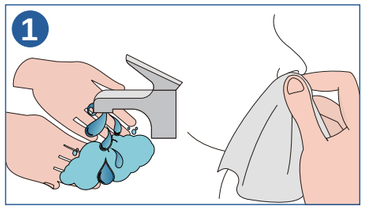
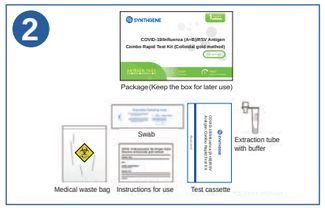
# COVID-19/Influenza (A+B)/RSV Antigen Combo Rapid Test Kit

## INSTRUCTIONS FOR USE

- Read these instructions before testing and follow the steps in order. Keep this guide as a reference until the entire kit is used.
- Store the test kit at room temperature or in a cool, dry place (4°C-30°C). Keep the kit away from direct sunlight and do not store it in a freezer. Keep the test kit away from children.
- The test pad should be used within 1 hour after unsealing the aluminum foil bag at 4-30°C and humidity <65%. It is recommended to use it immediately under high temperature or high humidity conditions.

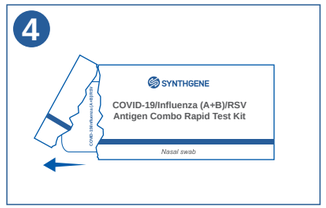


Before starting the test, wash your hands with soap or use hand sanitizer, dry your hands before testing. Clear your nasal passage by blowing your nose.

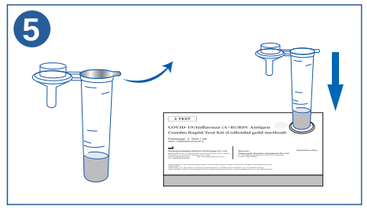



Check the expiration date on the box, unpack the test kit and make sure all components are included and undamaged.

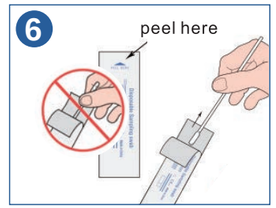

Read the instructions for use carefully.



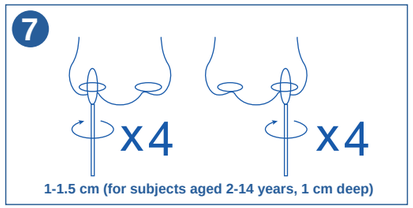

Tear the aluminum foil bag, take out the test cassette and place it flat on a clean table.



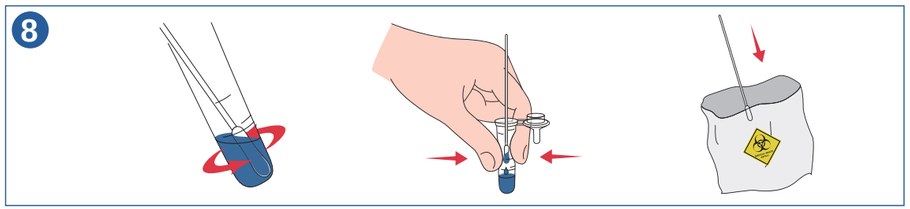
Remove the lid or sealing film on the tube. Insert the extraction tube straight into the pre-set hole on the package box or place the extraction tube vertically on a tube holder.



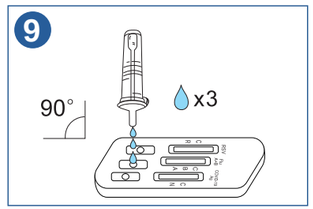

Take the swab out of the wrapper. ***Do not touch the swab head.***



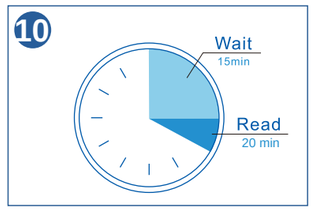

Gently insert the swab head into each nostril and slowly rotate the swab in a circular path for at least 4 times.



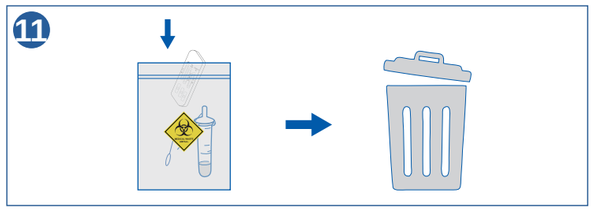
Insert the swab after sampling into the extraction tube, soak the swab in the sample diluent and rotate for at least 30 seconds, and at the same time squeeze the swab head through the outer wall of the extraction tube for at least 5 times.Discard the squeezed swab into a medical waste bag. Cover the extraction tube cap for later use.




Slowly add 3 drops (about 75 μL) of the treated sample into each sample well, and start timing.




Read the results within 15 minutes, the test results are valid within 15-20 minutes.

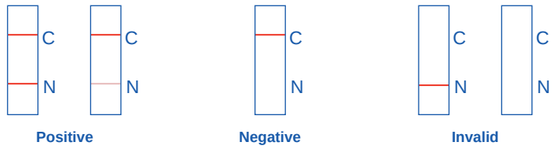


All used consumables, test cards and other wastes should be put into medical waste bags and disposed of properly in accordance with relevant national regulations. Wash or disinfect your hands again.

**Operation video**

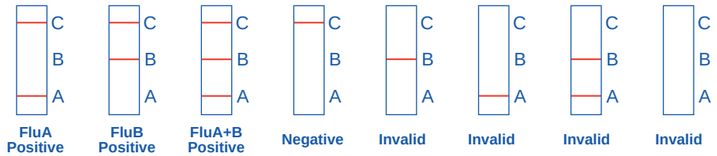
## INTERPRETATION OF TEST RESULTS

### COVID-19 test results:



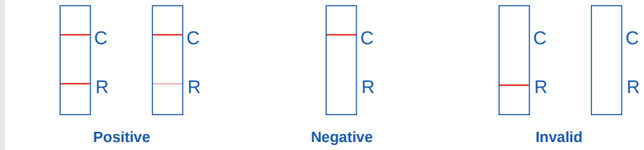

**Positive**
Two purple-red bands appear. One band is located in the detection area (N), and the other one is located in the quality control area (C).
**Negative**
Only a purple-red band appears in the quality control area (C), and no band appears in the detection area (N).
**Invalid**
There is no purple-red band in the quality control area (C), no matter whether there is a band in the detection area (N). The result is invalid, and it is recommended to retest.

### Influenza A and Influenza B virus test results:




**Positive**
Influenza A positive: There are purple-red bands in both the detection area (A) and the quality control area (C).
Influenza B positive: There are purple-red bands in both the detection area (B) and the quality control area (C).
Influenza A and influenza B positive: Purple-red bands appear in both the detection area (A and B) and the quality control area (C).
**Negative**
Only a purple-red band appears in the quality control area (C), and no band appears in the detection area (A and B).
**Invalid**
There is no purple-red band in the quality control area (C), no matter whether there is a red band in the detection area (A and B). The result is invalid, and it is recommended to retest.

### Respiratory syncytial virus:




**Positive**
Two purple-red bands appear. One band is located in the detection area (R), and the other one is located in the quality control area (C).
**Negative**
Only a purple-red band appears in the quality control area (C), and no band appears in the detection area (R).
**Invalid**
There is no purple-red band in the quality control area (C), no matter whether there is a band in the detection area (R). The result is invalid, and it is recommended to retest.

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**Note:**
**1. A weak or even a faint line in the detection area (N/A/B/R) still indicates for a positive result.**
**2. Do not read in dim light.**
**3. It is possible to test positive for more than one disease at the same time.**
**4. If you have a Covid-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings.**
**5. If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the healthdirect helpline on 1800 022 222.**
**6. If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.**
**7. If you have a Influenza or RSV POSITIVE result, individuals are advised to consult a medical practitioner for follow-up clinical care.**
**8. If you have symptoms like fever, cough and/or shortness of breath. Please retest in 1-3 days. You must continue following the applicable hygiene and distancing rules even with a negative result. If symptoms persist or if unwell please consult a medical practitioner for follow-up clinical care".**
**9. As for invalid review the test procedure and repeat the test with a new test pad and a freshly collected sample. If the problem persists, discontinue using the test kit immediately and contact your sponsor.**

***Sponsor and Customer Support Helpline: Chem-pack Supplies Australasia Pty Ltd 0285369500 Between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 5 days per week.***

EN

ENGLISH - AUSTRALIA

Version 002 2024.12.06

SYNTHGENE

# COVID-19/Influenza (A+B)/RSV Antigen Combo Rapid Test Kit (Colloidal gold method)

# INSTRUCTIONS FOR USE

## INTENDED USE

This product is intended for the qualitative detection of SARS-CoV-2 antigen, influenza A/B antigen and RSV antigen using the rapid immunochromatographic method in human nasal swab specimens from individuals within 7 days of onset of symptoms as an aid for diagnosis of COVID-19, within 4 days of onset of symptoms as an aid for diagnosis of Influenza A/B and RSV.

This product is intended for layperson's home use in a non-laboratory environment (e.g. in a person's residence or certain non-traditional places such as offices, sporting events, airports, schools, etc.).

## PRINCIPLE

This product uses colloidal gold immunochromatography combined with double-antibody sandwich principle to detect novel coronavirus N antigen, influenza A virus antigen, influenza B virus antigen and respiratory syncytial virus antigen in human nasal swab samples.

After adding the sample to be tested, the novel coronavirus (2019-nCoV), influenza A/B virus antigen, respiratory syncytial virus antigen in the sample react with the colloidal gold-chicken IgY-novel coronavirus antibody, colloidal gold-chicken IgY-influenza A monoclonal antibody 1 conjugate, colloidal gold-chicken IgY-influenza B monoclonal antibody 1 conjugate and colloidal gold-chicken IgY-respiratory syncytial virus monoclonal antibody 1 conjugate coated on the binding pad, and form antigen-colloidal gold complexes. As the liquid flows, the antigen-colloidal gold complexes are captured by the novel coronavirus antibody 2, influenza A mAb 2, influenza B mAb 2 and syncytial virus mAb coated in the nitrocellulose membrane detection line 2, and are trapped in the detection line, forming a color band. The chicken IgY colloidal gold marker specifically immunocombines with the anti-chicken IgY antibody coated in the quality control line on the nitrocellulose membrane, and is captured by the quality control line, regardless of whether the sample contains the novel coronavirus (2019-nCoV), influenza A/B antigens, respiratory syncytial virus antigens, and quality control bands will develop color.

## KIT CONTENTS

① Test casette ② Extraction tube with buffer
③ Swab ④ Medical waste bag ⑤ Instructions for use

* Materials not provided but required: Timer, hand cleansing materials and tissues.
** The surfaces that come in contact do not contain animal-sourced materials.

Tube holder: The 25 tests/kit package contains the tube holder,the 1 test/kit and 5 tests/kit package use the pre-set hole on the package box as tube holder.

| Test Kit Contents | | | |
|---|---|---|---|
| REF number | RQ00901001HKS | RQ00901005HKS | RQ00901025HKS |
| Specification | 1 test/kit | 5 tests/kit | 25 tests/kit |
| Test cassette | 1 pc | 5 pcs | 25 pcs |
| Extraction tube with buffer | 1 pc | 5 pcs | 25 pcs |
| Swab | 1 pc | 5 pcs | 25 pcs |
| Medical waste bag | 1 pc | 5 pcs | 25 pcs |
| Instructions for use | 1 pc | 1 pc | 25 pcs |

## STORAGE AND STABILITY

- The test can be stored at 4℃-30℃and all reagents are stable until the expiration dates marked on their outer packaging.
- Validity period: 24 months. Do not use after expiry.

## WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Ensure foil pouch containing test device is not damaged before opening for use.
3. The test pad should be used within 1 hour after unsealing the aluminum foil bag at 4-30 °C and humidity <65%. It is recommended to use it immediately under high temperature or high humidity conditions.
4. Do not substitute the swab and sample extraction buffer provided in this kit with components from other kits.
5. Place the soft tip of the swab into the nostril.
6. Strictly follow the operating instructions.
7. The samples should be tested immediately after collection.
8. Children aged 2 to 17 years old should have their samples collected and tested by anadult.
9. Do not use the test for anyone under 2 years of age.
10. Do not re-use any of the items in the test kit.
11. Please dispose of the test materials in a closed plastic bag with the household refuse.
12. Wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible.
13. Follow the directions of your local state or territory government health department to protect yourself.
14. Test kit buffer should only be used as directed; do not ingest.
15. Do not dip the swab into provided solution or other liquid before inserting the swab into the nose.
16. The buffer should avoid contact with skin and eyes.
17. The entire test kit should keep out of the reach of children and pets at all times before taking samples and after use.
18. If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre.
19. After the sample is collected, it should be processed as soon as possible with virus sampling solution or the sample diluent provided by this kit. The processed samples should be tested as soon as possible within 1 hour. If they cannot be tested immediately, they should be stored at 2-8°C for no more than 24 hours.
20. Sampling process will affect the test results, it is recommended that sampling personnel should operate according to the instructions.
21. Disposable sampling swab can only be used with the sample diluent from the same kit, and can only be used to collect samples from the same person. Mix use is prohibited.
22. During the sampling process, the sampling swab should be avoided from being contaminated, and it should be tested immediately after sampling.

## LIMITATIONS

1. False positive results may occur, particularly in individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of SARS-Cov-2 infections and without known exposure to COVID-19.
2. The risk of false negative results, particularly if testing is not performed within the first 4 days of symptom onset for Influenza and RSV and within the first 7 days for COVID-19.
3. The test is less reliable in the later phase of infection and in asymptomatic individuals.
4. Repeat testing within 1- 3 days is recommended in occupational risk, high risk settings or if there is an ongoing suspicion of infection.
5. Negative results may not mean that a person is not infectious and if symptoms are present the person must seek professional medical advice.
6. A negative result does not rule out infection with another type of respiratory virus.
7. If you have a COVID-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings. If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the healthdirect helpline on 1800 022 222. If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.
8. If you have a Influenza or RSV POSITIVE result or who are unwell are advised to consult a medical practitioner for follow-up clinical care.
9. In the early stages of infection or before symptoms appear, low antigen expression may lead to negative results.
10. The test cannot differentiate between SARS-CoV-2 and SARS-CoV.
11. The test results are related to the quality of the specimen collection, processing, transportation and storage. Any faults can lead to imprecise results. If the crosscontamination is not controlled during specimen processing, false-positive results may occur.
12. A positive result cannot necessarily determine if a person is infectious.

## PERFORMANCE CHARACTERISTICS

**1. Minimum detection limit:** the minimum detection limit of the novel coronavirus (2019-nCoV) in the kit is 100 $TCID_{50}$/mL, the minimum detection limit of RSV A is $1\times10^4$ $TCID_{50}$/mL and RSV B is $1.2\times10^4$ $TCID_{50}$/mL, the minimum detection limit of influenza A and B viruses is shown in the table below:

| Virus strains | Minimum detection limit |
|---|---|
| Influenza A H1N1/Wisconsin/588/2019 | $5\times10^2$$TCID_{50}$/mL |
| Influenza A H3N2/South Australia/34/2019 | $2.0\times10^3$$TCID_{50}$/mL |
| Influenza A H1N1/Bejing/262/95 | $1.0\times10^3$$TCID_{50}$/mL |
| Influenza A H1N1 A/Florida/3/2006 | $1.0\times10^3$$TCID_{50}$/mL |
| Influenza A H3N2 A/Hong Kong/8/68 | $7.5\times10^2$$TCID_{50}$/mL |
| Influenza B Phuket/3073/2013 (Yamagata lineage) | $1.25\times10^3$$TCID_{50}$/mL |
| Influenza B Austria/1359417/2021(Victoria lineage) | $1.5\times10^3$$TCID_{50}$/mL |
| Influenza B Victoria Lineage B/Florida/78/2015 | $1.0\times10^3$$TCID_{50}$/mL |
| Influenza B Yamagata Lineage B/Florida/4/2006 | $1.0\times10^3$$TCID_{50}$/mL |

**2. Variants Information**

The following SARS-CoV-2 variants can be detected with this product: Alpha, Beta, Gamma, Epsilon, Delta and Omicron.

The following Influenza A (H1N1) variants can be detected with this product: A/Beijing/262/95, A/Florida/3/2006, A/Wisconsin/588/2019, A/Victoria/2570/2019, A/Guangdong-Maonan/SWL1536/2019, A/Brisbane/02/2018, A/Michigan/45/2015, A/California/7/2009, A/Sydney/5/2021.

The following Influenza A (H3N2) variants can be detected with this product: A/Darwin/6/2021, A/Hong Kong/8/68, A/Darwin/9/2021, A/Hong Kong/2671/2019, A/Victoria/361/2011, A/Texas/50/2012, A/South Australia/34/2019, A/Switzerland/8060/2017, A/Singapore/INFIMH-160019/2016.

The following Influenza B (Victoria Lineage) variants can be detected with this product: B/Florida/78/2015, B/Austria/1359417/2021, B/Washington/0 2/2019, B/Colorado/06/2017.

The following Influenza B (Yamagata Lineage) variants can be detected with this product: B/Florida/4/2006, B/Phuket/3073/2013, B/Massachusetts/2/2012.

The following RSV variants can be detected with this product: A-2, Long, 9320, Washington, B-1 wild type.

**3. Cross-reactivity**

The following pathogenic microorganisms were tested, and the test results were negative, indicating that there is no cross-reaction with the following test substances: Mumps virus, Adenovirus(type 1,2,3,4,5,7,55),Avirulent Mycobacterium tuberculosis, Bordetella pertussis, Candida albicans, Chlamydia pneumoniae, Cytomegalovirus, Epstein-Barr virus, Endemic human coronavirus (229E, OC43, NL63, HKU1 H7N9),Enterovirus (group A,B,C,D), Haemophilus influenzae, Human coronavirus, Human cytomegalovirus, Human Metapneumovirus (hMPV), Human parapneumovirus Influenza A virus (H3N2, H5N1) Influenza B virus (Yamagata, Victoria), Seasonal H1N1 Influenza Virus ,Klebsiella pneumoniae, Legionella pneumophila, Measles virus, MERS coronavirus, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Neisseria meningitidis, Norovirus, Parainfluenza virus (type 1,2,3,4), Pneumocystis jiroveci, Pooled human nasal wash - to represent diversemicrobial flora in the human respiratory tract, Respiratory syncytial virus (type A, B), Rhinovirus (group A, B, C), Rotavirus ,SARS coronavirus, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, and Varicella-zoster virus.

**4. Interference**

The following internal and external interfering substances were tested, and the test results were negative, indicating that there is no interference with the following test substances:

mucin, blood (human), guaifenesin, arbidol hydrochloride hydrate, zanamivir, meropenem, oseltamivir, ritonavir, histamine hydrochloride, levofloxacin, oxymetazoline, ceftriaxone, cefradine, cefalexin, benzocaine, tobramycin, lopinavir, azithromycin, watermelon frost, dexamethasone, flunisolide, peramivir, ibuprofen, aspirin, triamcinolone , hydrocortisone, albuterol, chlorpheniramine, diphenhydramine, budesonide, mometasone, fluticasone, menthol, quinine, lamivudine, phenylephrine, acetaminophen, beclomethasone, sodium chloride, alpha interferon, human anti-mouse antibody (HAMA), ribavirin, lopinavir, kanamycin, sodium benzoate, flunisolide, sodium chloride solution with preservative, epinephrine.

**5. Clinical performance**

Comparing the results of COVID-19/Influenza (A+B)/RSV Antigen Combo Rapid Test Kit (Colloidal gold method) with the results of SARS-CoV-2 and Influenza A/B Virus Multiplex Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) and RSV Nucleic Acid Test Kit (PCR-fluorescence probe method) in valid cases. The results are shown below.

**Statistics of test results of nasal swab samples:**

| COVID-19/Influenza (A+B)/RSV Antigen Combo Rapid Test Kit | | RT-PCR Test (Reference) | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| COVID-19 Antigen Test | Positive | 97 | 0 | 97 |
| | Negative | 3 | 450 | 453 |
| | Total | 100 | 450 | 550 |
| Positive coincidence rate(Sensitivity) | | 97.00%(95%CI: 91.48% to 99.38%) | | |
| Negative coincidence rate(Specificity) | | 100.00%(95%CI: 99.18% to 100.00%) | | |
| Total coincidence rate | | 99.45% (95%CI: 98.41% to 99.89%) | | |

Positive coincidence rate (Clinical sensitivity): 97.00%(95%CI: 91.48% to 99.38%);
Negative coincidence rate (Clinical specificity): 100.00%(95%CI: 99.18%~100.00%);
Total coincidence rate(Accuracy): 99.45% (95%CI: 98.41% to 99.89%)

**Influenza A+B Test:**

| COVID-19/Influenza (A+B)/RSV Antigen Combo Rapid Test Kit | | Type A | | | Type B | | |
|---|---|---|---|---|---|---|---|
| | | RT-PCR Test (Reference) | | Total | RT-PCR Test (Reference) | | Total |
| | | Positive | Negative | | Positive | Negative | |
| Influenza A+B Antigen Test | Positive | 59 | 0 | 59 | 50 | 1 | 51 |
| | Negative | 1 | 100 | 101 | 0 | 99 | 99 |
| | Total | 60 | 100 | 160 | 50 | 100 | 150 |
| Positive coincidence rate (Sensitivity) | | 98.33% (95% CI: 91.06% ~ 99.96%) | | | 100.00% (95% CI: 92.89% ~ 100.00%) | | |
| Negative coincidence rate(Specificity) | | 100.00% (95%CI: 96.38% ~ 100.00%) | | | 99.00% (95%CI: 94.55% ~ 99.97%) | | |
| Total coincidence rate | | 99.37% (95%CI: 96.57% ~ 99.98%) | | | 99.33% (95%CI: 96.34%~ 99.98%) | | |

Influenza A:
Positive coincidence rate (Clinical sensitivity): 98.33% (95% CI: 91.06% ~ 99.96%);
Negative coincidence rate (Clinical specificity):100.00%(95%CI: 96.38% ~ 100.00%);
Total coincidence rate (Accuracy): 99.37% (95%CI: 96.57% ~ 99.98%)
Influenza B:
Positive coincidence rate (Clinical sensitivity): 100.00%(95% CI: 92.89% ~ 100.00%);
Negative coincidence rate (Clinical specificity): 99.00%(95%CI: 94.55% ~ 99.97%);
Total coincidence rate (Accuracy): 99.33% (95%CI: 96.34%~ 99.98%)

**RSV antigen Test**:

| COVID-19/Influenza (A+B)/RSV Antigen Combo Rapid Test Kit | | RT-PCR Test (Reference) | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| RSV Antigen Test | Positive | 97 | 0 | 97 |
| | Negative | 3 | 200 | 203 |
| | Total | 100 | 200 | 300 |
| Positive coincidence rate(Sensitivity) | | 97.00%(95%CI: 91.48% to 99.38%) | | |
| Negative coincidence rate(Specificity) | | 100.00%(95%CI: 98.17% to 100.00%) | | |
| Total coincidence rate | | 99.00% (95%CI: 97.11% to 99.79%) | | |

Positive coincidence rate (Clinical sensitivity): 97.00%(95%CI: 91.48% to 99.38%);
Negative coincidence rate (Clinical specificity): 100.00%(95%CI: 98.17% to 100.00%);
Total coincidence rate(Accuracy): 99.00% (95%CI: 97.11% to 99.79%)

**6. Usability Study**

During the testing of these 170 participants, comparing the results of these participants with the results of reference reagent kit, the test results are 100.00% (170/170) of participants are highly consistent with those of laboratory technician. This shows that the product has better usability and higher consistency, thus verifying that the COVID-19/Influenza (A+B)/RSV Antigen Combo Rapid Test Kit (Colloidal gold method) are presumed to be usable.

## REFERENCES


1.Lamarre A, Talbot PJ. Effect of pH and temperature on the infectivity of human coronavirus 229E. Canadian Journal of Microbiology. 1989; 35(10): 972-4.

2.Bucknall RA, King LM, Kapikian AZ, Chanock RM. Studies with human coronavi ruses II. Some properties of strains 229E and OC43. Proceedings of the Society for Experimental Biology and Medicine. 1972;139(3):722-7.


**INDEX OF SYMBOL**

| | | | |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Date of manufacture |
| Σ | Tests per kit | | Use-by date |
| | Manufacturer | 4℃ 30℃ | Temperature limit: 4~30°C |
| REF | Catalogue number | | Keep dry |
| | Do not use if package is damaged | | Keep away from sunlight |
| | Consult instructions for use | | Do not re-use |
| LOT | Batch code | | |


**Nanjing Synthgene Medical Technology Co., Ltd.**
Address: Building B6-2, No. 9, Weidi Road, Xianlin University Town, Xianlin Subdistrict, Qixia District, Nanjing City, China
Phone : 025-83108036
Website : http://www.syngenemed.com/
Service Email : sales@syngenebio.com

Sponsor

**Chem-pack Supplies Australasia Pty Ltd**
27 Marshall Road Kirrawee NSW 2232 Australia
Phone: 0285369500


If you encounter any performance or usability issues with this device, please report them to the Therapeutic Goods Administration (TGA) using the following contact methods:
• Email: iris@health.gov.au
• Phone: 1800 809 361

***Sponsor and Customer Support Helpline: Chem-pack Supplies Australasia Pty Ltd 0285369500 Between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 5 days per week.***