Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)

An Antigen rapid test for the detection of SARS-Cov-2 in nasal swab. For self-testing use.

Read the instructions carefully before taking the test.

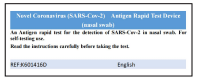
REF:K601416D English

◆ MATERIALS PROVIDED

Test device

Nozzle

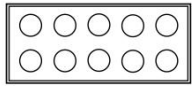
Extraction Tube with buffer



Package Insert

Sterilized Swab

Biohazard Specimen Bag



Tube stand(The 25 tests/kit package contains the tube stand,the 1 test/kit and 5 tests/kit package use the test box itself as tube stand.)

Materials required but not provided

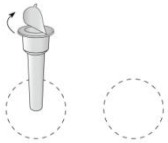
Timer

◆ TEST PROCEDUR

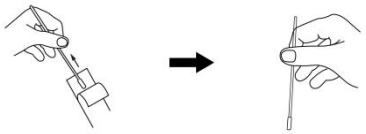
Step 1
Wash or clean your hands at least 20 seconds and make sure they are dry before starting the test.

Step 2
Read the instruction for use carefully.

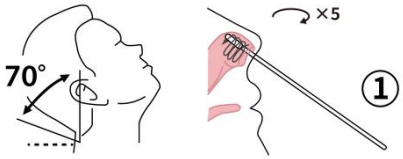
Step 3
Take out one extraction tube, pull off the sealed aluminum foil on the extraction tube and place extraction tube in the tube stand or in the hole in the box.



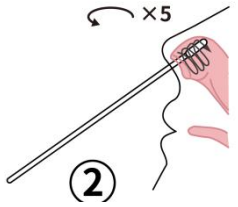
Step 4
Unpack the swab. **Caution: The swab should not contact with anything else, otherwise the result could be falsified.**



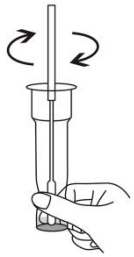
Step 5
Tilt your head back slightly. Insert the swab about 2 cm - at least with the entire soft swab tip - into the left nostril. Gently rotate the swab at least five times against the nasal wall.



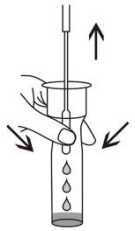
Step 6
Insert the same swab about 2 cm - at least with the entire soft swab tip - into the right nostril. Again, gently rotate the swab at least five times against the nasal wall. Remove the swab from the second nostril. **Caution: If the swab stick breaks during specimen collection, please use a new swab.**



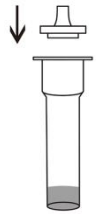
Step 7
Dip the soft swab tip into the liquid. Rotate the swab for at least 15 seconds while pressing the head against the inside of the tube to dissolve the specimen in the liquid.



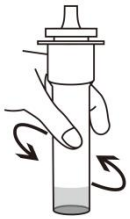
Step 8
Now pull the swab out of the extraction tube and wipe it off the edge of the tube. Discard the swab in a trash bag.



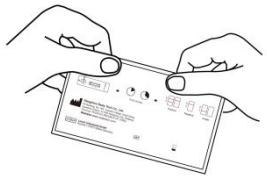
Step 9
Screw on and tighten the nozzle onto the extraction tube.



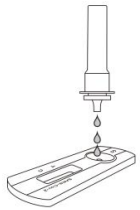
Step 10
Shake the extraction tube vigorously to mix the specimen and the sample extraction buffer.



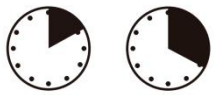
Step 11
Open the foil pouch and take out the test cassette.Place the checked test cassette on a flat, clean surface. **CAUTION: Perform the test within 60 minutes after the foil pouch is opened.**



Step 12
Add 3 drops of the solution from the specimen collection tube to the sample well of the test cassette.

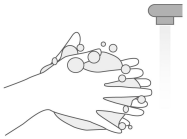


Step 13
Set timer for 10 minutes. CAUTION: **Do not read the result beforehand, even if a line has already appeared at control region C.**

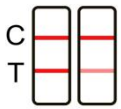
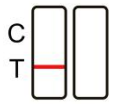


Step 14
Please dispose of the test materials in a closed plastic bag with the household refuse.If there are local regulations, please follow them.

Step 15
Wash hands thoroughly after test completion.



◆ INTERPRETATION OF RESULTS

Positive	Negative	Invalid
		
Two red lines appear. A red line appears in the control region (C) and a red line in the test region (T). **The shade may vary, but if even a faint line appears, it should be considered positive. If the test result is positive, you must immediately isolate. Please contact your State or Territory Coronavirus testing services to get a laboratory PCR test. Stay away from other people and isolate yourself.**	Only one red line appears in the control region(C), and no line in the test region (T). The negative result indicates that there are no Novel coronavirus particles in the sample or the number of viral particles is below the detectable range. However, a negative result does not rule out COVID-19. **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.**	No red line appears in the control region(C). The test is invalid even if there is a line on test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. **Review the test procedure and repeat the test using a new test device.**

INTENDED USE

This kit is intended for the qualitative detection the N protein of SARS-CoV-2 antigens in human anterior nasal swab specimens from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.It is used for self-testing.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Individuals who test positive results should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management.

This kit is intended for layperson's home use in a non-laboratory environment (e.g. in a person's residence or in certain non-traditional places such as offices, sporting events, airports, schools, etc.). Test results of this kit are for clinical reference only. It is recommended that a comprehensive analysis of the disease be conducted based on clinical manifestations of patients and other laboratory tests.

PRINCIPLE

This kit is based on colloidal gold immunochromatographic technology for rapid detection the N protein of SARS-CoV-2 antigens in human anterior nasal swab specimen. The sample is dropped into the test cassette during the test, and the liquid is chromatographed through the capillary action to the top. After the test is complete, observe the color reaction of the colloidal gold on the T-line and C-line to determine the SARS-CoV-2 antigen result.

PRECAUTIONS

- For in vitro diagnostic use only.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform the test at room temperature 15 to 30℃.
- Do not substitute the swab and sample extraction buffer provided in this kit with components from other kits.
- Place the soft tip of the swab into the nostril.
- Strictly follow the operating instructions.
- The samples should be tested immediately after collection.
- Children should be tested by an adult or under their supervision.
- Avoid eating and drinking before conducting the test.

STORAGE AND STABILITY

- The test can be stored at 2℃-30℃ for 12 months from the date of manufacture.
- Do not use after expiry.

LIMITATIONS

- Test should be performed within 7 days of the onset of symptoms. False negative rate for Result of individual not performed within 7 days after the onset of symptoms or asymptomatic will increase significantly Because of low level of concentration. The reliability of the product's result detection 7 days after the onset of symptoms or in asymptomatic people still needs to be verified.
- The test is less reliable in the later phase of infection and in asymptomatic individuals.
- It is a presumptive test only and the need for confirmatory testing of positive results by a laboratory PCR test and for follow-up clinical care.
- Repeat testing within 1 - 3 days is recommended in occupational risk, high risk settings or if there is an ongoing suspicion of infection.
- 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.
- A negative result does not rule out infection with another type of respiratory virus.
- A positive test result indicates that the sample contains SARS-CoV-2 antigen. It cannot be proved that the individuals is infected with the disease. Therefore, the positive result needs to be further confirmed, and the positive individual needs to contact your State or Territory Coronavirus testing services to get a laboratory PCR test.
- The test result of this kit is not the only confirmatory indicator for clinical indications. The infection should be confirmed by a specialist in combination with other laboratory results, clinical symptoms, epidemiology, and additional clinical data.
- In the early stages of infection or before symptoms appear, low antigen expression may lead to negative results. Individuals with a history of exposure to the virus should be tested for 3 consecutive days to determine whether they are infected
- 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 cross-contamination is not controlled during specimen processing, false-positive results may occur.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Using Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) by professional was compared to the RT-PCR kit. A sensitivity of 96.30% (130/135 known confirmed Postives) and a specificity of >99% (450/450 known confirmed Negatives) were determined for the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab).

Variants Information

Using Recombinant protein and clinical specimen of different variants perform the study of analytical sensitivity of the product, the result demonstrated this test is not affected by variants Alpha, Beta, Gamma ,Epsilon and Delta.

Limit of Detection (LOD)

The Limit of Detection (LoD) of the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) is confirmed as 625 $TCID_{50}$/mL.

Cross Reaction

The Cross reactive study results show that below presented microorganism naturally occurring in respiratory tracts or causing respiratory tract disease do not affect the test results of Novel Coronavirus:

Virus/Bacteria/Parasite	Strain	Virus/Bacteria/Parasite	Strain
MERS-coronavirus	N/A	Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]
			178 [Poland 23F-16]
Adenovirus	Type 1		262 [CIP 104340]
	Type 3		Slovakia 14-10 [29055]
	Type 5	Streptococcus pyrogens	Typing strain T1[NCIB 11841, SF 130]
	Type 7	Mycoplasma pneumoniae	Mutant 22
	Type 8		FH strain of Eaton Agent [NCTC 10119]
	Type 11		36M129-B7
	Type 18	Coronavirus	229E
	Type 23		OC43
	Type 55		NL63
Influenza A	H1N1 Denver		HKU1
	H1N1 WS/33	Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002
	H1N1 A/Mal/302/54	Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003
	H1N1 New Caledonia	Parainfluenza virus	Type 1
	H3N2 A/Hong Kong/8/68		Type 2
Influenza B	Nevada/03/2011		Type 3
	B/Lee/40		Type 4A
	B/Taiwan/2/62	Rhinovirus A16	N/A
Respiratory syncytial virus	N/A	candida albicans	CICC 1965
Legionella pneumophila	Bloomington-2	pseudomonas aeruginosa	ATCC9027
	Los Angeles-1	staphylococcus epidermis	ATCC 14990
	82A3105	staphylococcus salivarius	ATCC 25975
Mycobacterium tuberculosis	K	Enteroviruse	EV68
	Erdman		
	HN878		EV71
	CDC1551	chaamydia pneumoniae	VR2282
	H37Rv	haemophilus influenzae	ATCC9006
bordetella pertussis	ATCC9340	/	/

Interfering Substances Reaction

The interfering study results show that the substances below do not affect the test results of Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab):

Substance	Substance
Mucin	Acetylsalicylic acid
Whole Blood	Ibuprofen
Biotin	Mupirocin
Neo-Synephrine (Phenylephrine)	Tobramycin
Afrin Nasal Spray (Oxymetazoline)	Erythromycin
Saline Nasal Spray	Ciprofloxacin
Homeopathic	Ceftriaxone
Sodium Cromoglycate	Meropenem
Olopatadine Hydrochloride	Tobramycin
Zanamivir	Histamine Hydrochloride
Oseltamivir	Peramivir
Artemether-lumefantrine	Flunisolide
Doxycycline hyclate	Budesonide
Quinine	Fluticasone
Lamivudine	Lopinavir
Ribavirin	Ritonavir
Daclatasvir	Abidor
Acetaminophen	Pooled human nasal wash
Staphylococcus aureus	HAMA

FREQUENTLY ASKED QUESTIONS

- **When can I test myself?**

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, more false positive results may occur. Testing of individuals without symptoms should be limited to contacts of confirmed or probable cases or to other epidemiological reasons to suspect a COVID-19 infection and should be followed by additional confirmatory testing with a molecular test.

- **What do I have to do in order to get the most precise test result possible?**

Always follow the instructions very carefully. Perform the test immediately after the specimen is collected and prepared. Add the drops from the specimen collection tube only into the sample well of the test cassette. Add three drops from the specimen collection tube. Adding too many or too few drops may lead to an incorrect or invalid test result.

- **The test strip is heavily discolored. What is the reason, or what did I do wrong?**

The reason for a clearly visible discoloration of the test strip is that too many drops have been added from the tube into the well of the test cassette. The indicator strip can only hold a limited amount of liquid. If the control line does not appear or the test strip is heavily discolored, please repeat the test with a new test cassette according to the instructions.

- **What should I do if I have taken the test, but I saw no control line?**

In this case, the test result is to be considered invalid. Please repeat the test with a new kit according to the instructions. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

- **I'm not sure how to interpret the results. What should I do?**

In case you cannot clearly determine the result of the test, contact the nearest medical facility that applies your local regulations.

- **My result is negative. What should I do?**

If there is only one horizontal colored line in the control region (C), it could mean that your result is negative or that the number of viral particles is below the detectable range.

If you encounter symptoms such as headache, migraines, fever, losing your sense of smell and taste, contact the nearest medical facility that applies your local regulations. You can also repeat the test with a new test kit.

The users with negative test results don't mean they are free to disregard social distancing and other measures to socialize, travel, attend events, etc. Please follow local Covid-19 guidelines or requirements.

- **Can this test cassette be reused or used by more than one person?**

This test device is intended for a single use only. It cannot be reused or shared by several people.

SYMBOL

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number	Σ	Contains sufficient for <n> tests

For the test device

Hangzhou Realy Tech Co., Ltd.
#2 Building, No. 763, Yuansha Village, Xinjie Street, Xiaoshan District, 311200 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
Website: www.realytech.com

EC REP
Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
E-mail: peter@lotusnl.com

CE 2934

For the sterilized swab

Shenzhen Kangdaan Biological Technology Co., Ltd.
East-1, Floor 3, Building 2, Shunheda Plant Area,
Liuxiandong Industrial Zone, Xili Street, Shenzhen.

EC REP
Share info consultant service LLC Repräsentanzbüro
Heerdter Lohweg 83,40549 Düsseldorf, Germany.

CE 0197

Number:1100071001
Version: 1.0
Effective Date: 2022-02-08