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

Instructions for Use

REF LS-C-T-008

【Intended Use】

2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography) is an in vitro diagnostic rapid test for the qualitative detection of 2019-nCoV antigen (Ag) in human saliva specimens. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by 2019-nCoV.The test provides preliminary test results. Negative results cannot exclude 2019-nCoV infection and they cannot be used as the sole basis for treatment or other management decision.

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

【Introduction】

The Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or 2019-nCoV) . It is an enveloped non-segmented positive-sense RNA virus, which is contagious in humans. 2019-nCoV has several structural proteins including spike (S), envelope (E), membrane (M), and nucleocapsid (N). It is spread by human-to-human transmission via droplets or direct contact, and infection has been estimated to have a mean incubation period of 6.4 days. Among patients with pneumonia caused by SARS-CoV-2 or 2019-nCoV, fever was the most common symptom, followed by cough. The main IVD assays used for COVID-19 employ real-time reverse transcriptase-polymerase chain reaction (RT-PCR) that takes a few hours. The availability of a cost-effective, rapid point-of-care diagnostic test is critical to prevent further spread of the virus. Antigen tests will play a critical role in the fight against COVID-19.

【Test Principle】

This kit applies immuno-chromatography technology to detect the presence or absence of 2019-nCoV nucleocapsid proteins (N) in saliva specimen.2019-nCoV Ag Rapid Detection Kit Test Cartridge contains a membrane strip. There are two pre-coated lines, "C" Control line, "T" Test line on the surface of the nitrocellulose membrane. Mouse monoclonal anti-2019-nCoV antibody is coated on the test line region and mouse monoclonal anti-Chicken IgY antibody is coated on the control line region.Both the control line and test line in the result window are not visible before applying any specimens. During the test, 2019-nCoV antigen in the specimen interact with monoclonal anti-2019-nCoV antibody conjugated with color particles making antigen-antibody color particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the mouse monoclonal anti-2019-nCoV antibody. A colored test line would be visible in the result window if 2019-nCoV antigens are present in the specimen.The intensity of colored test line will vary depending upon the amount of 2019-nCoV antigen present in the specimen. If 2019-nCoV antigens are not present in the specimen, then no color appears in the test line. Regardless of whether the sample contains viral antigens, the chicken IgY in the gold label pad and the mouse monoclonal anti-Chicken IgY antibody on the control line (C line) will form a specific binding, forming a purple-red band at the control line (C line).The control line is used for procedural control.

【Component】

NO.	Component	1/10/20/40 T/Kit
1	2019-nCoV Ag Rapid Detection Kit Test Cartridge	1/10/20/40 Pcs
2	Saliva Sample Collection Kit	1/10/20/40 Pcs

【Materials Required but not Provided】

1. Personal Protective Equipment per local recommendations (i.e. gown/lab coat, face mask, face shield/eye goggles and gloves)
2. Timer
3. Biohazard container

【Storage and Stability】

1. The kit should be stored at a temperature between 4-35 °C. Do not freeze the kit or its components. Open the kit and allow all kit components to stand for 30 minutes at room temperature (15 ° C to 30 ° C), if previously stored in a cool place, before performing the test.The test cartridge should be used within 30 minutes after removing from the foil pouch.
2. Do not use the test kit beyond its expiration date.
3. The shelf life of the kit is as indicated on the outer package.
4. Do not use the test kit if the pouch is damaged or the seal is broken.

【Test Procedure】

Test Preparation

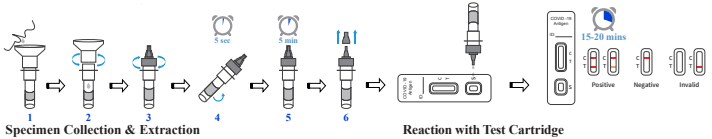
1. Allow all kit components to equilibrate to room temperature (15-30°C) prior to testing for 30 minutes.
2. Do not place anything in the mouth including food,drink,gum, tobacco,water and mouthwash products for at least 30 minutes prior to collection of oral fluid specimen.

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

1. Remove a test cartridge from the sealed pouch by tearing at the notch and place it on a level surface.Drip 3~4 drops (about 100 μL) of extracted specimens vertically into the specimen well (S) on the test cartridge by squeezing the collection tube. Do not handle or move the test cartridge until the test is complete and ready for reading.
2. 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 faint pink-red control line (C), together with a faint pink-red test line (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:

- There is currently a suspicion of COVID-19 infection.
- Contact a doctor / general practitioner or a local health department immediately.
- Follow local guidelines for self-isolation.
- Have a PCR confirmation test performed.

2. Negative Test

If only a pale pink control line (C) and no test line (T) can be seen in the result window, the test result is negative. The test result indicates that there are no 2019-nCoV antigens in the sample.

If the test result is negative:

- Continue to follow all applicable rules regarding contact with others and protective measures.
- Even if the test is negative, there may be an infection.
- If you suspect, repeat the test after 1 - 2 days, as the coronavirus has not been accurately detected in all phases of an infection.

3. Invalid Test

If no control line (C) or only a test line (T) is visible in the results window, the results are invalid.

In the event of an invalid test result:

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

【Limitations】

1. The contents of this kit are for professional use 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. 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

The limit of detection has been evaluated at 6.5×10^2 $TCID_{50}$/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
Whole Blood	4%
Mucin	0.5%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v
CVS Nasal Drops (Phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic (Alkalol)	1:10 dilution
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 μg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Tamiflu (Oseltamivir Phosphate)	5 mg/mL

4. HOOK EFFECT:

There is no hook effect at 1.5×10^6 $TCID_{50}$/mL of SARS-CoV-2 which was isolated from a COVID-19 confirmed patient in China.

5. CLINICAL EVALUATION

Clinical evaluation was performed to compare the results obtained by The 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography) and RT-PCR. The results were summarized below:

2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography) performance within 7 days of symptom onset against the RT-PCR test method

SARS-CoV-2	Reference Extracted SARS-CoV-2 RT-PCR assay						95% CI	
							LCI	UCI
		POS	NEG	Total	PPA	92.43%	88.25%	95.26%
2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	POS	232	1	233	NPA	99.66%	97.84%	99.98%
	NEG	19*	296	315	PPV	99.57%	97.26%	99.98%
	Total	251	297	548	NPV	93.97%	90.58%	96.23%
					Prevalence	45.80%	41.59%	50.08%
					OPA	96.35%	94.43%	97.63%
					Kappa	92.61%	89.98%	95.24%

*6 of the discrepant samples had high Ct values (>30) when tested by the comparative method

PPA - Positive Percent Agreement (Sensitivity)
NPA - Negative Percent Agreement (Specificity)
PPV - Positive Predictive Value
NPV - Negative Predictive Value
OPA - Overall Percent Agreement
CI - Confidence Interval
LCI - Lower Confidence Interval
UCI - Upper Confidence Interval

【Warnings and Precautions】

1. For in vitro diagnostic use only. Do not reuse the kit components.
2. These instructions must be strictly followed to achieve accurate results. All users have to read the instruction prior to performing a test.
3. Do not eat or smoke while handling specimens.
4. Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
5. Avoid splashing or aerosol formation of specimen and buffer.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Do not store the test kit in direct sunlight.
8. Dispose of all specimens and potentially contaminated materials (i.e. collection funnel, extraction tube, test cartridge) used to perform the test as bio-hazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
9. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products and is forbidden to swallow.
10. The sample extraction buffer may contain trace particles or sediments, but it does not affect the test results.
11. Avoid skin or eyes touching the sample extraction buffer. If accidentally touch sample extraction buffer, immediately use plenty water to wash the skin or eyes. Forbid drinking the sample extraction buffer. If carelessly intake,please gargle thoroughly. Go to hospital if you feel not well.

【Symbol Explanation】

Symbols	Title of symbol	Symbols	Title of symbol	Symbols	Title of symbol
IVD	In vitro diagnostic device	LOT	Batch code		Temperature limit
	Do not re-use		Manufacturer	EC REP	Authorized representative in the European Community
	Avoid direct sunlight		Use-by date	CE	CE mark
	Consult instructions for use		Do not use if package is damaged		

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