fluorecare®

CE 2934

SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit

PRODUCT NAME

Common Name: **SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)**

REF **MF-71**

WHAT DOES THE KIT TEST?

The fluorecare® SARS-CoV-2 & Influenza A/B & RSV Antigen Combined Test Kit is applicable to the simultaneous qualitative detection and differentiation of novel Coronavirus (SARS-CoV-2 Antigen), Influenza A virus, Influenza B virus Antigen and/or RSV Antigen in population Nasal swabs samples in vitro.

It can be used as an aid to diagnose coronavirus infection disease (COVID-19), caused by SARS-CoV-2, in symptomatic patients within 7 days of onset. It can also be used to aid in the diagnosis of diseases caused by Influenza A/B or RSV.

For in vitro diagnostic use only. For self-testing use.

User age requirement

This kit is suitable for people over 2 years old.

People under the age of 2-14 cannot operate by themselves. This kit should be used by adults or parents (18-60 years old) for sample collection and testing.

People aged 14-17 can use this kit to collect samples and test samples under the supervision of adults or parents (18-60 years old). Supervisors should ensure that users have a detailed understanding of the requirements of the instructions and watch whether the user's operation is correct.

For people over 75 years old, it is recommended that family members or guardians (18-60 years old) use this kit to collect samples and test samples.

BACKGROUD

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

Influenza (flu) is a contagious respiratory illness caused by influenza viruses. Influenza viruses can cause mild to severe illness. Serious outcomes of the flu can result in hospitalization or death. Some people, such as older people, young children, and people with certain underlying health conditions, are at higher risk for serious flu complications. There are two main types of influenza viruses: types A and B. Both type A and B influenza viruses regularly spread in people, and are responsible for seasonal flu each year. Influenza viruses can be spread to others before and after a person shows signs and symptoms of being sick.

Respiratory syncytial virus (RSV) belongs to the genus Pneumovirus of the family Paramyxoviridae. It can be infected by coughing and air droplets, mainly causing lower respiratory tract infections such as bronchiolitis and pneumonia in infants under 6 months, and upper respiratory tract infections such as rhinitis and cold in older children and adults, and bronchitis or pneumonia in the elderly.

PRINCIPLE

The SARS-CoV-2 & Influenza A/B & RSV Antigen test is a qualitatively test to detect SARS-CoV-2 Antigen / Influenza A/B Antigen/RSV Antigen in Nasal swabs samples by the colloidal gold method. After sample added, the SARS-CoV-2 Antigen (or Influenza A/B & RSV) in the sample to be tested is combined with the SARS-CoV-2 (or Influenza A/B & RSV) antibody labelled with colloidal gold on the Conjugate pad to form the SARS-CoV-2 Antigen (or Influenza A/B & RSV) antibody-colloidal gold complex. Due to chromatography, the SARS-CoV-2 Antigen (or Influenza A/B & RSV)-antibody-colloidal gold complex diffuses along the nitrocellulose's membrane. Within the detection line area, the SARS-CoV-2 Antigen (or Influenza A/B & RSV)-antibody complex binds to the antibody enclosed within the detection line area, showing a purple-red band. Colloidal gold labelled SARS-CoV-2 (or Influenza A/B & RSV) antibody diffuses to the quality control line (C) region and is captured by Goat anti-mouse IgG to form red bands. When the reaction is over, the results can be interpreted by visual observation.

MAKE SURE YOUR TEST KIT CONTAINS

1. Test Card
2. Sample treatment solution
3. Sterile nasal swabs
4. Sample treatment tube

.

Specifications

1 Test/box，2 Tests/box ,5 Tests/box

Components	REF MF-71-1	REF MF-71-2	REF MF-71-5	Major Components
	1 Test/box	2 Tests/box	5 Tests/box	
Test Card (including the desiccant）	1 cassette	2 cassettes	5 cassettes	Each test card is mainly composed of a plastic shell and strips. The test strip contains: The Nitrocellulose membrane is coated with SARS-CoV-2, RSV and Influenza A/B antibody, and the Conjugate pad contains colloidal gold-labeled SARS-CoV-2, RSV and Influenza A/B antibody. Other components include PVC pad and absorbent paper.
Instruction of use	1 copy	1 copy	1 copy	/
Sterile nasal swabs	1 piece	2 pieces	5 pieces	/
Prefilled Sample treatment tube	1 tube	2 tubes	5 tubes	The bottle contains buffers of PBS, Trolaton-100, NP-40, and SDS. 0.5 mL per tube

Specific information of Sterile nasal swab:

Manufacturer	CITOTEST Labware Manufacturing Co.,Ltd	Shenzhen MandeLab Co., Ltd.	Shenzhen KangDaAn Biological Technology Co., Ltd.	Biocomma Limited	Huachenyang (Shenzhen) Technology Co., Ltd.	Medico Technology Co., Ltd
Authorized representative	Wellkang Ltd	SUNGO Europe B.V.	Share Info Consultant Service LLC Repräsentanzbüro	CMC MEDICAL DEVICES & DRUGS, S.L.	R Sight B.V.	Wellkang Ltd
Sterilization methods	Sterilized using irradiation	Sterilized using ethylene oxide	Sterilized using irradiation	Sterilized using ethylene oxide	Sterilized using irradiation	Sterilized using ethylene oxide
CE mark	CE 0197	CE 0197	CE 0197	CE 0413	CE 2862	CE 0413

WHAT ELSE DO YOU NEED?

Timer.

STORAGE CONDITION AND EXPIRY DATE

1.Test kit store at 2-30℃ in dry place and protect from light. Test kit is valid for 18 months.

2.The Test Card must remain in the sealed pouch until use. Once the test card pouch is opened, the test should be performed within 1 hour.

HOW TO USE THE TEST?

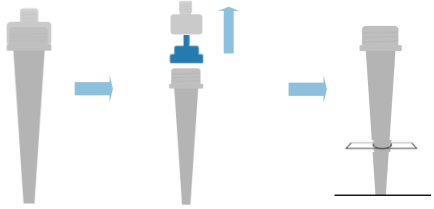
Use a disinfectant to disinfect your hands after washing your hands

Clean the tabletop on which the test will be performed.

Before testing, read the operating instructions carefully, and restore the testing kit and samples to room temperature (20- 25℃) before using. The test should be done at 20~25℃. If the kit is removed from the refrigerator, allow it to stand at room temperature(20- 25℃) for 5 minutes before testing.

1. Twist off the cap of the Sample treatment tube and remove the inner blue stopper. The purpose of the blue stopper is to prevent the product from leaking during transportation, the blue stopper should be removed before use!

Insert the treatment tube into the hole of the kit or use other items to hold the treatment tube in place.



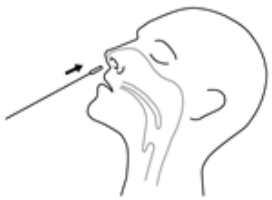
2. Tear open the foil bag, take out the test card, and use it as soon as possible within 1 hour.

3. Sample collection

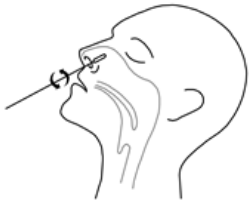
Nasal swab collection method:

1) Carefully remove sterile nasal swab from the packaging. (Avoid touching the end with the cotton swab)

Insert the nasal swab into the left nostril to a depth of 2.5 cm (1 inch) from the edge of the nostril.



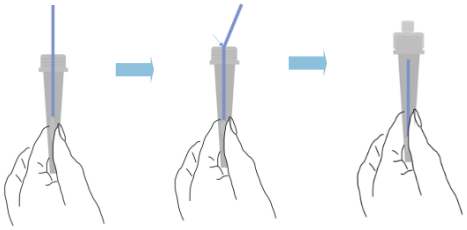
2) Rotate the nasal swab on the nostril wall (mucous membrane) 5 times to ensure adequate sampling.



3) Repeat the process in the right nostril with the same nasal swab, collecting from both nasal passages to ensure an adequate sample.

4. Place the swab sample into the tube, then break the swab at t

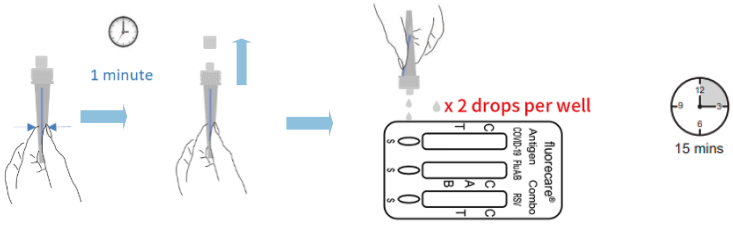
half in the treatment tube. Close the cap.



5. Squeeze the swab 10 times in the test tube. Then wait for 1 minutes of sample reaction. Unscrew the terminal at the top of the cap. If the terminal on the top of the cap is not unscrewed, and if the blue stopper inside the sample processing tube is not removed, it will not be possible to drip liquid!

Each sample well of the test card requires 2 drops (about 60 μL) of the treated sample solution. The wells marked with an "S" under the COVID-19, Influenza A/B or RSV characters are the sample wells. You can add 3 sample wells at the same time to detect 3 different types of antigens, or you can add only one sample well to detect one type of antigen. Only 2 drops of the treated sample solution can be added to each sample well ! Adding too much or too little of the treated sample solution may result in invalid test results !

After the sample has been added, the cap, the top terminal of the cap and the blue stopper are all capped back into the treatment tube and treated as contaminants.



6. The test card is kept at room temperature for 15 minutes to observe the test results, but the observation results over 20 minutes were invalid. If you read the test results after 20 minutes, the test results may be wrong or invalid. While waiting, you cannot touch the test card or lift the test card from the desktop

TAKE MEASURES DURING THE TEST TO PREVENT SPREAD INFECTION

1. After the completion of observation and testing, put the used product components into a plastic bag, close and put the bag into another plastic bag and discard it. Reapply hand sanitizer to disinfect your hands.

2. Please complete the above test operation alone in an isolated room.

HOW TO READ THE RESULTS?

1. Positive of COVID-19 Antigen or RSV: Two purple Lines, both the detection line (T line) and the quality control line (C line) display color.

NOTE: It does not matter the line (T) is lighter or darker than the other; the result is "Positive".

2. Positive of Influenza A/B: Line A and quality control line (Line C) are appeared to represent Influenza A is positive. Line B and control line (line C) are appeared to represent Influenza B is positive. Line A, line B and quality control line (line C) are appeared indicating that both Influenza A and Influenza B are positive.

NOTE: It does not matter the Line A or Line B is lighter or darker than the other two, the result is "Positive".

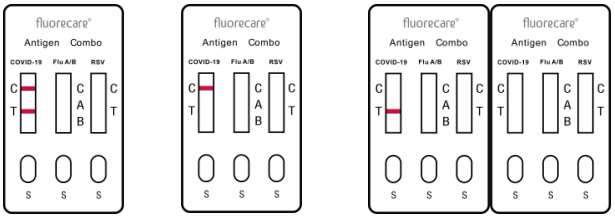
3. Negative: A purple Line, Only quality control line (C line) appeared.

4. Invalid: The position of the quality control line (Line C) in the observation window does not appeared, indicating that the test is invalid. Sampling should be re-tested with new kits.

If the retest result is still shows invalid, please contact us:

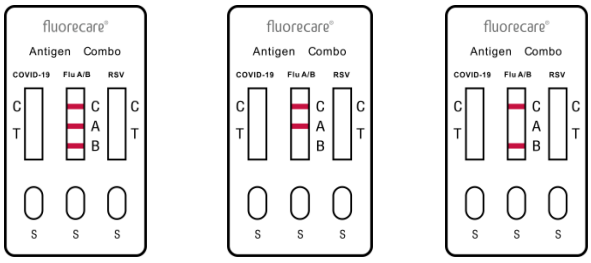
bio@microprofit.com.

Result of COVID-19 Antigen:

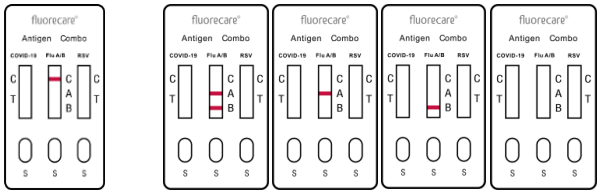


Positive Negative Invalid

Result of Influenza A/B:

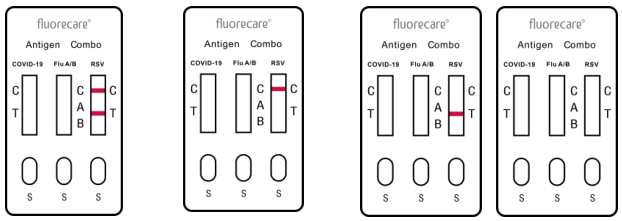


FLU A/B Positive FLU A Positive FLU B Positive



Negative Invalid

Result of RSV:



Positive Negative Invalid

WHAT SHOULD YOU DO AFTER READING THE TEST RESULT ?

1. A positive result for COVID-19 Antigen means that you may have COVID-19 disease. Please contact your doctor for further medical advice. You may be asked to be isolated at home to avoid spreading the virus to others. Wear a mask when advised and wash your hands regularly with soap and water. A positive result for Influenza A/B or RSV means you may have Influenza or RSV disease. Please contact your doctor for further medical advice. Wear a mask when advised to avoid spreading the disease to others.

2. A negative result for COVID-19, Influenza A/B or RSV Antigen means the virus that causes COVID-19, Influenza A/B or RSV was not found in your sample. A negative test result does not guarantee that you do not or have never had COVID-19, nor does it confirm whether or not you are currently contagious. If you have cold symptoms, dyspnea or high fever, you should assume that you have covid-19, Influenza A/B or RSV because the home test does not provide complete certainty. You can contact your doctor to find out if another test is needed. In the meantime, try to avoid leaving your home and have as less contact as possible with others, including the people you live with. Use disposable tissues and throw them straight in the bin. Sneeze and cough into the crook of

your elbow. Wash your hands regularly and wear a face mask.

3. You should not make any medically related decisions without first consulting your doctor. Actions you take after getting your test results must comply with current local regulations.

4. If there is a mixed infection of COVID-19 virus, Influenza virus and RSV virus, the disease may be more serious, and there will be corresponding complications. You should pay attention to personal protection to prevent infecting others, and go to the hospital for diagnosis as soon as possible.

LIMITATION OF METHODOLOGY

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis.

2. Negative test results may occur if the level of antigen in a sample is below the detection limit of the test, or from improper sample collection, and the negative results are not intended to exclude other non COVID-19 virus, Influenza virus or RSV virus infections.

3. Unreasonable sampling, transportation, handling, and low virus content in samples may lead to false negatives.

4. This reagent is a qualitative assay. As it is with any diagnostic procedure, a confirmed virus infection diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.

5. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.

6. A negative test result for COVID-19, Influenza A/B or RSV Antigen does not rule out COVID-19, Influenza A/B or RSV infection and does not exempt you from the applicable rules for spread control (e.g. contact restrictions and protective measures).

QUESTION & ANSWER

Q1. How does the SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit work?

The SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit is an antigen test that is to detect novel Coronavirus (SARS-CoV-2 Antigen), Influenza A virus, Influenza B virus Antigen and/or RSV Antigen in population Nasal swabs samples in vitro.

Q2.What is the difference between a COVID-19 antigen, molecular, and antibody test?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus.

Antigen tests are very specific for the virus but are not as sensitive as molecular tests.

Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection.

Q3. Will this test hurt?

No, the disposable sterile swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly.

Q4. Why do I swab both nostrils?

Swabbing both nostrils gives you the best chance of collecting sufficient sample to generate an accurate result.

It has been observed in some cases that only one nostril has detectable virus, so it is important to collect from both nostrils. Correct swabbing is important to obtain a correct result.

You should not make any medically related decisions without first consulting your doctor.

Q5. What does it mean if I have a positive test result?

A positive result for COVID-19 Antigen means that you may have COVID-19 disease. Please contact your doctor for further medical advice. You may be asked to be isolated at home to avoid spreading the virus to others. Wear a mask when advised and wash your hands regularly with soap and water. A positive result for Influenza A/B or RSV means you may have Influenza or RSV disease. Please contact your doctor for further medical advice.Wear a mask when advised to avoid spreading the disease to others.

Actions you take after getting your test results must comply with current local regulations.

If there is a mixed infection of COVID-19 virus, Influenza virus and RSV virus, the disease may be more serious, and there will be corresponding complications. You should pay attention to personal protection to prevent infecting others, and go to the hospital for diagnosis as soon as possible.

Q6. What does it mean if I have a negative test result for COVID-19 Antigen?

A negative result means the virus that causes COVID-19 was not found in your sample.

A negative test result does not guarantee that you do not or have never had COVID-19, nor does it confirm whether or not you are currently contagious.

Do you have cold symptoms in addition to the negative at-home test? Since the at-home test does not provide complete certainty, you should assume that you have COVID-19. You can contact your doctor to find out if another test is needed. In the meantime, try to avoid leaving your home and have as little contact as possible with others, including the people you live with. Use disposable tissues and throw them straight in the bin. Sneeze and cough into the crook of your elbow. Wash your hands regularly and wear a face mask. Are your symptoms getting worse (difficulty breathing, high fever, etc.)? Contact your doctor/health provider immediately.

Q7. How accurate is the SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit?

The test has been shown in field clinical evaluations performed by professional health care persons to correctly identify 96.11% (642/668) of 2019-nCoV samples (known as the test's accuracy). Further, in field clinical evaluations conducted, the test correctly identified 100% (100/100) 2019-nCoV negative samples when performed by self test users.

Q8. Is there any chance that I get a "false" negative result with this test?

It is possible for this test to give an incorrect negative (false negative) result". This means that you could still have COVID-19 or Influenza or RSV even though the test result is negative. If your result is negative and you still experience symptoms related to COVID-19 , such as fever, cough and/or shortness of breath, you should seek help from your healthcare provider.

Q9. Is there any chance that I get an incorrect positive result?

There is a very small chance that this test gives you a positive result that is incorrect (false positive). If you get a positive result, you should self-isolate and seek medical help from you healthcare provider.

Q10. I have used the test but no colored band appears at control line (C). What should I do?

If there is no colored band appears at control line (C) within 15 minutes of performing the test, then the test has not worked. You should test again, using a new test, taking care to follow the instruction. At the same time, contact our email: bio@microprofit.com immediately.

Q11.Can any medication or medical conditions affect the results?

We have done research on the effects of the drug, see Chapter 5 of the **INDEX OF CHARACTERISTICS**. The results showed that the drugs listed in Section 5 had no effect on the test results. If you are taking medicines other than those listed, ask your doctor for advice.

Q12. What are the possible risks of this test?

Possible Risks:

- Discomfort during the sampling
- Incorrect test results (see Interpreting Results and Limitations Sections).

Q13. What should I do if there is blood on the nasal swab when I use it?

Please check for damage to the nasal cavity due to the nasal swab. If so, contact your doctor after the test is complete. Blood does not affect test results.

INDEX OF CHARACTERISTICS

1. Positive reference coincidence rate: the positive reference coincidence rate of the enterprise should be 100%.

2. Negative reference product conformity rate: the negative reference product conformity rate of the enterprise should be 100%

3. Limit of detection (LoD)：

① The LoD of SARS-CoV-2 is: 49 $TCID_{50}$/mL.

② The LoD of the Influenza A is:

Virus strains	LoD
2009H1N1	1.96×10^4TCID50/mL
Seasonal H1N1	2×10^4TCID50/mL
Type A H3N2	4×10^4TCID50/mL

③ The LoD the Influenza B is:

Virus strains	LoD
B/Victoria	5×10^3TCID50/mL
B/Yamagata	2.625×10^3TCID50/mL

④RSV type A is 1.15×10^4 $TCID_{50}$/mL, RSV type B is 1.6×10^4 $TCID_{50}$/mL.

4. Cross-reactivity:

① Virus/bacteria listed below are confirmed not to have cross-reactivity with SARS-CoV-2 antigen Test：

Human Coronavirus (OC43) 3.8 x 10^5PFU/ml ;Human Coronavirus (229E) 2.3 x 10^4PFU/ml ;Human Coronavirus MERS (Florida/USA-2_Saudi Arabia_2014) 1.05 x 10^5PFU/ml ;Human Coronavirus (NL63) 2.8 x 10^4PFU/ml ;Human Coronavirus (HKU1) (N-protein) 45μg/ml ;Adenovirus Type 01 (Species C) 8.34x 10^4PFU/ml ;Adenovirus Type 02 (Species C) 1.05 x 10^5PFU/ml ;Adenovirus Type 11 (Species B) 1.02 x 10^7PFU/ml ;Enterovirus Type 68 (2014 Isolate) 1.05 x 10^5PFU/ml ;Human Metapneumovirus(16 Type A1) 3.80 x 10^5PFU/ml ;Human Metapneumovirus (3 Type B1 strain Peru 2_2002) 1,41 x 10^4PFU/ml ;Parainfluenza Virus (Type 1) 1.26 x 10^5PFU/ml ;Parainfluenza Virus (Type 2) 1.26 x 10^5PFU/ml ;Parainfluenza Virus (Type 3) 3.39 x 10^6PFU/ml ;Parainfluenza Virus (Type 4B) 3.80 x 10^5PFU/ml ;Respiratory Syncytial Virus Type A (Isolate: 2006) 7.35 x 105PFU/ml ;Rhinovirus (Type 1A) 1.05 x 10^6PFU/ml ;Influenza Type A, H3N2 (HK/8/68) 1.51 x 10^4PFU/ml;Influenza Type A, H1N1 (Brisbane/59/07) 4.57 x 10^5PFU/ml ;Influenza Type A, H1N1pdm (Canada/6294/09) 1.26 x 10^5PFU/ml;Influenza Type B (Texas/6/11) 2.26 x 10^5PFU/ml;Influenza Type B (Alabama/2/17) 3.16 x 10^5PFU/ml ;Staphylococus aureus (Protein A) DSM 21705 (E. Domann) 3.62 x 10^9CFU/ml ;Staphylococus aureus (Protein A) DSM 21979 (E. Domann, Univ.) 7.64x 10^9CFU/ml ;Staphylococus aureus (Protein A) DSM 46320 (E. Domann) 4.58x 10^9CFU/ml ;Staphylococcus epidermidis DSM 1798 (PCI 1200) 4.90 x 10^9CFU/ml ;Staphylococcus epidermidis DSM 20044 (Fussel) 5.10 x 10^9CFU/ml ;Bordetella pertussis DSM 4923 (Walker) 2.71 x 10^9CFU/ml ;Bordetella pertussis DSM 4926 (Sato and Arai) 2.02 x 10^9CFU/ml ;Bordetella pertussis DSM 5571 8.07 x 10^9CFU/ml ;Legionalle pneumophila DSM 7513 (Philadelphia-1) 4.50 x 10^9CFU/ml ;Legionalle pneumophila DSM 7514 (Los Angeles-1) 1.17 x 10^{10}CFU/ml ;Streptococcus pyogenes DSM 20565 (SF130, T1) 1.37 x 10^8CFU/ml ;Streptococcus pyogenes DSM 2071 (S. Koshimura, Sv) 9.30 x

10^7CFU/ml ;Haemophilus influenzae DSM 24049 (TD-4) 7.77 x 10^8CFU/ml ;Haemophilus influenzae DSM 4690 (Maryland) 1.41 x 10^7CFU/ml ;Haemophilus influenzae DSM 23393 (Pittman 576) 1.23 x 10^8CFU/ml ;Mycobacterium tuberculosis DSM 43990 (BCGT, tice) 4.69 x 10^8CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 20566 (SV1) 4.05 x 10^8CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 11967 (Jorgensen262) 3.80 x 10^7CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 25971 (Gyeonggi) 2.70 x 10^8CFU/ml ;Mycoplasma pneumoniae DSM 23978 (Eaton Agent, FH) >10^5 cells/ml ;Mycoplasma pneumoniae DSM 23979 (M129-B7) >10^5 cells/ml ;Candida albicans DSM 1386 (NIH 3147) 6.53 x 10^8CFU/ml ;Candida albicans DSM 1665 (132) 2.39 x 10^8CFU/ml ;Candida albicans DSM 5817 (806M) 2.55 x 10^8CFU/ml ;Pseudomonas aeruginosa DSM 1117 (Boston 41501) 1.31 x 10^9CFU/ml ;Pseudomonas aeruginosa DSM 3227 (Schutze) 3.93 x 10^9CFU/ml ;Streptococcus salivarius DSM 20560 (275) 5.44 x 10^8CFU/ml ;Streptococcus salivarius DSM 20067 (21367) 5.09 x 10^8CFU/ml.

②Virus/bacteria listed below are confirmed not to have cross-reactivity with Influenza A：

Human Coronavirus (OC43) 3.8 x 10^5PFU/ml ;Human Coronavirus (229E) 2.3 x 10^4PFU/ml ;Human Coronavirus MERS (Florida/USA-2_Saudi Arabia_2014) 1.05 x 10^5PFU/ml ;Human Coronavirus (NL63) 2.8 x 10^4PFU/ml ;Human Coronavirus (HKU1) (N-protein) 45μg/ml ;Adenovirus Type 01 (Species C) 8.34x 10^4PFU/ml ;Adenovirus Type 02 (Species C) 1.05 x 10^5PFU/ml ;Adenovirus Type 11 (Species B) 1.02 x 10^7PFU/ml ;Enterovirus Type 68 (2014 Isolate) 1.05 x 10^5PFU/ml ;Human Metapneumovirus(16 Type A1) 3.80 x 10^5PFU/ml ;Human Metapneumovirus (3 Type B1 strain Peru 2_2002) 1,41 x 10^4PFU/ml ;Parainfluenza Virus (Type 1) 1.26 x 10^5PFU/ml ;Parainfluenza Virus (Type 2) 1.26 x 10^5PFU/ml ;Parainfluenza Virus (Type 3) 3.39 x 10^6PFU/ml ;Parainfluenza Virus (Type 4B) 3.80 x 10^5PFU/ml ;Respiratory Syncytial Virus Type A (Isolate: 2006) 7.35 x 105PFU/ml ;Rhinovirus (Type 1A) 1.05 x 10^6PFU/ml ;Influenza Type B (Texas/6/11) 2.26 x 10^5PFU/ml;Influenza Type B (Alabama/2/17) 3.16 x 10^5PFU/ml ;Staphylococus aureus (Protein A) DSM 21705 (E. Domann) 3.62 x 10^9CFU/ml ;Staphylococus aureus (Protein A) DSM 21979 (E. Domann, Univ.) 7.64x 10^9CFU/ml ;Staphylococus aureus (Protein A) DSM 46320 (E. Domann) 4.58x 10^9CFU/ml ;Staphylococcus epidermidis DSM 1798 (PCI 1200) 4.90 x 10^9CFU/ml ;Staphylococcus epidermidis DSM 20044 (Fussel) 5.10 x 10^9CFU/ml ;Bordetella pertussis DSM 4923 (Walker) 2.71 x 10^9CFU/ml ;Bordetella pertussis DSM 4926 (Sato and Arai) 2.02 x 10^9CFU/ml ;Bordetella pertussis DSM 5571 8.07 x 10^9CFU/ml ;Legionalle pneumophila DSM 7513 (Philadelphia-1) 4.50 x 10^9CFU/ml ;Legionalle pneumophila DSM 7514 (Los Angeles-1) 1.17 x 10^{10}CFU/ml ;Streptococcus pyogenes DSM 20565 (SF130, T1) 1.37 x 10^8CFU/ml ;Streptococcus pyogenes DSM 2071 (S. Koshimura, Sv) 9.30 x 10^7CFU/ml ;Haemophilus influenzae DSM 24049 (TD-4) 7.77 x 10^8CFU/ml ;Haemophilus influenzae DSM 4690 (Maryland) 1.41 x 10^7CFU/ml ;Haemophilus influenzae DSM 23393 (Pittman 576) 1.23 x 10^8CFU/ml ;Mycobacterium tuberculosis DSM 43990 (BCGT, tice) 4.69 x 10^8CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 20566 (SV1) 4.05 x 10^8CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 11967 (Jorgensen262) 3.80 x 10^7CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 25971 (Gyeonggi) 2.70 x 10^8CFU/ml ;Mycoplasma pneumoniae DSM 23978 (Eaton Agent, FH) >10^5 cells/ml ;Mycoplasma pneumoniae DSM 23979 (M129-B7) >10^5 cells/ml ;Candida albicans DSM 1386 (NIH 3147) 6.53 x 10^8CFU/ml ;Candida albicans DSM 1665 (132) 2.39 x 10^8CFU/ml ;Candida albicans DSM 5817 (806M) 2.55 x 10^8CFU/ml ;Pseudomonas aeruginosa DSM 1117 (Boston 41501) 1.31 x 10^9CFU/ml ;Pseudomonas aeruginosa DSM 3227 (Schutze) 3.93 x 10^9CFU/ml ;Streptococcus salivarius DSM 20560 (275) 5.44 x 10^8CFU/ml ;Streptococcus salivarius DSM 20067 (21367) 5.09 x 10^8CFU/ml ; SARS-CoV-2(5.6 x 105 TCID50/mL),New coronavirus variant strain B.1.1.7 (alpha) （ 1.0x 106 TCID50/mL), New coronavirus variant strain B.1.351 (Beta) （ 1.3x 106 TCID50/mL), New coronavirus variant strain P.1 (gamma) (2.2x 106 TCID50/mL), New coronavirus variant strain B.1.617.2 (delta) (1.9x 106 TCID50/mL), New coronavirus variant strain B.1.1.529 (omicron) (3.1x 106 TCID50/mL).

③Virus/bacteria listed below are confirmed not to have cross-reactivity with Influenza B antigen Test:

Human Coronavirus (OC43) 3.8 x 10^5PFU/ml ;Human Coronavirus (229E) 2.3 x 10^4PFU/ml ;Human Coronavirus MERS (Florida/USA-2_Saudi Arabia_2014) 1.05 x 10^5PFU/ml ;Human Coronavirus (NL63) 2.8 x 10^4PFU/ml ;Human Coronavirus (HKU1) (N-protein) 45μg/ml ;Adenovirus Type 01 (Species C) 8.34x 10^4PFU/ml ;Adenovirus Type 02 (Species C) 1.05 x 10^5PFU/ml ;Adenovirus Type 11 (Species B) 1.02 x 10^7PFU/ml ;Enterovirus Type 68 (2014 Isolate) 1.05 x 10^5PFU/ml ;Human Metapneumovirus(16 Type A1) 3.80 x 10^5PFU/ml ;Human Metapneumovirus (3 Type B1 strain Peru 2_2002) 1,41 x 10^4PFU/ml ;Parainfluenza Virus (Type 1) 1.26 x 10^5PFU/ml ;Parainfluenza Virus (Type 2) 1.26 x 10^5PFU/ml ;Parainfluenza Virus (Type 3) 3.39 x 10^6PFU/ml ;Parainfluenza Virus (Type 4B) 3.80 x 10^5PFU/ml ;Respiratory Syncytial Virus Type A (Isolate: 2006) 7.35 x 105PFU/ml ;Rhinovirus (Type 1A) 1.05 x 10^6PFU/ml ;Influenza Type A, H3N2 (HK/8/68) 1.51 x 10^4PFU/ml ;Influenza Type A, H1N1 (Brisbane/59/07) 4.57 x 10^5PFU/ml ;Influenza Type A, H1N1pdm (Canada/6294/09) 1.26 x 10^5PFU/ml; Staphylococus aureus (Protein A) DSM 21705 (E. Domann) 3.62 x 10^9CFU/ml ;Staphylococus aureus (Protein A) DSM 21979 (E. Domann, Univ.) 7.64x 10^9CFU/ml ;Staphylococus aureus (Protein A) DSM 46320 (E. Domann) 4.58x 10^9CFU/ml ;Staphylococcus epidermidis DSM 1798 (PCI 1200) 4.90 x 10^9CFU/ml ;Staphylococcus epidermidis DSM 20044 (Fussel) 5.10 x 10^9CFU/ml ;Bordetella pertussis DSM 4923 (Walker) 2.71 x 10^9CFU/ml ;Bordetella pertussis DSM 4926 (Sato and Arai) 2.02 x 10^9CFU/ml ;Bordetella pertussis DSM 5571 8.07 x 10^9CFU/ml ;Legionalle pneumophila DSM 7513 (Philadelphia-1) 4.50 x 10^9CFU/ml ;Legionalle pneumophila DSM 7514 (Los Angeles-1) 1.17 x 10^{10}CFU/ml ;Streptococcus pyogenes DSM 20565 (SF130, T1) 1.37 x 10^8CFU/ml ;Streptococcus pyogenes DSM 2071 (S. Koshimura, Sv) 9.30 x 10^7CFU/ml ;Haemophilus influenzae DSM 24049 (TD-4) 7.77 x 10^8CFU/ml ;Haemophilus influenzae DSM 4690 (Maryland) 1.41 x 10^7CFU/ml ;Haemophilus influenzae DSM 23393 (Pittman 576) 1.23 x 10^8CFU/ml ;Mycobacterium tuberculosis DSM 43990 (BCGT, tice) 4.69 x 10^8CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 20566 (SV1) 4.05 x 10^8CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 11967 (Jorgensen262) 3.80 x 10^7CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 25971 (Gyeonggi) 2.70 x 10^8CFU/ml ;Mycoplasma pneumoniae DSM 23978 (Eaton Agent, FH) >10^5 cells/ml ;Mycoplasma pneumoniae DSM 23979 (M129-B7) >10^5 cells/ml ;Candida albicans DSM 1386 (NIH 3147) 6.53 x 10^8CFU/ml ;Candida albicans DSM 1665 (132) 2.39 x 10^8CFU/ml ;Candida albicans DSM 5817 (806M) 2.55 x 10^8CFU/ml ;Pseudomonas aeruginosa DSM 1117 (Boston 41501) 1.31 x 10^9CFU/ml ;Pseudomonas aeruginosa DSM 3227 (Schutze) 3.93 x 10^9CFU/ml ;Streptococcus salivarius DSM 20560 (275) 5.44 x 10^8CFU/ml ;Streptococcus salivarius DSM 20067 (21367) 5.09 x 10^8CFU/ml; SARS-CoV-2(5.6 x 10^5 TCID50/mL),New coronavirus variant strain B.1.1.7 (alpha) （1.0x 10^6 TCID50/mL), New coronavirus variant strain B.1.351 (Beta) （ 1.3x 10^6 TCID50/mL), New coronavirus variant strain P.1 (gamma) (2.2x 10^6 TCID50/mL), New coronavirus variant strain B.1.617.2 (delta) (1.9x 10^6 TCID50/mL), New coronavirus variant strain B.1.1.529 (omicron) (3.1x 10^6 TCID50/mL).

④Virus/bacteria listed below are confirmed not to have cross-reactivity with RSV antigen Test：

Human Coronavirus (OC43) 3.8 x 10^5PFU/ml ;Human Coronavirus (229E) 2.3 x 10^4PFU/ml ;Human Coronavirus MERS (Florida/USA-2_Saudi Arabia_2014) 1.05 x 10^5PFU/ml ;Human Coronavirus (NL63) 2.8 x 10^4PFU/ml ;Human Coronavirus (HKU1) (N-protein) 45μg/ml ;Adenovirus Type 01 (Species C) 8.34x 10^4PFU/ml ;Adenovirus Type 02 (Species C) 1.05 x 10^5PFU/ml ;Adenovirus Type 11 (Species B) 1.02 x 10^7PFU/ml ;Enterovirus Type 68 (2014 Isolate) 1.05 x 10^5PFU/ml ;Human Metapneumovirus(16 Type A1) 3.80 x 10^5PFU/ml ;Human Metapneumovirus (3 Type B1 strain Peru 2_2002) 1,41 x 10^4PFU/ml ;Parainfluenza Virus (Type 1) 1.26 x 10^5PFU/ml ;Parainfluenza Virus (Type 2) 1.26 x 10^5PFU/ml ;Parainfluenza Virus (Type 3) 3.39 x 10^6PFU/ml ;Parainfluenza Virus (Type 4B) 3.80 x 10^5PFU/ml ;Rhinovirus (Type 1A) 1.05 x 10^6PFU/ml ;Influenza Type A, H3N2 (HK/8/68) 1.51 x 10^4PFU/ml ;Influenza Type A, H1N1 (Brisbane/59/07) 4.57 x 10^5PFU/ml ;Influenza Type A, H1N1pdm (Canada/6294/09) 1.26 x 10^5PFU/ml ;Influenza Type B (Texas/6/11) 2.26 x 10^5PFU/ml ;Influenza Type B (Alabama/2/17) 3.16 x 10^5PFU/ml ;Staphylococus aureus (Protein A) DSM 21705 (E. Domann) 3.62 x 10^9CFU/ml ;Staphylococus aureus (Protein A) DSM 21979 (E. Domann, Univ.) 7.64x 10^9CFU/ml ;Staphylococus aureus (Protein A) DSM 46320 (E. Domann) 4.58x 10^9CFU/ml ;Staphylococcus epidermidis DSM 1798 (PCI 1200) 4.90 x 10^9CFU/ml ;Staphylococcus epidermidis DSM 20044 (Fussel) 5.10 x 10^9CFU/ml ;Bordetella pertussis DSM 4923 (Walker) 2.71 x 10^9CFU/ml ;Bordetella pertussis DSM 4926 (Sato and Arai) 2.02 x 10^9CFU/ml ;Bordetella pertussis DSM 5571 8.07 x 10^9CFU/ml ;Legionalle pneumophila DSM 7513 (Philadelphia-1) 4.50 x 10^9CFU/ml ;Legionalle pneumophila DSM 7514 (Los Angeles-1) 1.17 x 10^{10}CFU/ml ;Streptococcus pyogenes DSM 20565 (SF130, T1) 1.37 x 10^8CFU/ml ;Streptococcus pyogenes DSM 2071 (S. Koshimura, Sv) 9.30 x 10^7CFU/ml ;Haemophilus influenzae DSM 24049 (TD-4) 7.77 x 10^8CFU/ml ;Haemophilus influenzae DSM 4690 (Maryland) 1.41 x 10^7CFU/ml ;Haemophilus influenzae DSM 23393 (Pittman 576) 1.23 x 10^8CFU/ml ;Mycobacterium tuberculosis DSM 43990 (BCGT, tice) 4.69 x 10^8CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 20566 (SV1) 4.05 x 10^8CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 11967 (Jorgensen262) 3.80 x 10^7CFU/ml ;Streptococcus pneumoniae (Protein G) DSM 25971 (Gyeonggi) 2.70 x 10^8CFU/ml ;Mycoplasma pneumoniae DSM 23978 (Eaton Agent, FH) >10^5 cells/ml ;Mycoplasma pneumoniae DSM 23979 (M129-B7) >10^5 cells/ml ;Candida albicans DSM 1386 (NIH 3147) 6.53 x 10^8CFU/ml ;Candida albicans DSM 1665 (132) 2.39 x 10^8CFU/ml ;Candida albicans DSM 5817 (806M) 2.55 x 10^8CFU/ml ;Pseudomonas aeruginosa DSM 1117 (Boston 41501) 1.31 x 10^9CFU/ml ;Pseudomonas aeruginosa DSM 3227 (Schutze) 3.93 x 10^9CFU/ml ;Streptococcus salivarius DSM 20560 (275) 5.44 x 10^8CFU/ml ;Streptococcus salivarius DSM 20067 (21367) 5.09 x 10^8CFU/ml. SARS-CoV-2(5.6 x 105 TCID50/mL),New coronavirus variant strain B.1.1.7 (alpha) （1.0x 106 TCID50/mL), New coronavirus variant strain B.1.351 (Beta) （1.3x 106 TCID50/mL), New coronavirus variant strain P.1 (gamma) (2.2x 106 TCID50/mL), New coronavirus variant strain B.1.617.2 (delta) (1.9x 106 TCID50/mL), New coronavirus variant strain B.1.1.529 (omicron) (3.1x 106 TCID50/mL).

5. Interference

Substances listed below are confirmed not to have interference response with SARS-CoV-2 , Influenza A /B and RSV antigen Test:

Substances listed below are confirmed not to have interference response with SARS-CoV-2 & Influenza A/B & RSV Antigen Combined Test Kit. Benzocaine (150 mg/dL), Blood (human) (5%), Mucin(5 mg/mL), Naso GEL (NeilMed) (5%), CVS Nasal Drops (phenylephrine) (0.5%), Afrin (Oxymetazoline) (0.05%), CVS Nasal Spray (Cromolyn) (1 5 %) , Zicam Cold Remedy (5%), Homeopathic (Alkalol) (1.0%), Sore Throat Phenol Spray (1.5%), Tobramycin(3.3mg/dL), Mupirocin(0.15mg/dL), Fluticasone (0.000126mg/dL),Tamiflu (Oseltamivir phosphate) (500mg/dL), Budenoside (0.00063 mg/dL), Biotin (0.35mg/dL), Methanol (150mg/dL), Acetylsalicylic Acid (3mg/dL), Diphenhydramine (0.0774mg/dL), Dextromethorphan (0.00156mg/dL), Dexamethasone (1.2 mg/dL), Mucinex(5%).

6.Hook

When the Virus strains in the sample do not exceed the concentration in the following table, the high concentration of Virus strains in the sample has no effect on the detection results of the fluorecare® SARS-CoV-2 & Influenza A/B & RSV Antigen Combined Test Kit.

Virus strains	Limit value
SARS-CoV-2	1.8 x 10^5 $TCID_{50}$/mL
2009H1N1	9.8x $10^6$$TCID_{50}$/mL
Seasonal H1N1	1.3x 10^7 $TCID_{50}$/mL
Type A H3N2	2.1x $10^8$$TCID_{50}$/mL
B/Victoria	1x $10^6$$TCID_{50}$/mL
B/Yamagata	1x 10^6 $TCID_{50}$/mL
RSV type A	4.6×10^8 $TCID_{50}$/mL
RSV type B	3.2×10^7 $TCID_{50}$/mL

7. Clinical Accuracy

7.1. Results and Analysis of SARS-CoV-2:

Method		RT-PCR		Total Results
SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	342	0	342
	Negative	26	450	476
Total Results		368	450	818

Cycle Threshold (CT)	# of RT-PCR positive	fluorecare® SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)		
		# of positive results	PPA	NPA
<25	105	104	99.05%	100%
<30	217	214	98.62%	
<35	297	292	98.32%	
<38	368	342	92.93%	

Positive correct rate (Clinical sensitivity)at Ct<38=92.93% (95%CI:89.82%~95.33%)
Negative correct rate (Clinical specificity) = 100% (95%CI:99.18% ~100%)

Method		RT-PCR		Total Results
by Lay person	Results	Positive	Negative	
	Positive	30	0	30
	Negative	2	87	89
Total Results		32	87	119

7.2 Results and Analysis of Influenza A:

Method		Reference product		Total Results
SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	104	0	104
	Negative	9	555	564
Total Results		113	555	668

Clinical sensitivity =92.04% (95%CI:85.42% ~96.29%)
Clinical specificity =100.00% (95%CI:99.34%~100.00%)

Method		Reference product Professional test		Total Results
self-test	Results	Positive	Negative	
	Positive	17	0	17
	Negative	0	102	102
Total Results		17	102	119

7.3 Results and Analysis of Influenza B:

Method		Reference product		Total Results
SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	80	0	80
	Negative	8	580	588
Total Results		88	580	668

Clinical sensitivity =90.91% (95%CI:82.87% ~95.99%)
Clinical specificity =100.00% (95%CI:99.37%~100.00%)

Method		Reference product Professional test		Total Results
self-test	Results	Positive	Negative	
	Positive	11	0	11
	Negative	1	107	108
Total Results		12	107	119

7.4 Results and Analysis of RSV:

Method		Reference product		Total Results
SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	63	0	63
	Negative	3	602	605
Total Results		66	602	668

Clinical sensitivity =95.45% (95%CI:87.45% ~99.05%)
Clinical specificity =100.00% (95%CI:99.39%~100.00%)

Method		Reference product Professional test		Total Results
self-test	Results	Positive	Negative	
	Positive	31	0	31
	Negative	1	87	88
Total Results		32	87	119

8. Repeatability: The repeatability reference products of the enterprise were tested, repeated for 10 times, and the positive coincidence rate is 100%.

9. The fluorecare® SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit is test for SARS-CoV-2 nucleocapsid protein, the mutants of SARS-CoV-2 Alpha, Beta, Gamma, Delta and Omicron can be identified by the fluorecare® SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit.

WARNING AND PRECAUTION

1. Read the Instruction for use completely before using the product. Follow the instructions carefully. Failure to do so may result in an inaccurate result.
2. The kit is only used for in vitro diagnosis; it cannot be used repeatedly. Do not swallow.
3. Avoid getting the buffer solution into the eyes or skins.
4. Keep out of reach children.
5. The test kit is for single use only, do not reuse any components of the test kit.
6. Do not use this test beyond the expiration date printed on the outer package. Always check expiry date prior to testing.
7. Do not touch the reaction area of the test cassette.
8. Do not use the kit if the pouch is punctured or not well sealed.
9. DIPOSAL: All specimens and the used-kit has the infectious risk. The process of disposing the diagnostic kit must follow the local, state and federal infectious disposal laws/regulations.
10. During the time of interpretation, no matter the shade of the color band, it can be found to be positive as long as two lines appear on the quality control area and the detection area, respectively.
11. Please ensure that an appropriate amount of sample is used for testing, too much or too little of sample amount will cause the result deviation.
12. The final result should be read in 15 minutes. Please do not read the result after 20 minutes.
13. Various components of different batch of reagents cannot be used interchangeably in order to avoid wrong results

INTERPRETATION OF ICONS

	Do not re-use		Temperature limit

IVD	*In vitro* diagnostic medical device		Consult instructions for use
Σ	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
	Keep away from sunlight		Caution
	Manufacturer	CE 2934	CE marking
REF	Catalogue number	LOT	Batch code
	Date of manufacture		Use-by date
	Self-test		Do no use if package is damaged

GENERAL INFORMATION

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