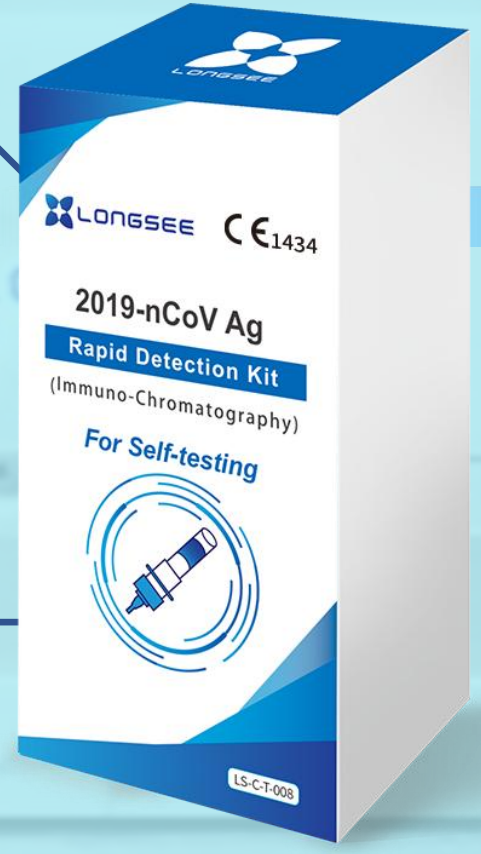
LS-C-T-008 U3

2019-nCoV Ag Rapid Detection Kit

—(Immuno-Chromatography)

LONGSEE LS-C-T-008

Scan the QR code to get the English operation video!!!



Product Pictures

LONGSEE CE1434

For Self-testing

2019-nCoV Ag Rapid Detection Kit
(Immuno-Chromatography)

REF: LS-C-T-008(U3)

Simpler! Faster! Non-invasive!

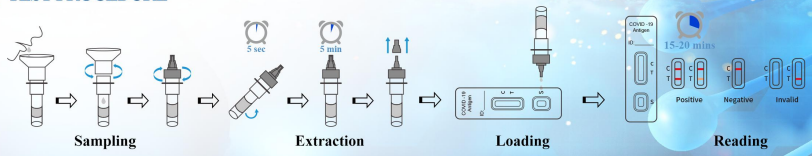
INTRODUCTION

The kit is an in vitro diagnostic rapid test for the qualitative detection of 2019-nCoV nucleocapsid protein antigens in human saliva specimens from individuals with symptoms or other epidemiological reasons to suspect a 2019-nCoV infection,but it is not for determining infection status. The kit is authorized for non-prescription home use with self-collected direct saliva specimens from individuals aged 13 years or older or adult collected saliva specimens from individuals aged less than 13 years old.

PRODUCT ADVANTAGE

Non-invasive
Rapid result in 15-20 minutes
Easy to use at home

TEST PROCEDURE



Guangdong Longsee Biomedical Co., Ltd.
Tel:+86-20-66234660
E-mail:info@longseemed.com
More information: http://www.longseemed.com/
Add:5/F Building A, No.83, Ruihe Road, Huangpu District, 510000, Guangzhou, China

Specifications

Info. of the Test Kit and Export Packing Cartons

Product Name	Specifications	Size (cm)	Quantity/Box
2019-nCoV Ag Rapid Detection Kit(Immuno-Chromatography) LS-C-T-008 (mini版)	1 T/Kit	5.2x4.1x9.8	600 Kits/Box (600 T/Box)

Size of Carton	CBM	G.W.	N.W.
63.5x51.5x44cm	0.143891 m³	17.5kg	16.1kg

User Manual

LONGSEE English IVD CE

2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)

Instructions for Use REF LS-C-T-008 (U3)

【Intended Use】

The kit is an *in vitro* diagnostic rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in human saliva specimens from individuals with symptoms or other epidemiological reasons to suspect a SARS-CoV-2 infection,but it is not for determining infection status. The kit is authorized for non-prescription home use with self-collected direct saliva specimens from individuals aged 13 years or older or adult collected saliva specimens from individuals aged less than 13 years old.

For in vitro diagnostic use only. For self-testing.

【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.

【Test Principle】

The kit is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in samples by the double antibody sandwich method .When specimens are processed and added to the test cartridge and concentration of the SARS-CoV-2 antigens in specimens is higher than or equal to the minimum detection limit,these antigens react separately with corresponding antibodies to form complexes. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. Color bands will show up when antigen-conjugate is deposited at the test area(T) and the control area(C) on the device.The test result is positive. Otherwise, the result is negative,when only a color band appearing at the control area(C) on the device.Under normal testing conditions, the control area(C) should appear a color band to indicate that the test is valid.

【Components】

NO.	Component	1 T/Kit
1	2019-nCoV Ag Rapid Detection Kit Test Cartridge	1 Pc
2	Saliva Sample Collection Kit	1 Pc
3	Specimen Bag	1 Pc
4	Instructions for Use	1 Pc

【Materials Required but not Provided】

1. Timer

【Warnings and Precautions】

1. Read carefully the entire instructions prior to performing test.
2. For self-testing *in vitro* diagnostic use only.
3. The test is for one time use only, do not reuse the test. Do not use after expiration date.
4. DO NOT eat, drink, smoke, brush teeth, or chew gum for 30 minutes before collecting saliva.
5. DO NOT eat, drink or smoke in the area where the specimens or kits are handled.
6. DO NOT drink the buffer in the kit. Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
7. DO NOT swallow desiccant in foil pouch.
8. DO NOT use test if pouch is damaged.
9. Remove the test cartridge from the sealed pouch only when you are ready to perform the test and it should be used within 30 minutes.
10. Test for children and young people need adult supervision.
11. Keep the test kit away from children to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
12. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.If the result is preliminary positive, share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements.
13. Even if your test result is negative, continue to observe all applicable hygiene and safety measures. Even with a negative result, you may still be infectious. If you are showing symptoms you must seek immediate further testing by a laboratory PCR.
14. After disinfection,the test kit components and user samples can be disposed of with normal household waste in compliance with the applicable local regulations.Other components contacted with the sample (e.g. used fragment of the tabletop, timer surface) can be a source of infection even if the test is negative and should be disinfected. Hands should be washed or disinfected after and also before the procedure.
15. If you have any questions or need help, please contact the manufacturer (as email at the end of the instructions), or local distributor to solve problems timely.
16. NOTICE TO THE USER: Any serious incident that has occurred in relation to the LONGSEE 2019-nCoV Ag Rapid Detection Kit shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

【Storage and Stability】

1. Store at 4-35 ℃ up to the expiration date printed on the package.
2. Do not freeze the kit or its components.

【Test Procedure】

Test Preparation

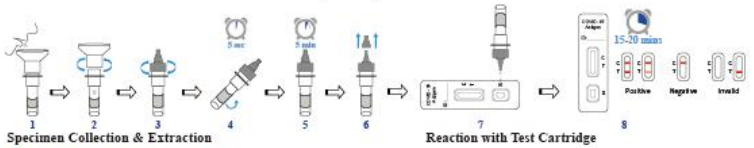
1. Allow all kit components to equilibrate to room temperature (15-30°C) prior to testing for 30 minutes,if previously stored in a cool place.
2. Do not eat, drink, smoke, brush teeth, or chew gum for 30 minutes before collecting saliva.

Specimen Collection & Extraction

1. Spit the expectorated saliva into the collection funnel gently as much as possible close to 1mL.
2. Unscrew the collection funnel gently to allow the saliva flow into the collection tube completely.
3. Screw the nozzle onto the collection tube.
4. Turn upside down the collection tube slightly for 5 seconds, so that the diluent can mix with the saliva sample evenly.
5. Leave the collection tube stand at room temperature for 5 minutes
6. Remove the nozzle cap.

Reaction with Test Cartridge

7. Remove a test cartridge from the sealed pouch by tearing at the notch and place it on a level surface.Drip vertically 2~3 drops of liquid at 2~3 second intervals into the specimen well (S) on the test cartridge by squeezing the tube. Do not handle or move the test cartridge until the test is complete and ready for reading.
8. Start timer. Read result within 15 ~20 minutes of adding the sample. The test result is invalid after 20 minutes.



Specimen Collection & Extraction — Reaction with Test Cartridge

【Interpretation of the Result】

To read the test results, all you have to do is look at the results window.

1. Positive Test

If a color band at control area(C) and test area (T) is visible in the result window, the test result is positive. The test result indicates that the sample contains 2019-nCoV antigens.

If the test result is positive:

- The SARS-CoV-2 infection is very likely.
- Contact a doctor / general practitioner or a local health department immediately.
- Follow local guidelines for self-isolation.

2. Negative Test

If only a color band at control area(C) and no test area (T) is visible in the result window, the test result is negative. The test result indicates that there are no 2019-nCoV antigens in the sample or the concentration is below the detection limit of the set .

If the test result is negative:

- Continue to follow all applicable rules regarding contact with others and protective measures.
- If you suspect, repeat the test using new test kit after 1 - 2 days, as the coronavirus has not been accurately detected in all phases of an infection.
- Even if the test is negative, there may be an infection.
-If symptoms are present, you should consult it with a doctor to help determine the appropriate course of action, taking into account other possible causes of the symptoms.

3. Invalid Test

If no color band at control area(C) or only a color band at test area (T) is visible in the result window, the test result is invalid.

If the test result is invalid:

- May be caused by incorrect test performance.
- Repeat the test using new test kit.
- If the test results remain invalid, contact a doctor or a COVID-19 testing center.

【Limitations】

1. The contents of this kit are to be used for home use by laypersons and qualitative detection of 2019-nCoV antigen from saliva. Other specimen types may lead to incorrect results and must not be used.
2. Failure to follow the instructions for test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results. When dripping sample,dripping bubbles of the extraction tube into the specimen well may give inaccurate results.
3. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.

User Manual

LONGSEE

【Performance Characteristics】

1. LIMIT OF DETECTION

The limit of detection has been evaluated at 6.4×10^2 $TCID_{50}$/mL.

2. CROSS-REACTIVITY

There was no cross-reaction and interference with the potential cross-reacting microorganisms listed below.

	Potential Cross-Reactant	Test Concentration
Virus	Adenovirus	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus HKU1	1.0×10^5 $TCID_{50}$/mL
	MERS-coronavirus	1.0×10^5 $TCID_{50}$/mL
	SARS-coronavirus	1.0×10^5 $TCID_{50}$/mL
	Human Metapneumovirus (hMPV)	1.0×10^5 $TCID_{50}$/mL
	Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL
	Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL
	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL
	Parainfluenza virus 4	1.0×10^5 $TCID_{50}$/mL
	Influenza A	1.0×10^5 $TCID_{50}$/mL
	Influenza B	1.0×10^5 $TCID_{50}$/mL
	Enterovirus	1.0×10^5 $TCID_{50}$/mL
	Respiratory syncytial virus	1.0×10^5 PFU/mL
	Rhinovirus	1.0×10^5 PFU/mL
Bacteria	Bordetella pertussis	1.0×10^6 cells/mL
	Chlamydia pneumoniae	1.0×10^6 IFU/mL
	Haemophilus influenzae	1.0×10^6 cells/mL
	Legionella pneumophila	1.0×10^6 cells/mL
	Mycoplasma pneumoniae	1.0×10^6 U/mL
	Streptococcus pyogenes	1.0×10^6 cells/mL
	Streptococcus pneumoniae	1.0×10^6 cells/mL
	Mycobacterium tuberculosis	1.0×10^6 cells/mL
	Staphylococcus aureus	1.0×10^6 org/mL
	Staphylococcus epidermidis	1.0×10^6 org/mL
	Pooled human nasal wash	N/A
Yeast	Candida albicans	1.0×10^6 cells/mL

3. INTERFERING SUBSTANCES

There was no interference for potential interfering substances listed below.

Substance	Concentration
Throat Lozenges (benzocaine/menthol)	3 mg/mL
Cough drops (Dextromethorphan HBr)	3 mg/mL
Robitussin	5% v/v
Chloroseptic Sore Throat spray (Phenol, Glycerin)	5% v/v
Emergen-C (Zinc, Magnesium, Riboflavin, Vitamin C)	3 mg/mL
Listerine Mouthwash (Eucalyptol, menthol, Methyl Salicylate, Thymol)	5% v/v
Act dry mouth lozenges (Isomalt, xylitol, Glycerin)	3 mg/mL
Toothpaste (Colgate)	0.5% v/v
Nyquil (Acetaminophen, Doxylamine succinate, Dextromethorphan HBr)	3 mg/mL
Mucin: bovine submaxillary gland, type I-S	2.5 mg/mL
Human Genomic DNA	10 ng/μL
Vaseline (Petroleum Jelly)	3 mg/mL
Nicotine	0.03 mg/mL
Alcohol (Ethanol)	5%
White blood cells/Leukocytes	1 to 5×10^6 cells/mL
Whole Blood	2.5%

4. HOOK EFFECT:

No high dose hook effect was observed when tested with up to a concentration of 1.5×10^6 $TCID_{50}$/mL of heat inactivated 2019-nCoV.

5. CLINICAL EVALUATION

The performance of Test was established with 501 sample collected from symptomatic patients, with symptoms onset within 7 days.

2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	Comparative RT-PCR Test Result		
	Positive (+)	Negative (-)	Total
Detected Positive	174	1	175
Detected Negative	14	312	326
Total	188	313	501
Sensitivity	92.55%, 95% CI (87.57,95.71)		
Specificity	99.68%, 95% CI (97.95, 99.98)		
Accuracy	97.01%, 95% CI (95.12, 98.18)		

6.PRECISION

6.1. Test 5 replicates of negative and positive by using the reference materials of enterprises. The negative agreement and the positive agreement were 100%.

6.2. Test three different lots kits including positive and negative reference materials of enterprises. The negative results and the positive results were 100%.

7.MUTATIONS IMPACT STUDY

The SARS-CoV-2 variant strains ·(USA-WA1/2020， hCoV-19/USA/OR-OHSU-PHL00037/2021 (Lineage B.1.1.7; Alpha Variant)，hCoV-19/USA/MD-HP01542/2021 (Lineage B.1.351; Beta Variant)，hCoV-19/USA/PHC658/2021 (Lineage B.1.617.2; Delta Variant)，hCoV-19/Japan/TY7-503/2021 (Brazil P.1; Gamma Variant)）， obtained from BEI Resources，had been tested.The results of study and analysis on such indicators as appearance, width of film strip, liquid moving speed, lowest detection limit, Precision, specificity, hook effect, sample stability, sample size, operating temperature, detection time of the kit, have reached intended requirements and can meet the needs of clinical practice.

【Symbol Explanation】

Symbols	Title of symbol	Symbols	Title of symbol	Symbols	Title of symbol
IVD	*In vitro* diagnostic medical device	LOT	Batch code	4℃ 35℃	Store between 4~35℃
	Do not re-use		Date of manufacture	EC REP	Authorized representative in the European Community
	Keep away from sunlight		Use-by date	CE 0434	CE mark with number of Notified Body
	Keep dry		Do not use if package is damaged		Manufacturer
	Contains sufficient for <n> tests		Consult instructions for use	REF	Catalogue number

Guangdong Longsee Biomedical Co.,Ltd.
5/F Building A, No.83, Ruihe Road, Huangpu District, 510000, Guangzhou, China
E-mail: info@longseemed.com
Website: http://www.longseemed.com/

EC REP Qarad EC-REP BV
Pas 257, 2440 Geel, Belgium

Rev. B /1-S-EN-EU
Rel.:2022-06-01

Certificates

DECLARATION OF CONFORMITY

According to the *In vitro* Diagnostic Medical Device Directive 98/79/EC

Manufacturer	Guangdong Longsee Biomedical Co.,Ltd.
Address	5/F Building A, No.83, Ruihe Road, Huangpu District, 510000, Guangzhou, China
European Representative	Qarad EC-REP BV
Address	Pas 257, 2440 Geel, Belgium
Product Information	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)
Catalogue No.	LS-C-T-008
Classification	Other, for professional use
Conformity Assessment Route	IVDD Annex III (Excluding section 6)
General Applicable Directives:	*In vitro* Diagnostic Medical Device Directive 98/79/EC

Standards Applied	EN 13612:2002	EN 13612:2002/AC:2002
	EN ISO 23640:2015	EN 13641:2002
	EN ISO 14971:2012	EN ISO 15223-1:2016
	EN ISO 18113-1:2011	EN ISO 18113-2:2011
	EN ISO 13485:2016	EN ISO 13485:2016/AC:2018
	EN 62366-1:2015	

We,the manufacturer, hereby declare under our sole responsibility that the above mentioned products meet the provisions of the above EC Council Directives and Standards. The products meet prospective uses and all supporting documentations are retained under the premises of the manufacturer.

Notified Body:	Not Applicable
Address:	/
EC Certificate(s):	/
Expiry date of the Certificate(s):	/

Place, date of issued: Guangzhou, P. R. China, May 1, 2022

Signature of Chief Executive Officer:

Shizhou Deng

(Shizhou Deng)

CE

Doc No.: RA—001—IVDD—01 Effective: 2022-03-15 page 1 of 1

LONGSEE Profile

Guangdong Longsee Biomedical Co.,Ltd is a national high-tech enterprise dedicated to the core technology, data, product development and production of "intestinal microecological clinical medicine and health management". Its industries include five major areas: IVD (reagents + equipment), functional food, whole intestinal flora microbiota transplantation (FMT), living biological medicine and medical care services (clinical scientific research, medical testing, AI+ Internet medical treatment, high-end health care clinic). Longsee Biomedical has established R&D, data, technical services, and business bases in Guangzhou, Beijing, Nanjing, Chongqing, Wuhan, Singapore and other regions.