LS-C-T-009

2019-nCoV Ag Rapid Detection Kit

—(Immuno-Chromatography)

IFU

LONGSEE

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

REF: LS-C-T-009

25 T/Kit

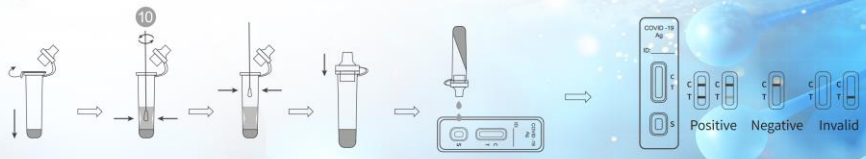
INSTRUCTION

The kit is an in vitro immunochromatographic test for rapid, qualitative detection of the 2019-nCoV nucleocapsid antigen extracted from the nasopharyngeal swab, oropharyngeal swab or nasal swab specimens from persons suspected of COVID-19 by a healthcare provider . The kit is intended to support the rapid diagnosis of 2019-nCoV infection.

PRODUCT ADVANTAGE

- Non-invasive
- Rapid result in 15~20 min
- High stability
- Easy to use

TEST PROCEDURE



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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-009	25 T/Kit	21x12.5x7.2	42 Kits/Carton (1050 T/Carton)

Size of Carton	CBM	G.W.	N.W.
53.5x43.5x39.5cm	0.0919 m^3	13.05kg	11.95kg

User Manual

LONGSEE English

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

Instructions for Use

【Intended Use】

The kit is an immunochromatographic test for rapid, qualitative detection of the 2019-nCoV nucleocapsid antigen extracted from the nasopharyngeal swab，oropharyngeal swab or nasal swab specimens from persons suspected of COVID-19 . The kit is intended to support the rapid diagnosis of 2019-nCoV infections.

For *in vitro* diagnostic use only. For professional use only.

【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】

This kit applies immunochromatography technology to detect the presence or absence of 2019-nCoV nucleocapsid proteins in swab specimens from patients with signs and symptoms of infection suspected of having 2019-nCoV by the double antibody sandwich method. While the concentration of the 2019-nCoV antigens in samples is higher than or equal to the minimum detection limit, these antigens react separately with corresponding antibodies to form complexes, and the 2019-nCoV antibodies are coated in the detection area (T). These antigens are captured and a red line of reaction is formed. The result is rated as positive. Otherwise the result formed in T without a red line is assessed as negative. Under normal test conditions, the quality control area (C) should be colored to indicate that the test is valid.

【Components】

	Component	1 T/kit REF LS-C-T-009-1	5 T/kit REF LS-C-T-009-5	25 T/kit REF LS-C-T-009
1	Test Cartridge	1 pc	5 pcs	25 pcs
2	One-off Swab(sterilized)	1 pc	5 pcs	25 pcs
3	Extraction Tube	1 pc	5 pcs	25 pcs
4	Instructions for Use	1 pc	1 pc	1 pc

Materials Required but Not Provided

1. Timer 2.Personal protective equipment, such as protective gloves, medical mask, goggles and lab coat. 3. Appropriate biohazard waste container and disinfectants.

【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.

【Warnings and Precautions】

1. Read carefully the entire instructions prior to performing test.
2. For professional 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 or smoke in the area where the specimens or kits are handled.
5. 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.
6. DO NOT swallow desiccant in foil pouch.
7. DO NOT use test if pouch is damaged.
8. DO NOT open the test cartridge until ready to use. If the test cartridge is open for 30 minutes or longer, invalid test results may occur.
9. 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.
10. 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.
11. After disinfection,the test kit components and user samples should be disposed of 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.
12. 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.
13. 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.

【Specimen Collection and Preparation】

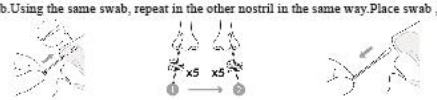
The test can be performed with nasopharyngeal swab，oropharyngeal swab or nasal swab specimens.

1.Nasopharyngeal swab specimen collection: Tilt patient's head back 70 degrees.Gently and slowly insert a minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.Gently rub and roll the swab.Leave swab in place for several seconds to absorb secretions.Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection.If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.Place swab ,tip first, into the extraction tube provided.

2. Oropharyngeal swab specimen collection: Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.Place swab ,tip first, into the extraction tube provided.

3. Nasal swab specimen collection:

Gently insert the entire absorbent tip of the swab into 1 nostril (no more than 2.5 cm).Using medium pressure, rub the swab tip against the inside wall of the one nostril.Make at least 5 large circles (about 15 seconds). Make sure collect nasal substances present on the swab.Gently remove the swab.Using the same swab, repeat in the other nostril in the same way.Place swab ,tip first, into the extraction tube provided.



4. It is recommended that specimens be treated with the sample extraction buffer provided with the kit as soon as possible after collection. If immediate processing is not possible, the specimen can be stored in a dry, sterilized and tightly sealed plastic tube at 2~8°C for up to 8 hours.

【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.

Extraction

1.Remove the foil from the top of the tube with the extraction buffer and place it stand up.

2.Immerse the sampled swab tip into the extraction tube and rotate the swab tip 10 times while pressing the swab tip against to the tube. Leave the swab in the tube for 1 min.

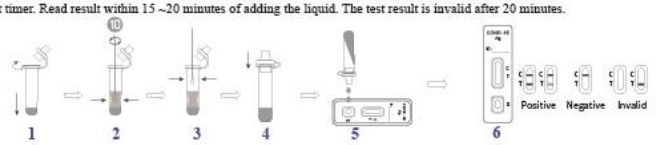
3.Remove the swab while squeezing the sides of the tube to express as much liquid as pososible from the swab.

4.Attach the dropper tip firmly onto the tube.

Reaction with Test Cartridge

5.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.

6.Start timer. Read result within 15 ~20 minutes of adding the liquid. The test result is invalid after 20 minutes.



【Interpretation of the Result】

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

1. Positive Test

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

2. Negative Test

If only a color band at control area(C) and no color band at 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.

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.The sample should be taken again and the test repeated.

User Manual

LONGSEE

【Limitations】

1. The contents of this kit are for professional use and qualitative detection of 2019-nCoV antigen from swab specimen. 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.
3. Due to the limitations of the methodology, experimenters should pay more attention to negative results.A negative test result may occur if the specimen was collected, extracted or transported improperly. A negative test result does not eliminate the possibility of 2019-nCoV infection and should be confirmed by viral culture or a molecular assay.
4. Positive test results do not rule out co-infections with other pathogens. Positive results may occur in cases of infection with SARS-CoV.
5. Test results must be evaluated in conjunction with other clinical data available to the physician.
6. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.

【Performance Characteristics】

1. Limit of Detection (LoD)

The limit of detection has been evaluated at $6.00\times10^{2}TCID_{50}$/mL .

2. Precision (repeatability and reproducibility)

Repeatability and reproducibility was established according to the CLSI guideline EP05-A3. Three operators using each a different lot test cards measured 5 samples in 5 replicates on 5 different days. Three (3) different concentrations of references – negative, low positive reference (2×LOD) and moderately positive reference (5×LOD) were tested as the instructions to determine the test results.Repeatability & reproducibility of three lots of kit was studied, and the detection rates of negative and positive were both 100%.

3. Cross Reactivity (Analytical Specificity)

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

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

4.Interfering Substances

There was no interference for potential interfering substances listed below:

Substance	Concentration	Substance	Concentration
Whole Blood	4%	Zicam	5% v/v
Mucin	0.5%	Homeopathic (Alkalol)	1:10 dilution
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Sore Throat Phenol Spray	15% v/v
Naso GEL (NeilMed)	5% v/v	Tobramycin	4 μg/mL
CVS Nasal Drops (Phenylephrine)	15% v/v	Mupirocin	10 mg/mL
Afrin (Oxymetazoline)	15% v/v	Fluticasone Propionate	5% v/v
CVS Nasal Spray (Cromolyn)	15% v/v	Tamiflu (Oseltamivir Phosphate)	5 mg/mL

5. High Dose 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.

6. Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by the 2019-nCoV Antigen Rapid Test Kit and RT-PCR. The results were summarized below:

6.1 Nasopharyngeal Swab

2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	Comparative RT-PCR Test Result		
	Positive (+)	Negative (-)	Total
Detected Positive	340	1	341
Detected Negative	16	362	378
Total	356	363	719
Sensitivity	95.51%, 95% CI (92.66,97.32)		
Specificity	99.72%, 95% CI (98.23,99.99)		
Accuracy	97.64%, 95% CI (96.25, 98.52)		

6.2 Oropharyngeal Swab

2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	Comparative RT-PCR Test Result		
	Positive (+)	Negative (-)	Total
Detected Positive	339	1	340
Detected Negative	17	362	379
Total	356	363	719
Sensitivity	95.22%, 95% CI (92.32,97.11)		
Specificity	99.72%, 95% CI (98.23,99.99)		
Accuracy	97.50%, 95% CI (96.08,98.41)		

6.3 Nasal Swab

2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	Comparative RT-PCR Test Result		
	Positive (+)	Negative (-)	Total
Detected Positive	179	1	178
Detected Negative	11	312	323
Total	188	313	501
Sensitivity	94.15%, 95% CI (89.50,96.89)		
Specificity	99.68%, 95% CI (97.95, 99.98)		
Accuracy	97.60%, 95% CI (95.86, 98.62)		

【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	CE mark
	Keep dry		Do not use if package is damaged		Manufacturer
	Contains sufficient for <n> tests		Consult instructions for use	REF	Catalogue number
STERILE R	Sterilized using irradiation				

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

Rev. B /2-P-EN-EU
Rel.:2022-06-11

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-009, LS-C-T-009-1, LS-C-T-009-5
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.