INNOVITA

No test too small, No matter too big.

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

Innovita (Tangshan) Biological Technology Co., Ltd

No. 699 Juxin Street, High-Tech Industrial Development Zone, Qian'an, Hebei, 064400 CHINA

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 SARS-CoV-2 nucleocapsid protein antigen in anterior nasal swab that is self-collected by an individual aged 18 years or older or is collected by an adult from young individuals. It only recognizes the N protein and cannot detect the S protein or its mutation site.

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℃-30℃, the validity period is 18 months (see the label for the specific batch number and expiration date).
2. After the pouch is unsealed, the device should be used as soon as possible within 1 hour.

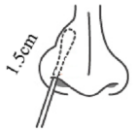
Step 1: Preparation

1. Read the instructions carefully before starting the test.

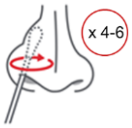
2. Find a clean and light work surface with enough space. Have a watch or device that can time next to the test cassette.
3. Allow the test device to equilibrate to **room temperature (15–30℃)** prior to opening the pouch.
4. Wash or disinfect your hands before starting the test and after finishing the test.

Step 2: Specimen Collection

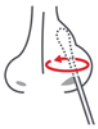
1. Take out the swab from the package without touching the padding.



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

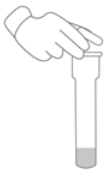


3. Using moderate pressure, turn the swab **4 - 6 times** in a circular motion for at least 1**5 seconds**.

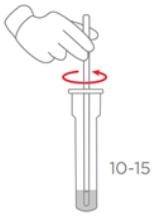


4. Repeat the sampling with the same swab in the other nostril.

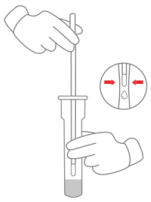
Step 3: Specimen Handling



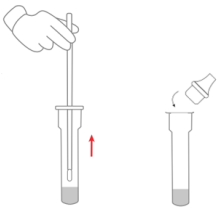
1. Peel the cover.



2. 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.

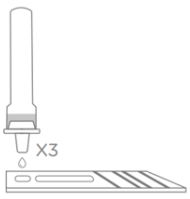


3. Squeeze the tube.



4. Remove the swab and then cover the lid and the extraction solution can be used as the test specimen.

Step 4: Test Procedure



1. Apply **3 drops** of the test specimen into the specimen well.

wait 15~30 minutes

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

Positive

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. Immediately you should get into the self-quarantine according to local guidelines and call your doctor or the local health department according to the specifications of your local authorities. Your test result will be checked by a PCR test and the next steps will be explained to you.

Negative

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, refer to your local authorities to the nearest medical facility. You can also repeat a test with a new test device. In case of suspicion, repeat the test after 1-2 days.

Invalid

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 discard it in a hazardous waste bin in accordance with local, state, and federal regulations.

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. The desiccant in pouch is only used for product storage, not for other purposes.
3. Do not use damaged test kit. **Do not reuse the test kit.**
4. Do not use kits or reagents after the expiration dates shown on the labels.
5. Do not open any package until you are ready to begin your test.
6. Use the test within 60 minutes after unsealing the foil pouch.
7. Read results between 15~30 minutes.
8. This test should be performed at 15 to 30℃. If stored refrigerated, ensure that the pouch and extraction diluent are brought to operating temperature before performing testing.
9. It is preferred to test the specimen immediately after collection and should not be repeatedly frozen and thawed.
10. Use the collectors and diluent provided by this reagent to collect specimens. Do not mix different batches of the test device and diluent.
11. Inadequate or inappropriate specimen collection are likely to yield false test results.
12. Do not perform the test in direct sunlight.

13. Keep out of reach of children. The test contains small parts that may present a choking hazard.
14. 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.
15. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
16. Disinfection and disposal of all potentially contagious materials must be in accordance with local, state, and federal guidelines.

Warning

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.

Performance Characteristics

1. Use the national or enterprise reference controls for testing, and the results meet the detection requirements of national or enterprise reference controls.
2. 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.

3. Endogenous/Exogenous Potentially Interfering Substances

Low titer SARS-CoV-2 inactivated positive culture virus and negative specimens were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positive or false negative results were found with the following:

Name of Substance	Concentration	Name of Substance	Concentration
Whole blood	5% V/V	Mucin	5 mg/mL
Oxymetazoline	15% V/V	Oseltamivir	5 mg/mL
Xlear	5% V/V	Mupirocin	10 mg/mL
Naso GEL	5% V/V	Ambroxol Hydrochloride Tablets	0.6 mg/mL
Nasal spray（mometasone furoate）	0.05% V/V	Nasal drops (phenylephrine)	0.5% V/V
Nasal cleansing liquid (NaCl)	5% V/V	--	--

4. Clinical Performance

The clinical performance of the INNOVITA 2019-nCoV Ag Test was evaluated with a total of 237 clinical specimens. Of these, 115 were from individuals with confirmed positive PCR test results for SARS-CoV-2 RNA, and 122 were from individuals with negative PCR test results for SARS-CoV-2 RNA.

INNOVITA 2019-nCoV Ag Test	Number of PCR specimens	
	Positive	Negative
Positive	109	0
Negative	6	122
total	115	122
Sensitivity	94.78%, 95% CI: 88.99%-98.06%	
Specificity	100%, 95% CI: 97.02%-100%	

5. Hook effect

No high dose hook effect was observed up to 1.0 x 10^6 $TCID_{50}$/mL with the SARS-CoV-2 inactivated culture virus.

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).

Basic Information

INNOVITA (TANGSHAN) BIOLOGICAL TECHNOLOGY CO., LTD.
No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, Hebei, 064400, China.

Osmunda Medical Technology Service GmbH
Treskowallee 108, 10318 Berlin, Germany
Tel: 0049-30-81865123

Index of Symbols

	Do not reuse	IVD	For in vitro diagnostic use only
4℃ 30℃	Stored between 4~30℃		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.
EC REP	Authorized Representative in the European Community		

Version 2.0,14th May, 2021

Scan for Instructional Video

INNOVITA BIOLOGICAL TECHNOLOGY CO., LTD.
Tel: +86 10 83681277
Fax: +86 10 83682966
Email: export@innovita.com.cn
Website: www.innovita.com.cn