SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method)

SYNTHGENE

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 reagent should be used as soon as possible within 1 hour after unpacking the aluminum foil bag; it is recommended to use it as soon as possible when the surrounding temperature is higher than 30°C or high humidity.

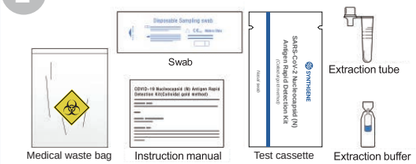
A. Before starting

1

Before starting the test, wash your hands with soap or use hand sanitizer, dry your hands before testing.

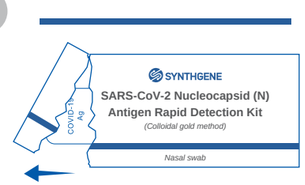
B. Prepare for testing

2



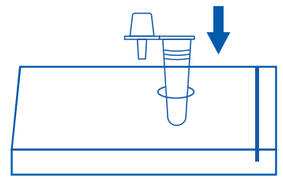
Check the expiration date on the box, unpack the test kit and make sure all components are included and undamaged.

3



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

4



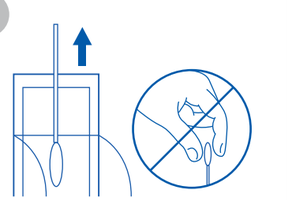
Insert the extraction tube straight into the pre-set hole on the package box or place the extraction tube vertically on a tube holder.

C. Collect the nasal swab sample

5

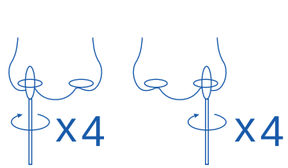
Drop all the liquid into the tube carefully.

6



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

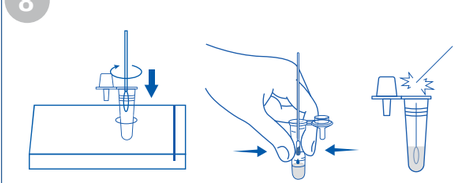
7



Gently insert the swab head (1/2~3/4) into each nostril and slowly rotate the swab in a circular path for at least 4 times.

D. Process the nasal swab sample

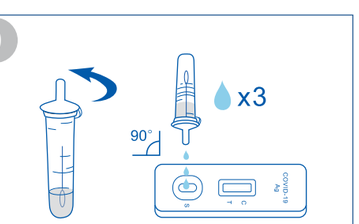
8



Insert the swab with the sample into the extraction tube. Rotate the swab or pinch the extraction tube with fingers at least 30 seconds, and then break off part of the swab.

E. Test the sample

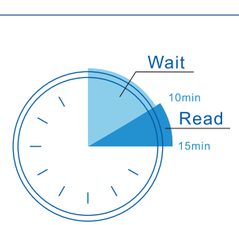
9



Install the dripper, drop 3 drops of the diluted sample vertically into the sample hole (S) of the test pad, and start timing.

F. Read the result

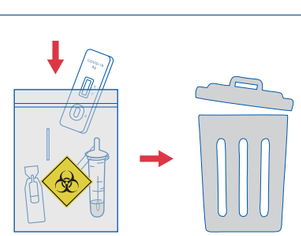
10



Read the result in 10-15 minutes. The result is valid within 15 minutes.

G. Safely dispose of your test kit

11



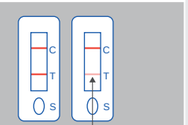
Put the used components into the medical waste bag and dispose of them according to local regulations. Wash hand and disinfect after testing.

Operation video

INTERPRETATION OF TEST RESULTS

Positive

Red band appears in the detection area (T) and the control area (C). Even a weak or faint band in the detection area (T) indicates a positive result. Follow local guidelines for self-quarantine.



Note: A Positive test result means that COVID-19 is found in your sample and it is very likely that youhave been infected. For guidance contact your State or Territory Coronavirus testing services. If unwell, seek medical attention.

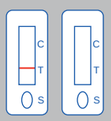
Negative

No red band appears in the detection area (T), and a red band appears in the control area (C). The results show the samples do not contain COVID-19.

Note: If your rst test result is negative, you should test again in 24 hours but not after 36 hours. A negative test result means that the virus is not found in your sample. It is possible for this test to give anegative result that is incorrect (a false negative). This means that you could still have COVID-19 eventhough the test is negative. For guidance contact your State or Territory Coronavirus testing services. If unwell, seek medical attention.

Invalid

No red band appears in the control area (C), regardless of whether there is a red band in the detection area (T), the results is judged to be invalid, and it is recommended to perform another test.



Note: DO NOT reuse any components from the first test.

EN

ENGLISH - AUSTRALIA

SYNTHGENE

SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Detection Kit

(Colloidal gold method)

INSTRUCTIONS FOR USE

INTENDED USE

This kit is used for the qualitative detection of nucleocapsid (N) antigen from SARS-CoV-2 virus in anterior nasal swab specimens. This is used to aid in the diagnosis of COVID-19 infection. This kit can be used for symptomatic individuals who are suspected of being infected with COVID-19 within the first 7 days of symptom onset patients.

SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method) is intended for laypersons as self-testing at home or workplace (in offices, for sporting events, airports, schools, etc.).

SUMMARY

The novel coronaviruses belong to the beta genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the novel coronavirus are the main source of infection; infected people without symptoms can also infect others. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

PRINCIPLE

This product uses colloidal gold immunochromatography combined with the double-antibody sandwich principle to detect the N-antigen of novel coronavirus in human nasal swab samples.

KIT CONTENTS

1 Test casette 2 Extraction buffer 3 Extraction tube
4 Swab 5 Medical waste bag 6 Instruction manual

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

Content / REF	Test casette	Extraction buffer	Extraction tube	Swab	Medical waste bag	Instruction manual
RQ005	1	1	1	1	1	1

WARNINGS AND PRECAUTIONS

- For self-testing use only.
- Read instructions and follow all instructions prior to performing this test to ensure accurate results.
- Do not use the test kit contents beyond the expiry date.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- Do not store the test kit in direct sunlight.
- Store the test kit between 4~30℃ (39.2~86°F). Do not freeze.
- Do not eat, drink or smoke while collecting specimens.
- Wash your hands thoroughly before and after testing and make sure they are dry before handling the test kit.
- The test kit should be used within 1 hour after the foil pouch is opened.
- Read the test results after 10 minutes. Do not read after 15 minutes.
- Keep the test kit and its components out of reach of children and pets.
- To prevent contamination, do not touch the swab head.
- Avoid contact with any liquids with eyes and skin.
- Do not re-use any of the items in the test kit.
- Place all of the items in the bag provided and dispose in a non-recyclable rubbish bin after testing.
- Specimens collected by laypersons can be stored stably at room temperature of 4-30 ℃ (39.2~86℉) for 8 hours. It is recommended to complete the test as soon as possible within 2 hours.

LIMITATIONS

1. False negative or invalid results may occur if specimen is improperly collected or handled.
2. False negative test results may occur if testing is not performed within the first 7 days of symptom onset as the antigen level in the specimen may be too low for the test to detect.
3. Regardless of the intensity of the line in the detection area (T), this is a positive result. For guidance contact your State or Territory Coronavirus testing services. If unwell, seek medical attention.
4. Participants aged 18 and older can self-test. Participants aged 2-17 years old should be tested with presence of legal guardian or parents. Do not use the test for anyone under the age of 2 years old.
5. If the test result is negative and clinical symptoms persist it may be because it is too early in the virus's infection life cycle and so it may not be detected.
6. Negative test results should not rule out possibilities of other non-SARS viral or bacterial infections.
7. Negative results should be treated as presumptive as the amount of antigen in a sample may decrease as the duration of illness increases.
8. Positive test results of this product cannot distinguish different variants and sub-variants.
9. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence over time.
10. Test results may be less reliable in the later phase of infection and in asymptomatic individuals.
11. Inaccurate results may occur if: (1) not enough buffer has been used into the sample well, (2) the sample hole is overloaded with buffer, (3) buffer has been loaded too fast into the sample hole and formed air bubbles, (4) the swab specimen has not been swirled and squeezed into the extraction tube at least 5 times, or (5) the results are read before the 10 minutes or after 15 minutes.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD)

The LoD of SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method) is 100 $TCID_{50}$/mL.

Variants

SARS-CoV-2 variants including Alpha, Beta, Delta, Omicron can be detected by SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method).

High Dose Hook Effects

The sample with a concentration level of 1× $10^6$$TCID_{50}$/ml in the test of the novel coronavirus inactivated virus solution did not show the hook effect.

Precision

Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using three specimens of COVID-19 standard control. Three different lots of SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method) have been tested using negative, low positive and moderately positive standard samples. Three operators in different laboratories (lab A, lab B, and lab C) used the SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method) to test each of R1, R2, and R3 samples 3 times every day, repeatedly for 20 consecutive days. The specimens were correctly identified>99% of the time.

Cross-reactivity

No cross reactivity was observed with this kit for Coronavirus HKU1, Coronavirus OC43, Coronavirus NL63, Coronavirus 229E, MERS coronavirus, SARS coronavirus, Influenza A virus H1N1, Seasonal H1N1 influenza virus, H3N2, H5N1, H7N9, Influenza B Yamagata, Influenza B Victoria, Parainfluenza virus (types I, II, III), Respiratory syncytial virus (type A, B), Rhinovirus (groups A, B, C), Adenovirus (type 1, 2, 3, 4, 5, 7, 55), Enterovirus (groups A, B), Epstein-Barr virus, Human cytomegalovirus, Rotavirus, Norovirus, Mumps virus, Varicella-zoster virus, Mycoplasma pneumoniae, Chlamydia pneumoniae, Haemophilus influenzae, Staphylococcus aureus, Streptococcus pneumoniae, Klebsiella pneumoniae, Mycobacterium tuberculosis, Candida albicans, human nasal swabs eluate.

Interfering Substances

No false positive or false negative results were found: mucin, blood (human), methocarbamol, arbidol hydrochloride, zanamivir, meropenem, oseltamivir, ritonavir, histamine hydrochloride, levofloxacin, oxymetazoline hydrochloride, ceftriax sodium, cefradine, cephalexin, benzocaine, tobramycin, lopinavir, azithromycin, watermelon cream throat lozenges, dexamethasone, flunisolide, peramivir, ibuprofen, aspirin, triamcinolone acetonide, hydrocortisone, salbutamol, chlorpheniramine, diphenhydramine, budesonide, mometasone, fluticasone, nasal rinse, menthol, quinine, lamivudine, phenylephrine, acetaminophen, beclomethasone, sodium chloride, alpha-interferon, human anti-mouse antibody (HAMA), ribavirin, lopinavir.

Clinical Performance (Sensitivity, Specificity and Accuracy)

The clinical performance of Synthgene COVID-19 Antigen Rapid Test Kit was evaluated with a total of 580 clinical specimens. Of these, 202 were from individuals with confirmed positive PCR test results, and 378 were from individuals with negative PCR test results. The results show that the sensitivity is 98.51% (199/202), specificity is 99.47% (376/378) and the accuracy is 99.14% (575/580).

SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method)	Comparative RT-PCR test result		Total
	Positive	Negative	
Detected Positive	199	2	201
Negative	3	376	379
Total	202	378	580
Sensitivity	98.51% (95.72% to 99.69%)		
Specificity	99.47% (98.10% to 99.94%)		
Accuracy	99.14% (98.00% to 99.72%)		

Usability Study

The usability study was conducted with a pool of 90 lay persons in the self-testing environment. The results show that the sensitivity is 96.67% (29/30), specificity is 100% (60/60) and the accuracy is 98.89% (89/90).

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.

LOCAL HEALTH DEPARTMENT CONTACT INFORMATION

Australian Capital Territory Department of Health (8am-8pm daily)
Tel: 02 6207 7244
https://health.act.gov.au/

Northern Territory Department of Health
Tel: 1800 020 080
https://www.health.nt.gov.au/

South Australia Department of Health (9am -5 pm Daily)
Tel: 1800 253 787
https://www.sahealth.sa.gov.au/

Victoria Department of Health
Tel: 1800 675 398
https://dhhs.vic.gov.au/

New South Wales Department of Health (Service NSW 24/7)
Tel: 137 788
https://www.health.nsw.gov.au/

Queensland Department of Health
Tel: 134 268
https://health.qld.gov.au/

Tasmanian Department of Health
Tel: 1800 671 738
https://www.health.tas.gov.au/

Western Australia Department of Health (8am-6pm Mon-Fri)
Tel: 1800 595 206
https://ww2.health.wa.gov.au/

TGA Contact Information for Reporting Poor Performance and Usability Issues:
Call 1800 809 361 or email iris@health.gov.au

INDEX OF SYMBOL

IVD	In vitro diagnostic medical device	LOT	Batch code
Σ	Contains sufficient for<n>tests		Date of manufacture
	Manufacturer		Use-by date
REF	Catalogue number	4℃ 30℃	Temperature limit: 4~30℃
	Biological risks		Keep dry
	Do not use if package is damaged		Keep away from sunlight
	Consult instructions for use		Do not re-use

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
Boston Med Pty Ltd.
21 Fyfe Dr Lower Templestowe VIC 3107
Phone: 0432 990 691 9AM-7PM AEST
Email: covidtest@bostonmed.com.au
Website：www.bostonmed.com.au