 TCID50/mL	NO
24	Mycobacterium tuberculosis	2.0 x 10^7 TCID50/mL	NO
25	Pneumocystis jirovecii (PJP)	2.0 x 10^7 TCID50/mL	NO
26	Normal nasal flush fluid	/	NO

Note :1 TCID50/mL≈0.7CFU/mL

Based on the data generated by this study, the substances tested SARS-CoV-2 Antigen Rapid Qualitative Test do not cross-react.

MICROBIAL INTERFERENCE STUDIES

Human sputum matrix

The starting material was spiked into a volume of pooled human sputum (the most challenging respiratory matrix) obtained from healthy donors and confirmed negative for SARS-CoV-2. Based on the LoD studies, a low (3xLoD) SARS-CoV-2 concentration matrix contrived sputum sample was chosen. The specimen was confirmed positive for SARS-CoV-2 with faintly line on Line T. Furthermore, the above-mentioned specimen was divided into 30. Finally, the microorganism indicated below was respectively spiked into the divided specimen to obtain microbial interference specimens that SARS-CoV-2 is present in a specimen with one microorganism.

Each microbial interference specimen was tested individually. At each test, 75 µL samples were added to swab. The results shows that the specimen was confirmed positive for SARS-CoV-2 with faintly line on Line T. Based on the study, no appreciable interference was observed for the following substances at the spiked levels indicated below in sputum matrix.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
1	Human coronavirus 229E	2.0 x 10^6 TCID50/mL	NO
2	Human coronavirus OC43	2.0 x 10^6 TCID50/mL	NO
3	Human coronavirus NL63	2.0 x 10^6 TCID50/mL	NO
4	SARS-coronavirus	2.0 x 10^6 TCID50/mL	NO
5	MERS-coronavirus	2.0 x 10^6 TCID50/mL	NO
6	Human Metapneumovirus (hMPV)	2.0 x 10^6 TCID50/mL	NO
7	Parainfluenza virus 1	2.0 x 10^6 TCID50/mL	NO
8	Parainfluenza virus 2	2.0 x 10^6 TCID50/mL	NO
9	Parainfluenza virus 3	2.0 x 10^6 TCID50/mL	NO
10	Parainfluenza virus 4	2.0 x 10^6 TCID50/mL	NO
11	Influenza A	2.0 x 10^6 TCID50/mL	NO
12	Influenza B	2.0 x 10^6 TCID50/mL	NO
13	Enterovirus EV71	2.0 x 10^6 TCID50/mL	NO
14	Enterovirus CA16	2.0 x 10^6 TCID50/mL	NO
15	Respiratory syncytial virus	2.0 x 10^6 TCID50/mL	NO
16	Rhinovirus	2.0 x 10^6 TCID50/mL	NO
17	Haemophilus influenzae	2.0 x 10^7 TCID50/mL	NO
18	Streptococcus pneumoniae	2.0 x 10^7 TCID50/mL	NO
19	Streptococcus pyogenes	2.0 x 10^7 TCID50/mL	NO
20	Bordetella pertussis	2.0 x 10^7 TCID50/mL	NO
21	Mycoplasma pneumoniae	2.0 x 10^7 TCID50/mL	NO
22	Chlamydia pneumoniae	2.0 x 10^7 TCID50/mL	NO
23	Legionella pneumophila	2.0 x 10^7 TCID50/mL	NO
24	Mycobacterium tuberculosis	2.0 x 10^7 TCID50/mL	NO
25	Pneumocystis jirovecii (PJP)	2.0 x 10^7 TCID50/mL	NO
26	Normal nasal flush fluid	/	NO

Human NP swabs samples without VTM matrix

The starting material was spiked into a volume of pooled NP swabs samples without VTM (the most challenging respiratory matrix) obtained from healthy donors and confirmed negative for SARS-CoV-2. Based on the LoD studies, a low (3xLoD) SARS-CoV-2 concentration was chosen. The specimen was confirmed positive for SARS-CoV-2 with faintly line on Line T. Furthermore, the above-mentioned specimen was divided into 30. Finally, the microorganism indicated below was respectively spiked into the divided specimen to obtain microbial interference samples that SARS-CoV-2 is present in a specimen with one microorganism.

Each microbial interference specimen was tested individually. At each test, 75µL samples were added to swab. The results shows that the specimen was confirmed positive for SARS-CoV-2 with faintly line on Line T. Based on the study, no appreciable interference was observed for the following substances at the spiked levels indicated below in NP swabs samples without VTM matrix.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
1	Human coronavirus 229E	2.0 x 10^6 TCID50/mL	NO
2	Human coronavirus OC43	2.0 x 10^6 TCID50/mL	NO
3	Human coronavirus NL63	2.0 x 10^6 TCID50/mL	NO
4	SARS-coronavirus	2.0 x 10^6 TCID50/mL	NO
5	MERS-coronavirus	2.0 x 10^6 TCID50/mL	NO
6	Human Metapneumovirus (hMPV)	2.0 x 10^6 TCID50/mL	NO
7	Parainfluenza virus 1	2.0 x 10^6 TCID50/mL	NO
8	Parainfluenza virus 2	2.0 x 10^6 TCID50/mL	NO
9	Parainfluenza virus 3	2.0 x 10^6 TCID50/mL	NO

10	Parainfluenza virus 4	2.0 x 10^6 TCID50/mL	NO
11	Influenza A	2.0 x 10^6 TCID50/mL	NO
12	Influenza B	2.0 x 10^6 TCID50/mL	NO
13	Enterovirus EV71	2.0 x 10^6 TCID50/mL	NO
14	Enterovirus CA16	2.0 x 10^6 TCID50/mL	NO
15	Respiratory syncytial virus	2.0 x 10^6 TCID50/mL	NO
16	Rhinovirus	2.0 x 10^6 TCID50/mL	NO
17	Haemophilus influenzae	2.0 x 10^7 TCID50/mL	NO
18	Streptococcus pneumoniae	2.0 x 10^7 TCID50/mL	NO
19	Streptococcus pyogenes	2.0 x 10^7 TCID50/mL	NO
20	Bordetella pertussis	2.0 x 10^7 TCID50/mL	NO
21	Mycoplasma pneumoniae	2.0 x 10^7 TCID50/mL	NO
22	Chlamydia pneumoniae	2.0 x 10^7 TCID50/mL	NO
23	Legionella pneumophila	2.0 x 10^7 TCID50/mL	NO
24	Mycobacterium tuberculosis	2.0 x 10^7 TCID50/mL	NO
25	Pneumocystis jirovecii (PJP)	2.0 x 10^7 TCID50/mL	NO
26	Normal nasal flush fluid	/	NO

Endogenous Interference Substances Studies:

Human sputum matrix

A study was performed to demonstrate that eighteen (18) potentially interfering substances that may be found in the lower respiratory tract do not cross-react or interfere with the detection of SARS-CoV-2 in the SARS-CoV-2 Antigen Rapid Qualitative Test.

S.N.	Interfering Substance	Concentration	Cross-Reactive Results*	Interference Results**
1	Whole Blood	4%	Negative	Positive
2	Mucin	0.50%	Negative	Positive
3	Ricola (Menthol)	1.5 mg/mL	Negative	Positive
4	Sucrets (Dyclonin/ Menthol)	1.5 mg/mL	Negative	Positive
5	Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Negative	Positive
6	Naso GEL (NeilMed)	5% v/v	Negative	Positive
7	CVS Nasal Drops (Phenylephrine)	15% v/v	Negative	Positive
8	Afrin (Oxymetazoline)	15% v/v	Negative	Positive
9	CVS Nasal Spray (Cromolyn)	15% v/v	Negative	Positive
10	Nasal Gel (Oxymetazoline)	10% v/v	Negative	Positive
11	Zicam	5% v/v	Negative	Positive
12	Homeopathic (Alkalol)	1:10 dilution	Negative	Positive
13	Fisherman's Friend	1.5 mg/mL	Negative	Positive
14	Ore Throat Phenol Spray	15% v/v	Negative	Positive
15	Tobramycin	4µg/mL	Negative	Positive
16	Mupirocin	10 mg/mL	Negative	Positive
17	Fluticasone Propionate	5% v/v	Negative	Positive
18	Tamiflu (Oseltamivir Phosphate)	5mg/mL	Negative	Positive

Based on the data generated by this study, the substances tested SARS-CoV-2 Antigen Rapid Qualitative Test do not cross-react or interfere.

* The negative matrix was chosen for the Cross-Reactive Study.

* * The positive matrix was chosen for the Interference Study.

Human NP swabs samples without VTM matrix

A study was performed to demonstrate that eighteen (18) 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 the SARS-CoV-2 Antigen Rapid Qualitative Test.

S.N.	Interfering Substance	Concentration	Cross-Reactive Results*	Interference Results**
1	Whole Blood	4%	Negative	Positive
2	Mucin	0.50%	Negative	Positive
3	Ricola (Menthol)	1.5 mg/mL	Negative	Positive
4	Sucrets (Dyclonin/ Menthol)	1.5 mg/mL	Negative	Positive
5	Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Negative	Positive
6	Naso GEL (NeilMed)	5% v/v	Negative	Positive
7	CVS Nasal Drops (Phenylephrine)	15% v/v	Negative	Positive
8	Afrin (Oxymetazoline)	15% v/v	Negative	Positive
9	CVS Nasal Spray (Cromolyn)	15% v/v	Negative	Positive
10	Nasal Gel (Oxymetazoline)	10% v/v	Negative	Positive
11	Zicam	5% v/v	Negative	Positive
12	Homeopathic (Alkalol)	1:10 dilution	Negative	Positive
13	Fisherman's Friend	1.5 mg/mL	Negative	Positive
14	Ore Throat Phenol Spray	15% v/v	Negative	Positive
15	Tobramycin	4µg/mL	Negative	Positive
16	Mupirocin	10 mg/mL	Negative	Positive
17	Fluticasone Propionate	5% v/v	Negative	Positive
18	Tamiflu (Oseltamivir Phosphate)	5mg/mL	Negative	Positive

Based on the data generated by this study, the substances tested SARS-CoV-2 Antigen Rapid Qualitative Test do not cross-react or interfere.
* The negative matrix was chosen for the Cross-Reactive Study.
* * The positive matrix was chosen for the Interference Study.

HIGH DOSE HOOK EFFECT

As part of the LoD study the highest concentration (or titer) of heat-inactivated SARS-CoV-2 samples available (6000xLoD) was tested. There was no Hook effect detected.

INDEX OF SYMBOLS

Symbol	Description	Symbol	Description
	In vitro diagnostic medical device		Do not re-use
	Expiry date		Consult instructions for use
	Warning, please refer to the instruction		Manufacturer
	Store at 2-30℃		Lot number
	Keep away from sunlight		Keep dry
	European authorized representative		Don't use the product when the package is damaged
	Date of manufacture		Biological risks
	Sterilized using ethylene oxide		CE mark
	Sterilized using irradiation		

IN VITRO DIAGNOSTIC MEDICAL DEVICE TECHNICAL ASSISTANCE

For technical assistance, call Innova Technical Services at +1(626)239-0025, email info@innovamedgroup.com, or visit Innova website at http:// www.innovamedgroup.com.

GENERAL INFORMATION

Made for

Innova Medical Group, Inc.
Address: 800 E Colorado Blvd., Ste 288 Pasadena, CA 91101 USA
Phone: +1(626)239-0025
Fax: +1(626)239-0038
Website: www.innovamedgroup.com
Email: info@innovamedgroup.com

Distributor

Tried&Tested www.triedandtested.tech

Manufacturer

Xiamen Biotime Biotechnology Co., Ltd.
3F/4F, No.188, Pingcheng South Road, Haicang Street, Haicang District, Xiamen, Fujian 361026, P. R. China.

EC REP Lotus Global Co., Ltd.
Tel: 0044-20-75868010
Fax: 0044-20-79006187
Address: 1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG, United Kingdom.

Version No.: A/05

Issuing Date: 2020-10-15