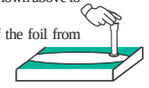
Step 1: Preparation

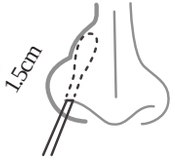
1. Read the instructions carefully before starting the test.
2. Ensure the device at **room temperature (15–30°C)** prior to use.
3. Wash or disinfect your hands before starting the test.
4. Open the box and remove each of the components shown above to perform a single test.
5. Keep extraction diluent tube upright and peel off the foil from extraction tube, then place the tube in the tube holder.



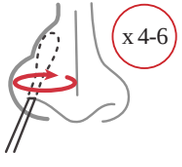
Step 2: Specimen Collection

1. Take out the swab from the package without touching the padding

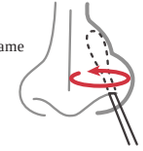
2. Carefully insert the swab **1.5cm** into the nostril until slight resistance is noticeable.



3. Using moderate pressure, rotate the swab **4-6 times** against the nasal wall for at least **15 seconds**.

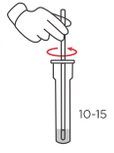


4. Repeat the sampling with the same swab in the other nostril.

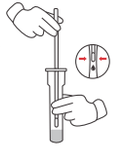


Step 3: Specimen Handling

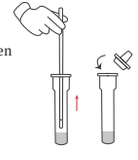
1. Insert the swab into the tube. The swab tip should be completely immersed in the diluent, and then stir 10-15 times to ensure that an adequate specimen is collected.



2. Remove the swab while squeezing the sides of the tube to extract the liquidfrom the swab.



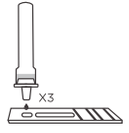
3. Dispose the swab to the bag and then seal the tube securely.



Step 4: Test Procedure

1. Open the pouch and remove the test cassette to place on a flat surface.

2. Apply 3 drops of the test specimen into the specimen well.



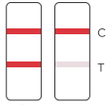
3. Read results between **15~30 minutes.** Do not read the result after 30 minutes.

wait 15~30 minutes

Step 5: Results Interpretation

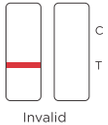
Children under 18 years using this product must be accompanied by their parents or guardians, and they must view and interpret the test results together.

1.**Positive:** The presence of two red lines (T and C) within the result window indicates positive for 2019-nCoV antigen.
If the test result is positive:
A positive result indicates a suspicious COVID-19 infection. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.



2.**Negative:** Only one red line appearing at the control line (C) indicates negative result.
If the test result is negative:
That means that you are negative or that the viral load is too low to be detected by the test. If you have symptoms such as headache, migraine, fever, loss of the smell or taste senses, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary,and if unwell seek medical assistance.

3.**Invalid:** If control line (C) fails to appear, no matter whether the T line is visible or not, the test is invalid. Review the procedure and repeat the test with a new test device.
If the test result is invalid:
It is possibly caused by incorrect test operation. Repeat the test. If the same problem still exists, please stop using the batch number of the product immediately and contact the manufacturer or the distributor. If the test results continue to be invalid, contact a doctor or a COVID-19 test center.



Step 6: Disposal

After testing, all used testing materials should be treated in a harmless manner to avoid the risk of cross-infection. Put it in a plastic bag, seal it, and dispose in rubbish bin or household waste

Before testing, scan the QR code to watch instructional video and open the instructions for use. For more information, please visit: https://bgi-australia.com.au/bgi-innovita-rat

BGI INNOVITA
No test too small, No matter too big.

For Customer Support :
Tel: +61733620475
Email: bgi-australia@genomics.cn
Website: https://bgi-australia.com.au
For information on the correct use of this test and for interpretation of the test results. Customer Service Hours: 9am-7pm(AEST) or 9am-8pm(AEDT), 7 Days a week.

For Customer Support Call +61733620475 for information on the correct use of this test and for interpretation of the test result. Customer Service Hours: 9am-7pm(AEST) or 9am-8pm(AEDT), 7 Days a week.

Instructions for 2019-nCoV Ag Test (Latex Chromatography Assay)

Product Name

2019-nCoV Ag Test (Latex Chromatography Assay)

Intended Use

The kit is intended for the direct and qualitative detection of N protein of SARS-CoV-2 antigen in anterior nasal swabs. The test is intended as an aid in diagnosis of symptomatic individuals within the first 7 days of symptom onset.
The kit is intended for layperson as self-testing at home or at work (in offices, for sports events, airports, schools, etc.).

What is self-test

A self-test is a test that you can carry out yourself at home, to reassure yourself that you are not infected before going to school or work. Self-test is recommended regardless whether you have symptoms or not to quickly check whether you need immediate attention. If your self-test produces a positive result, you probably have been infected with coronavirus. Please contact test center and doctor to arrange for a confirmation PCR test and follow the local COVID-19 measures.

Summary

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

Composition

Specification	Test cassette	Extraction diluent	Dropper tip	Swab	Garbage bags	IFU
1 test/box	1	1	1	1	1	1
2 tests/box	2	2	2	2	2	1
5 tests/box	5	5	5	5	5	1

1.Test cassette (in pouch) 2. Extraction diluent 3. Dropper tip 4. Swab

Storage and Stability

1. Stored at 4°C-30°C, the validity period is 18 months (see the label for the specific batch number and expiration date). **Not to use the kit beyond the expiry date.**
2. After the pouch is unsealed, the device should be used as soon as possible within 1 hour.

Precaution

1. This kit is for in vitro diagnosis use only. The test results of the kit are for clinical reference only and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.
2. This test is recommended to be used within 7 days post-onset of symptoms.
3. The desiccant in pouch is only used for product storage, not for other purposes.
4. Do not use damaged test kit. Do not reuse the test kit.
5. Do not use kits or reagents after the expiration dates shown on the labels.
6. Do not open any package until you are ready to begin your test.
7. Use the test within 60 minutes after unsealing the foil pouch.
8. Read results between 15~30 minutes.
9. This test should be performed at 15 to 30°C. If stored refrigerated, ensure that the pouch and extraction diluent are brought to operating temperature before performing testing.
10. It is preferred to test the specimen immediately after collection and should not be repeatedly frozen and thawed.
11. Use the collectors and diluent provided by this reagent to collect specimens. Do not mix different batches of the test device and diluent.
12. Inadequate or inappropriate specimen collection are likely to yield false test results.
13. Do not perform the test in direct sunlight.
14. Keep out of reach of children. The test contains small parts that may present a choking hazard.
15. During use, avoid contacting with the extraction diluent. If it accidentally splashes into the eyes, or touches the skin or mucous membrane, rinse with plenty of water as soon as possible. If irritation is found, please contact your doctor.
16. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
17. Children aged 2 to 18 years old should have their samples collected and tested by an adult. Do not use the test for anyone under the age of 2 years old.

Warnings and Limitations

1. The kit detects both viable and nonviable SARS-CoV-2 viral antigens and may yield a positive result in the absence of living microorganisms.
2. A negative test result may occur if the level of antigen in the specimen is below the detection limit of the test.
3. Failure of the user to follow the test procedure correctly may adversely affect the test performance and/or invalidate the test result.
4. False positive results may occur, particularly in individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 infections and without known exposure to COVID-19.
5. Positive test results do not exclude co-infection with other pathogens.
6. Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
7. A negative test result may occur particularly if the testing is not performe within the first 7 days of symptom onset.
8. Negative results may not mean that a person is not infectious and if symptoms are present the person must seek immediate further testing by PCR.
9. The kit is a presumptive test. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, 3 days) and if unwell seek medical assistance.
10. It will be recommended to repeat testing (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
11. The kit is less reliable in the later phase of infection and in asymptomatic individuals

Performance Characteristics

1. Cross reactivity
No cross reactivity was observed with this kit for Coronavirus OC43, Coronavirus NL63, Coronavirus 229E, MERS-coronavirus, Influenza A virus H1N1, Influenza B virus(BY), Respiratory Syncytial Virus, Parainfluenza virus type 1, Parainfluenza virus type 2, Parainfluenza virus type 3, Parainfluenza virus type 4a, Rhinovirus A30, Human Metapneumovirus A2, Adenovirus type 1, Adenovirus type 55, Enterovirus 71, Rotavirus, Mycoplasma pneumoniae, Chlamydia pneumoniae, Bordetella pertussis, Haemophilus influenzae, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes, Klebsiella pneumoniae, Candida albicans and Pooled human nasal wash.
2. Endogenous/Exogenous Potentially Interfering Substances
No false positive or false negative results were found: whole blood, Mucin, Oxymetazoline, Oseltamivir, Xlear, Mupirocin, Naso GEL, Ambroxol Hydrochloride Tablets, Nasal spray (mometasone furoate) , Nasal drops (phenylephrine), Nasal cleansing liquid (NaCl)
3. Clinical Performance
The clinical performance of the INNOVITA 2019-nCoV Ag Test was evaluated with a total of 410 clinical specimens. Of these, 110 were from individuals with confirmed positive PCR test results, and 300 were from individuals with negative PCR test results.

INNOVITA 2019-nCoV Ag Test	Number of PCR samples	
	Positive	Negative
Positive	105	1
Negative	5	299
total	110	300
Sensitivity	95.45%, 95% CI: 89.80% - 98.04%	
Specificity	99.67%, 95% CI: 98.14% - 99.94%	

4. Usability Study
209 people self-sampled and self-tested using the Innovita 2019-nCoV Antigen anterior nasal Self Test. 97 people were also tested with a PCR. The tests correctly identified 100% (35 out of 35 people) of positive samples and 100% (62 out of 62 people) of negative samples.
5. Limit of Detection
The limit of detection of Innovita 2019-nCoV Antigen anterior nasal Self Test is 125 TCID 50/mL.
6. The following SARS-CoV-2 variants can be detected with the Innovita 2019-nCoV Antigen anterior nasal Self Test: B.1.1.7 (Alpha) and sub-lineages; B.1.617.2 (Delta) and sub-lineages AY; B.1.351 (Beta) and sub-lineages. B.1.1.529 (Omicron) and sub-lineages.

References

1. Sohrabi C, Alsafi Z, O'Neill N, et al. World Health Organization declares global emergency: A review of the 2019 novel coronavirus (COVID-19). Int J Surg. 2020,76:71-76.
2. Chang, C.-k., Hou, M.-H., Chang, C.-F., Hsiao, C.-D., & Huang, T.-h. J. A. r. (2014). The SARS coronavirus nucleocapsid protein-forms and functions. 103, 39-50.
3. The Impetus of COVID -19 in Multiple Organ Affliction apart from Respiratory Infection: Pathogenesis, Diagnostic Measures and Current Treatment Strategy.Baby, Devan, Nair et al.Infect Disord Drug Targets (2020).

Assistance and Contact information

Additionally, you may wish to report poor performance or usability issues to the Therapeutic Goods Administration, please email iris@tga.gov.au or call 1800 809 361.

Contact Details: Australian State and Territory Health Departments:

Australian Capital Territory	Coronavirus Helpline (8 am to 8 pm daily): 02 6207 7244 Website: https://health.act.gov.au/
New South Wales	Coronavirus Helpline (Service NSW 24/7) :137 788 Website: https://www.health.nsw.gov.au/
Northern Territory	(National Coronavirus Helpline) :1800 020 080 Website: https://health.nt.gov.au/
Queensland	Coronavirus Helpline:134COVID (134 268) Website: https://www.health.qld.gov.au/
South Australia	Coronavirus Helpline (9 am to 5 pm daily) :1800 253 787 Website: https://www.sahealth.sa.gov.au/
Tasmania	Public Health Hotline (Coronavirus):1800 671 738 Website: https://www.health.tas.gov.au/
Victoria	Coronavirus Hotline (24/7) :1800 675 398 Website: https://www.dhhs.vic.gov.au/
Western Australia	Coronavirus Hotline (8 am to 6 pm, Mon to Fri):1800 595 206 Website: https://www.healthywa.wa.gov.au/

Basic Information

	INNOVITA (TANGSHAN) BIOLOGICAL TECHNOLOGY CO., LTD. No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, Hebei, 064400, China.
Sponsor	BGI HEALTH (AU) COMPANY PTY LIMITED Level 6, CBCRC Building, 300 Herston Road, Herston QLD 4006, Australia Email: bgi-australia@genomics.cn Tel: +61733620475

Basic Information

	Do not reuse	IVD	For in vitro diagnostic use only
4℃ 30℃	Stored between 4~30°C		Consult instructions for use
	Caution	LOT	Lot number
	Use by	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged
	Date of Manufacturing	REF	Catalogue No.

Version 1.2, 27 April 2022

For Customer Support Call +61733620475 for information on the correct use of this test and for interpretation of the test result. Customer Service Hours: 9am-7pm(AEST) or 9am-8pm(AEDT), 7 Days a week.

2019-nCoV Ag Test (Latex Chromatography Assay)

Instructions For Use
For In Vitro Diagnostic Use only
For Self-testing

REF YF320C-NS-HU-1T 1 test/box

REF YF320C-NS-HU-2T 2 tests/box

REF YF320C-NS-HU-5T 5 tests/box

Before testing, scan the QR code to watch instructional video and open the instructions for use. For more information, please visit: https://bgi-australia.com.au/bgi-innovita-rat

Innovita (Tangshan) Biological Technology Co., Ltd.
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