COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test (Nasal)

A rapid test for the qualitative detection of SARS-CoV-2, Influenza type A virus, Influenza type B virus, Respiratory Syncytial Virus, Adenovirus and Mycoplasma pneumoniae nucleocapsid antigens in anterior nasal swab specimens.
For professional in vitro diagnostic use only.
Please read the package insert carefully before using.

【SPECIFICATION】
1 Test/Kit, 20 Tests/Kit

【INTENDED USE】
The COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test is a lateral flow immunoassay intended for the *in vitro* rapid, simultaneous qualitative detection and differentiation of nucleocapsid antigen from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), Influenza type A virus, Influenza type B virus, Respiratory Syncytial Virus (RSV), Adenovirus (ADV) and Mycoplasma pneumoniae (M. pneumoniae) directly from anterior nasal swab specimens obtained from individuals, who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare providers, within the first seven days of symptoms onset.

【SUMMARY】
Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the SARS-CoV-2 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. Once infected with the SARS-CoV-2 virus, the patient may be hospitalized and some complications may occur. The virus may even lead to death for patients if prompt treatment is not received.

Influenza is a highly contagious acute viral infection of the respiratory tract. It is a communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat and malaise. The influenza A virus is more prevalent and is the primary pathogen associated with serious epidemics. The influenza B virus causes a disease that is generally not as severe as that caused by the influenza A virus.

An accurate diagnosis of influenza based on clinical symptoms is difficult because the initial symptoms of influenza are similar to many other illnesses. Therefore, it can be confirmed only by laboratory diagnostic testing. Early differential diagnosis of influenza type A or type B can allow for proper treatment with appropriate antiviral therapy while reducing the incidence of inappropriate treatment with antibiotics. Early diagnosis and treatment are of particular value in a clinical setting where an accurate diagnosis can assist the healthcare professionals with the management of influenza patients who are at risk for complications.

Respiratory Syncytial Virus is the most common cause of bronchiolitis and pneumonia among infants and children under 1 year of age. Illness begins most frequently with fever, runny nose, cough and sometimes wheezing. Severe lower respiratory tract disease may occur at any age, especially among the elderly or among those with compromised cardiac, pulmonary or immune systems. RSV is spread from respiratory secretions through close contact with infected persons or contact with contaminated surfaces or objects.

Adenoviruses most commonly cause respiratory illness; however, depending on the infecting serotype, they may also cause various other illnesses, such as gastroenteritis, conjunctivitis, cystitis and rash illness. In total, there are 47 different serotypes of adenovirus, all being causative of different symptoms; including conjunctivitis, bronchitis, pneumonia, diarrhea and others. Among them, the serotypes of 8, 14, 16 and 17 have been shown to cause conjunctivitis, while serotypes 7, 14, 21 cause respiratory symptoms. Symptoms of respiratory illness caused by Adenovirus infection range from the common cold syndrome to pneumonia, croup and bronchitis. Patients with compromised immune systems are especially susceptible to severe complications of Adenovirus infection. Adenovirus is transmitted by direct contact, fecal-oral transmission and occasionally waterborne transmission. Some types are capable of establishing persistent asymptomatic infections in tonsils, adenoids and intestines of infected hosts and shedding can occur for months or years.

Mycoplasma pneumoniae is a member of Mycoplasma genus of Mycoplasmataceae family. Mycoplasma is one of the smallest self-replicating organisms. It lacks cell wall and periplasmic space, has reduced genome and limited metabolic activity. M. pneumoniae cells are elongated, with a width of 0.1–0.2 μm and a length of 1-2 μm. It is the human pathogen of mycoplasma pneumonia, which is an atypical bacterial pneumonia related to cold agglutinin disease. Common mild symptoms include sore throat, wheezing and coughing, fever, headache, rhinitis, myalgia and restlessness. In rare cases, mycoplasma pneumonia may lead to death due to damage of epithelial lining and ulcers, pulmonary edema and bronchiolitis obliterans.

The COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test utilizes specific monoclonal antibodies to qualitatively detect SARS-CoV-2, Influenza A virus, Influenza B virus, RSV, ADV, and M. pneumoniae antigen in anterior nasal swab specimens. The test can be performed without cumbersome laboratory equipment, and the results are available at 15-30 minutes.

【TEST PRINCIPLE】
The COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test applies the chemical extraction of viral antigens and the double antibody sandwich method to detect the nucleocapsid protein antigen from SARS-CoV-2, Influenza A virus, Influenza B virus, RSV, ADV and M. pneumoniae in anterior nasal swab specimens. The test consists of test lines of monoclonal antibody and pads containing monoclonal antibody-dye conjugate. If the specimen contains the antigen, both the test line (T, A, and/or B) and the control line (C) will appear, and the result will be positive. If the specimen does not contain the antigen or no antigen is detected or the level of antigen is below the limit of detection, the test line (T, A, and/or B) will not appear, only control line (C) will appear.

When performing the test, an anterior nasal swab specimen is collected and placed into the extraction solution prefilled in extraction tube and manually squeezed, when the antigen is extracted from disrupted virus particles. Take out the test card from sealed foiled pouch and place on a clean, dry and level surface. Add the extracted specimens to the specimen well (S) on the test card, and the solution of extracted specimen will flow to the test strip and migrate through the pads and nitrocellulose membrane of the test strip. The pads contain detector antibodies conjugated to gold dye and the nitrocellulose membrane contains immobilized capture antibodies. If SARS-CoV-2, Influenza A virus, Influenza B virus, RSV, ADV and M. pneumoniae antigens are present in the specimen, they will react with anti-SARS-CoV-2 antibody, anti-influenza antibodies, anti-RSV antibody, anti-ADV antibody, and anti-M. pneumoniae antibody coupled to gold dye particles, migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody line(s) on the membrane, and generate a colored line in the specific test line region (T, A, and/or B), respectively. The rest of the sample and unbound/bound dye complexes continue to migrate to the control line region (C), where immobilized antibodies to the anti-SARS-CoV-2 antibody, anti-influenza antibodies, anti-RSV antibody, anti-ADV antibody and anti-M. pneumoniae antibody capture the dye complexes and form the control line, respectively.

An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control lines, regardless

of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test card and specimen.

【MATERIALS PROVIDED】

1 Test/Kit	20 Tests/Kit
1 x Test card individually foil pouched with a desiccant 1 x Extraction solution 2 x Sterile swab 1 x Package insert	20 x Test card individually foil pouched with a desiccant 20 x Extraction solution 40 x Sterile swab 1 x Package insert

【MATERIALS REQUIRED BUT NOT PROVIDED】

Timer, Pipette, Positive Control Swab, Negative Control Swab, Personal Protective Equipment per local recommendations (such as face mask, face shield/eye goggles and gloves), Biohazard Container.

【WARNINGS AND PRECAUTIONS】

1. For *in vitro* diagnostic use only.
2. Do not reuse the test.
3. Do not freeze the test kit or its components.
4. These instructions must be carefully read and strictly followed by a trained healthcare professional to achieve accurate results. All users should read the instructions before performing test.
5. The test kit is only for the detection of SARS-CoV-2, Influenza A virus, Influenza B virus, RSV, ADV and M. pneumoniae antigen, not for any other viruses or pathogens.
6. The test is intended for use with direct anterior nasal swab specimens.
7. Fresh samples are recommended for use to ensure optimal performance. Freshly collected specimens should be tested immediately.
8. Inadequate or inappropriate specimen collection, storage, and transportation are likely to result in false negative test results.
9. Training in specimen collection is highly recommended because of the importance of specimen quality.
10. To collect anterior nasal swab specimens, use the swab provided in this test kit only. Other swabs may not work properly.
11. Do not eat, drink or smoke in the area where handling specimens or performing the test.
12. Do not use the test kit beyond its expiration date.
13. Do not mix components from different kit lots.
14. Leave test card sealed in its foil pouch until just before use. Do not use the test card if the pouch is damaged or the seal is broken.
15. To avoid contamination or inaccurate test result, do not touch the absorbent tip of swab or reaction area of test card when performing the test.
16. Wear appropriate personal protection equipment and gloves when performing the test, collecting and handling patient specimens.
17. Change gloves between handling of suspected specimens and performing each test.
18. Dispose of all used test devices and potentially contaminated materials in a biohazard container as if they were infectious waste and dispose according to applicable local laws and regulations.

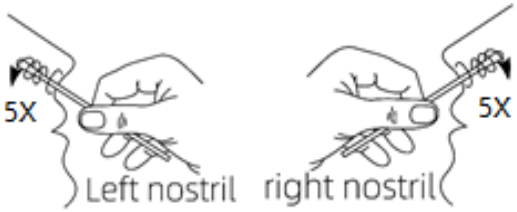
【STORAGE AND STABILITY】

1. The test kit should be stored at a temperature between 2-30°C, away from direct sunlight. Do not freeze the kit or its components.
2. The shelf life of the kit is as indicated on the outer package (24 months from date of manufacture).
3. This test kit is stable until the expiration date marked on the outer package and foil pouch. Ensure all test components are at room temperature (15-30°C) before use.
4. Perform the test immediately after taking out the test card from the foil pouch.

【SAMPLE COLLECTION AND STORAGE】

1. Specimen Collection

To achieve accurate test result, good sample collection is the most important first step. Therefore, carefully follow the instructions below to collect anterior nasal swab specimens to obtain as much secretion as possible.



Use the sterile swab provided in the COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test kit only. Allow the individual's head to relax naturally. Insert the entire soft end of the swab into the individual's nostril no more than 2.5 cm. Slowly rotate the swab in a circular path and gently press against the nostril wall into the nostril of the individual to the nasal palate at least 5 times for no less than 15 seconds. Get as much secretion as possible on the soft end of the swab. Gently withdraw the swab. Repeat the same process in the other nostril using the same swab. Use a second swab to collect specimen in the same way as described above.

2. Specimen Storage

If the specimen cannot be tested immediately after collection, properly store the specimen in a Viral Transport Media (VTM) or Universal Transport Media (UTM) contained in a lidded storage container. The specimens contained in VTM or UTM can be stored for up to 72 hours when refrigerated (2~8℃) or frozen (-20℃).

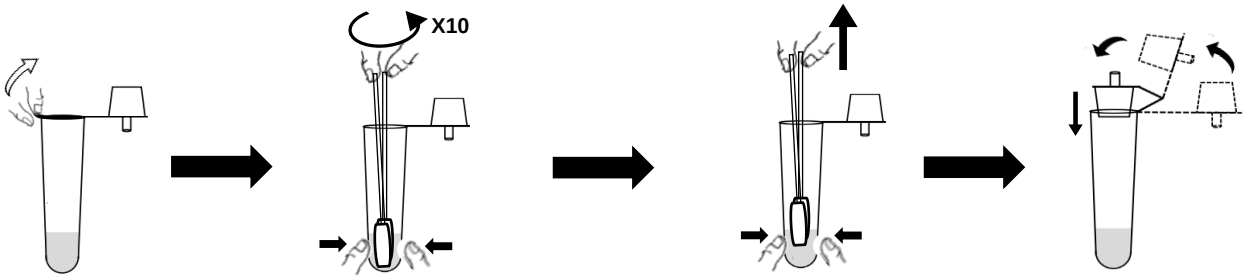
【TEST PREPARATION】

Before testing, open the package and equilibrate the test card, extraction solution and specimens to room temperature, and shake the extraction solution gently before use. The most suitable temperature condition to perform the test is room temperature (15~30℃). If the test kit is stored at room temperature, it can be opened and used immediately.

【TEST PROCEDURES】

1. Tear off the sealing film of the extraction solution tube.
2. Place the swab in the extraction solution tube, rotate the swab for about 10 times and no less than 15 seconds, and press the swab tip against the tube wall to release the antigen in the swab.
3. Squeeze the swab over the swab tip to withdraw the swab so as to extract as much liquid as possible from the swab. Dispose of used swabs according to biohazard waste disposal method and local regulations.
4. Install the dripper of the tube and shake well the tube.

5. Take out the test card from sealed foil pouch and place on a dry, clean and level surface. Add two drops of extracted specimen to each of the specimen well(S) on the test card, and start the timer.
   Notes: Applying sufficient amount of extracted specimen is essential for a valid test result. If migration (the wicking of membrane) is not observed in the test window after one minute, add one more drop to specimen well.
6. Read the results at 15 minutes, and the result after 30 minutes is no longer valid.

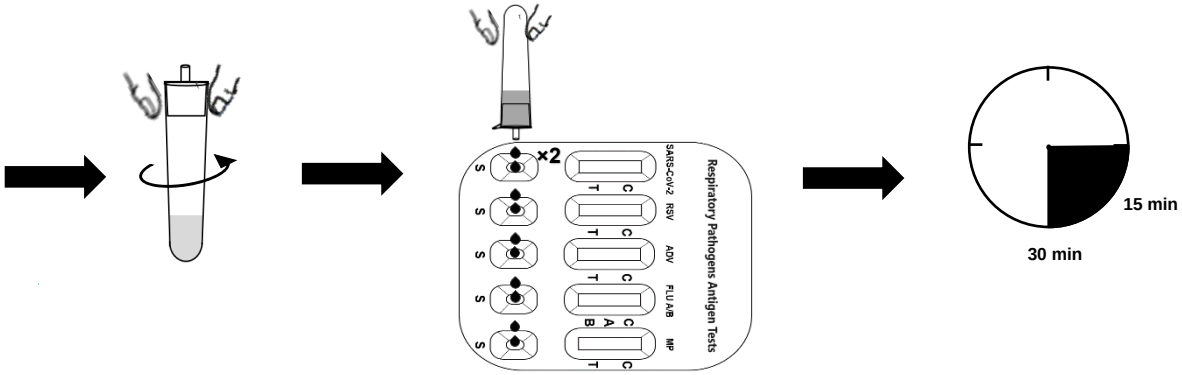


Tear off the sealing film.

Place the two swabs in the extraction solution tube, rotate the swabs and press the swab tips against the tube wall to release the antigen in the swabs.

Squeeze the swabs over the swab tips to withdraw the swabs so as to extract as much liquid as possible from the swab.

Install the dripper of the tube.



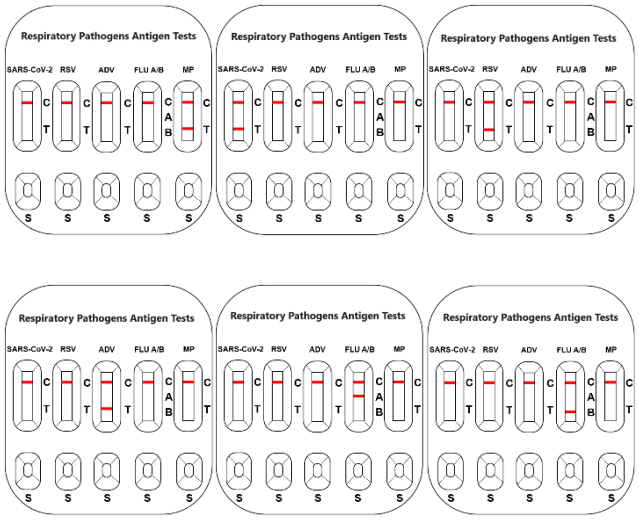
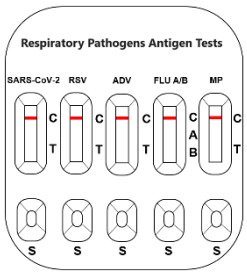
Shake well the tube.

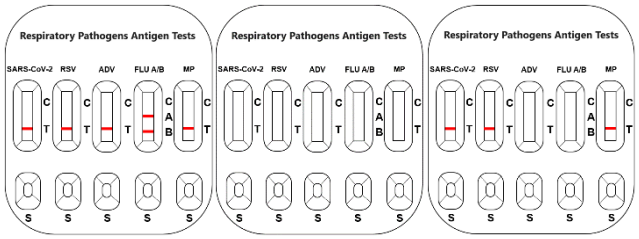
Add 2 drops of extracted specimen to each of the specimen well(S) on the test card, and start the timer.

Read the results at 15-30 minutes, and the result after 30 minutes is no longer valid.

【INTERPRETATION OF TEST RESULTS】

(Please refer to the illustrations below)

Positive* 	Presence of both a reddish purple quality control line (C) and a reddish purple test line(s) (T, and/or A, and/or B) indicate that SARS-CoV-2, RSV, ADV, M. pneumoniae antigen, Influenza A virus, and/or Influenza B virus antigen has been detected. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype. ***NOTE: Co-infection with more than one virus is rare. If test results are positive for more than one antigen, i.e., Influenza A, B and/or SARS-CoV-2, the specimens should be re-tested. The presence of any test line (T, A, B), no matter how faint, within the designated observation time, indicates a positive result.**
Negative 	If there is only a reddish purple quality control line (C) without test line at the T, A and B positions, indicates that SARS-CoV-2, Influenza A virus, Influenza B virus, RSV, ADV and M. pneumoniae antigen has not been detected. A negative result does not exclude SARS-CoV-2, Influenza A virus, Influenza B virus, RSV, ADV or M. pneumoniae infection. **NOTE: Negative results are presumptive and may need to be confirmed with a molecular assay.**

Invalid 	If the quality control line (C) is not observed in 15 minutes, the test result will be invalid regardless of whether there is a test line or not, and the test should be repeated using a new test card.

【LIMITATIONS】

1. The test kit is only used for qualitative testing and does not indicate the number of SARS-CoV-2, Influenza A virus, Influenza B virus, RSV, ADV and M. pneumoniae antigen in the specimens.
2. Failure to follow the instructions or interpretation of test results may adversely affect test performance and/or invalidate the test results.
3. A negative test result may occur if the level of antigen in a specimen is below the detection limit of the test.
4. Positive test results do not rule out co-infections with other pathogens.
5. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
6. Positive test results do not identify specific influenza A virus subtypes.
7. The test kit can identify SARS-CoV-2, influenza A&B virus, RSV, ADV, and M. pneumoniae, but it cannot differentiate influenza subtypes.
8. If differentiation of specific SARS, influenza A&B virus, RSV or ADV subtypes and strains is needed, it is required to perform additional testing in consultation with state or local public health authorities.
9. Individuals who received nasally administered influenza A vaccine may produce positive test results for up to three days after vaccination.
10. Sensitivity can differ with different virus strains due to difference in antigen expression.
11. The performance of this assay has not been evaluated for use in patients without signs and symptoms of respiratory infection.
12. The performance of this test has not been evaluated for immunocompromised individuals.
13. Negative results do not rule out infection with SARS-CoV-2, influenza A, influenza B, RSV, ADV, or M. pneumoniae, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
14. SARS-CoV-2 negative results should be evaluated in conjunction with a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
15. Negative results for patients with symptom onset for more than seven days should be treated as presumptive and confirmation with a molecular assay, and patient management may be performed according to state or local regulations as needed.
16. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low activity when prevalence is moderate to low.

【PERFORMANCE CHARACTERISTIC】

1. Analytical sensitivity (Limit of detection, LoD)

To test the limit of detection, heat inactivated viruses of the virus isolates of SARS-CoV-2, Influenza virus type A, Influenza virus type B, RSV and ADV were used. When tests were repeated 10 times with the diluted virus isolates, the lowest concentration at which more than 95% of the total tested number could be judged as positive test result was determined as the LoD. The LoD of the virus isolates are as follows.

Virus Type	Virus Strains	LoD ($TCID_{50}$/mL)
SARS-CoV-2	USA-WA1/2020	80
Influenza A	Liao Ning/1183/2007 (H1N1)	2.2×10^3
Influenza A	Brisbane /10/2007 (H3N2)	3.9×10^3
Influenza A	A/Taiwan/42/06	1.3×10^3
Influenza A	A/HongKong/8/68	2.58×10^4
Influenza A	A/Victoria/3/75	1.16×10^2
Influenza A	A/Beijing/302/54	3.6×10^3
Influenza A	A/swine/Guangdong/2/01	6.29×10^3
Influenza A	S-OIV A/HK/415742/09	1.68×10^3
Influenza A	S-OIV A/California/4/09	1.9×10^3
Influenza B	Guang Dong/1512/2010	1.6×10^3
Influenza B	Jiang Xi/32/2000	2.9×10^2
Influenza B	B/ Malaysia/2506/2004	3.2×10^5
Influenza B	B/1715	6.7×10^3
Influenza B	B/1704	6.8×10^2
Influenza B	B/Taiwan/2/62	1.58×10^3
Influenza B	B/179	1.98×10^3
Influenza B	B/668	1.5×10^4
Respiratory Syncytial Virus	A (A-2) (Long Subgroup A)	2.5×10^3
Respiratory Syncytial Virus	B WV/14617/85	5.0×10^3
Adenovirus	Adenovirus Type 5	3.9×10^4

2. Cross-reactivity

The cross-reactivity against various microorganisms and viruses that may exist in the specimens was tested. The COVID-

19/RSV/ADV/FLU/MP Antigen Rapid Test showed positive results on the test line (T, A, and B) for SARS-CoV-2 isolate, RSV isolate, ADV isolate, influenza virus type A isolate, influenza virus type B isolate, and M. pneumoniae isolate. Except for these viruses, the COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test does not show cross reactivity with the following pathogens up to the concentrations listed in the table below.

Interfering Substances	Concentration	Interfering Substances	Concentration
Staphylococcus aureus	10^6 cfu/mL	Rhinovirus	10^6 pfu/mL
Staphylococcus epidermidis	10^6 cfu/mL	OC43	10^6 pfu/mL
Streptococcus pneumoniae	10^6 cfu/mL	NL63	10^6 pfu/mL
Streptococcus pyogenes	10^6 cfu/mL	229E	10^6 pfu/mL
Candida albicans	10^6 cfu/mL	Adenovirus C1	10^6 pfu/mL
Bordetella pertussis	10^6 cfu/mL	Adenovirus 71	10^6 pfu/mL
Mycoplasma pneumoniae	10^6 cfu/mL	Human Metapneumovirus (hMPV)	10^6 pfu/mL
Chlamydia pneumoniae	10^6 cfu/mL	Parainfluenza virus 1	10^6 pfu/mL
Legionella pneumophila	10^6 cfu/mL	Parainfluenza virus 2	10^6 pfu/mL
Haemophilus influenzae	10^6 cfu/mL	Parainfluenza virus 3	10^6 pfu/mL
Influenza A	10^6 pfu/mL	Parainfluenza virus 4	10^6 pfu/mL
Influenza B	10^6 pfu/mL	MERS-coronavirus	10^6 pfu/mL
Enterovirus	10^6 pfu/mL	SARS-COV-2	10^6 pfu/mL
Respiratory syncytial virus	10^6 pfu/mL	Human coronavirus HKU1	10^6 pfu/mL
SARS-coronavirus (SARS-CoV)	10^6 pfu/mL	Respiratory Syncytial Virus (RSV)	10^6 pfu/mL

3. Endogenous Interference Studies

The potential interference of endogenous substances with the antibodies used for the detection of SARS-CoV-2, Influenza virus type A, Influenza virus type B, RSV, ADV, and M. pneumoniae was examined by testing below substances in a negative clinical matrix, in the absence or presence of each virus, at 3 x LOD concentrations for SARS-CoV-2, Influenza virus type A, Influenza virus type B, RSV, ADV, and M. pneumoniae. The interference study was conducted using medically relevant concentrations of the potentially interfering substances listed below to assess the potential interference of the substances on the performance of the COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test. No interference was seen with the listed substances when tested at the concentration presented in the table below.

Interfering substances	Concentration	Result
Whole Blood	0.04	No Interference
Mucin	0.005	No Interference
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No Interference
Naso GEL (NeilMed)	5% v/v	No Interference
CVS Nasal Drops (Phenylephrine)	15% v/v	No Interference
Afrin (Oxymetazoline)	15% v/v	No Interference
CVS Nasal Spray (Cromolyn)	15% v/v	No Interference
Zicam	5% v/v	No Interference
Homeopathic (Alkalol)	1:10 dilution	No Interference
Sore Throat Phenol Spray	15% v/v	No Interference
Tobramycin	4 µg/mL	No Interference
Mupirocin	10 mg/mL	No Interference
Fluticasone Propionate	5% v/v	No Interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No Interference

4. High Dose Hook Effect

A high-dose hook effect was not detected in the COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test for the SARS-CoV-2, Influenza virus type A, Influenza virus type B, RSV and ADV at the concentration listed below.

Virus Type	Virus Strains	Concentration
SARS-COV-2	USA-WA1/2020	1.0×10^5 $TCID_{50}$/mL
Influenza A (H1N1)	Liao Ning/1183/2007	1.3×10^5 $TCID_{50}$/mL
Influenza A (H3N2)	Brisbane /10/2007	3.1×10^5 $TCID_{50}$/mL
Influenza B	Guang Dong/1512/2010	1.06×10^5 $TCID_{50}$/mL
Influenza B	Jiang Xi/32/2000	2.8×10^5 $TCID_{50}$/mL
Respiratory Syncytial Virus	A (A-2) (Long Subgroup A)	3.0×10^5 $TCID_{50}$/mL
Respiratory Syncytial Virus	B WV/14617/85	5.0×10^5 $TCID_{50}$/mL
Adenovirus	Adenovirus Type 5	4.5×10^5 $TCID_{50}$/mL

【CLINICAL PERFORMANCE】

To evaluate the clinical performance of the COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test, directly collected anterior nasal swab specimens which were confirmed with reference PCR assay were tested. The positive percent agreement and negative percent agreement are as follows.

Clinical performance compared to PCR Assay: COVID-19 (SARS-CoV-2)

COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test	PCR Assay		
	Positive	**Negative**	**Total**
SARS-CoV-2 Positive	180	2	182
SARS-CoV-2 Negative	8	276	284
Total	188	278	466

Sensitivity (Positive Percent Agreement): 95.74% = 180/188 (95% CI: 91.83%~97.83%)
Specificity (Negative Percent Agreement): 99.28% = 276/278 (95% CI: 97.42%~99.80%)
Accuracy (Overall Percent Agreement): 97.85% = (180+276)/466 (95% CI: 96.10%~98.83%)

Clinical performance compared to PCR Assay: Influenza A

COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test	PCR Assay		
	Positive	**Negative**	**Total**
Influenza A Positive	163	16	179
Influenza A Negative	12	990	1002
Total	175	1006	1181

Sensitivity (Positive Percent Agreement): 93.14%=163/175 (95% CI: 88.40%~96.03%)
Specificity (Negative Percent Agreement): 98.40%=990/1006 (95% CI: 97.43%~99.02%)
Accuracy (Overall Percent Agreement): 97.62%=(163+990)/1181 (95% CI: 96.59%~98.35%)

Clinical performance compared to PCR Assay: Influenza B

COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test	PCR Assay		
	Positive	**Negative**	**Total**
Influenza B Positive	195	15	210
Influenza B Negative	12	1050	1062
Total	207	1065	1272

Sensitivity (Positive Percent Agreement): 94.20%=195/207 (95% CI: 90.14%~96.65%)
Specificity (Negative Percent Agreement): 98.59%=1050/1065 (95% CI: 97.69%~99.14%)
Accuracy (Overall Percent Agreement): 97.87%=(195+1050)/1272 (95% CI: 96.93%~98.54%)

Clinical performance compared to PCR Assay: RSV

COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test	PCR Assay		
	Positive	**Negative**	**Total**
RSV Positive	121	3	124
RSV Negative	9	297	306
Total	130	300	430

Sensitivity (Positive Percent Agreement): 93.07%=121/130 (95% CI: 87.37%~96.32%)
Specificity (Negative Percent Agreement): 99.00%=297/300 (95% CI: 97.10%~99.66%)
Accuracy (Overall Percent Agreement): 97.20%=(121+297)/430 (95% CI: 95.19%~98.40%)

Clinical performance compared to PCR Assay: ADV

COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test	PCR Assay		
	Positive	**Negative**	**Total**
ADV Positive	120	2	122
ADV Negative	10	298	308
Total	130	300	430

Sensitivity (Positive Percent Agreement): 92.30%=120/130 (95% CI: 86.42%~95.77%)
Specificity (Negative Percent Agreement): 99.33%=298/300 (95% CI: 97.59%~99.82%)
Accuracy (Overall Percent Agreement): 97.20%=(120+298)/430 (95% CI: 95.17%~98.39%)

Clinical performance compared to PCR Assay: Mycoplasma Pneumoniae (MP)

COVID-19/RSV/ADV/FLU/MP Antigen Rapid Test	PCR Assay		
	Positive	**Negative**	**Total**
MP Positive	132	2	134
MP Negative	18	298	316
Total	150	300	450

Sensitivity (Positive Percent Agreement): 88.00%=132/150 (95% CI: 81.83%~92.27%)
Specificity (Negative Percent Agreement): 99.33%=298/300 (95% CI: 97.59%~99.82%)
Accuracy (Overall Percent Agreement): 95.55%=(132+298)/450 (95% CI: 93.24%~97.10%)

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【INDEX OF SYMBOLS】

	Consult instruction for use	IVD	For *in vitro* diagnostic use only	REF	Catalog number		Temperature limit
LOT	Lot number		Use by		Do not reuse		Contains sufficient for <X> tests
	Keep dry		Manufacturer		Date of manufacture		Keep away from sunlight
	Do not use if package is damaged						

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