2019-nCoV Ag Rapid Test Kit

(Immunochromatography)

Catalog Number:
CY-F006-AG25(25 test/Kit)

INTENDED USE

This kit is used for in vitro qualitative detection of 2019-nCoV antigen. It is an Immunochromatography sandwich assay, intended for the qualitative detection of the nucleocapsid protein antigen from 2019-nCoV in nasopharyngeal (NP) and nasal (NS) swab specimens. This test is only for clinical laboratory use or for immediate inspection by medical personnel, not for home testing, and cannot be used as the basis for the diagnosis and exclusion of pneumonia caused by new coronavirus infection, and is not suitable for screening by the general population.
A positive test result needs further confirmation. A negative test result cannot rule out the possibility of infection.
The kit and test results are for clinical reference only. It is recommended to combine the patient's clinical manifestations and other laboratory tests for a comprehensive analysis of the condition.

SUMMARY AND EXPLANATION

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.

PRINCIPLE OF THE TEST

This reagent uses double-antibody sandwich to legally detect the antigen of novel coronavirus (2019-nCoV) in nasopharyngeal swab and oropharyngeal swab samples.During detection, the gold labeled anti-2019-nCoV monoclonal antibody in the labeling pad binds to the 2019-nCoV antigen in the sample to form a complex, and the reaction complex moves forward along the nitrocellulose membrane under the action of chromatography, It is captured by the anti-2019-nCoV monoclonal antibody pre-coated by the detection zone (T) on the nitrocellulose membrane, and finally a red color reaction line is formed in the T zone. If the sample does not contain 2019-nCoV antigen, a red color reaction line cannot be formed in the T zone. Regardless of whether the sample to be tested contains 2019-nCoV antigen, a red reaction line will always form in the quality control area (C).

MATERIALS AND COMPONENTS

Materials provided with the test kits

Main components:

Specifications / Ingredients	CY-F006-AG25
Test Cassette	25
Swab	25
Sample Buffe with Dropper	25
Instructions for use	1

Note: *The components in different batches of the kit cannot be mixed.*

Materials required but not provided

1. Transfer pipette
2. Timer

STORAGE AND STABILITY

1. Store at 2°C - 30°C in the sealed pouch up to the expiration date printed on the package, forbidden to store under 2°C and avoid using expired products.
2. The test card is used within 15 minutes after taking out from the foil envelope. Buffer solution are re-capped in time after use.
3. The buffer should be used immediately after dropping into the dropper.
4. MFD date and EXP date: marked on the label. The product will be expired after 24 months.

SAMPLE REQUIREMENTS

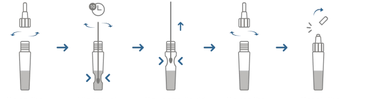
1. Collection of nasopharyngeal secretion: Insert the swab into the place where the nasopharyngeal secretions are the most, and rotate the swab close to the inner wall of the nasal cavity 3 times, remove the swab.
2. Collection of oropharyngeal secretion: Insert the swab from mouth completely into the oropharyngeal swelling, centering on the red part of the throat wall, epicondylitis, and tonsils, wipe and rotate 10 times with moderate force to avoid touching the tongue and remove the swab.
3. The samples should be used as soon as possible after collected (within half an hour).
4. Samples should not be inactivated.

TEST PROCEDURE

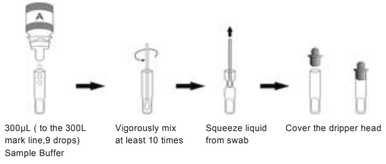
Sample processing:

1. Open the dripper head OR Take out the tube, add about 300μL of sample buffer (to 300uL mark line or 9 drops vertically) to the tube.
2. Completely immerse the swab head of the collected sample into the buffer in the tube.
3. Rotate the sample against the inner wall of the tube approximately 10 times or squeeze the tube 10 times to elute the sample to ensure that the sample on the swab is fully eluted into the buffer.
4. Squeeze the swab head along the inner wall of the tube to keep the liquid in the tube as much as possible.
5. Discard the swab and cover the cap （Dripper）to mix the liquid thoroughly.
6. Samples should be eluted and used immediately after collection; at the same time, the samples should not be inactivated, stored, or frozen and thawed.

Note: *Recommend to use a pipette to transfer the samples to reduce deviations.*



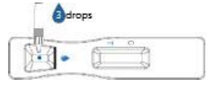
OR (for 0555C3X025)



Test Procedure:

Before test, please read the instruction manual.

1. Take the sample buffer and test cassette to equilibrate to room temperature.
2. Unpack the aluminum foil bag, place the test cassette horizontally on the table and mark it.
3. Add 80μL (3 drops) of the processed sample to the sample well, and timed. Recommended to use a pipette to take buffer/samples to reduce deviations.
4. As the test begins to work, the purple color move across the result window in the center of the test device.
5. Wait for 15 minutes and read the results. Do not read results after 20 minutes.



INTERPRETATION OF TEST RESULTS

This product can only perform qualitative analysis on the detection object.

Positive Result：

If both C and T lines are visible within 15 minutes, the test result is positive and valid.

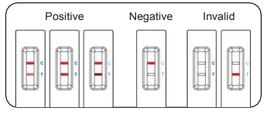
Note: *Specimens containing very low levels of target antibodies may develop two colored lines over 15 minutes.*

Negative Result：

If test area (T line) has no color and the control area displays a colored line, the result is negative and valid.

Invalid Result：

The test result is invalid if a colored line does not form in the control region. The sample must be re-tested, using a new test cassette.



1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information and further clinical data.
2. The contents of this kit are to be used for the qualitative detection of 2019-nCoV antigens from nasal swab and nasopharyngeal swab.
3. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
4. The Sample buffer and test card must be equilibrated to room temperature (18℃~26℃) before used, otherwise the results may be incorrect

LIMITATIONS

5. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
6. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
7. React less than 15 minutes may lead a false negative result; React more than 15 minutes may lead a false positive result.
8. Positive test results do not rule out co-infections with other pathogens.
9. Negative test results are not intended to rule in other viral or bacterial infections.
10. Negative results should be treated as presumptive and confirmed with a molecular assay.
11. Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
12. Users should test specimens as quickly as possible after specimen collection.
13. If the sample volume is not enough, the chromatography cannot be carried out successfully. Please pay attention to the prompt information of the instrument. It is recommended to use a pipette to add samples.

PERFORMANCE CHARACTERISTIC

1. Clinical Verification

The performance of 2019-nCoV Ag Rapid Test Kit (Immunochromatography)was established with 260 nasopharyngeal swabs collected from symptomatic patients, who with symptoms onset within 7 days.

Sensitivity: 58/60 96.67%, (95% CI: 88.64,99.08)

Specificity: 199/200 99.50%, (95% CI:97.22, 99.91).

2019-nCoV Ag Rapid Test Kit (Immunochromatography)	Comparative RT-PCR Test Result		
	Positive (+)	Negative (-)	Total
Detected Positive	58	1	59
Detected Negative	2	199	201
Total	60	200	260

Positive results broken down by days since symptom onset:

Days since symptom onset	RT-PCR Positive (+)	2019-nCoV Ag Rapid Test Kit (Immunochromatography)	PPA
1	6	6	100%
2	12	12	100%
3	20	20	100%
4	30	30	100%
5	40	40	100%
6	50	50	100%
7	60	58	96.67%

The performance of 2019-nCoV Ag Rapid Test Kit (Immunochromatography)with positive results stratified by thecomparative method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, As presented in the table below,

the positive agreement of the cycle threshold, As presented in the table below, the positive agreement of the 2019-nCoV Ag Rapid Test Kit (Immunochromatography)is higher with samples of a Ct count <25.

2019-nCoV Ag Rapid Test Kit (Immunochromatography)	Comparative RT-PCR Method (Positive by Ct Value)	
	Positive (Ct<=25)	Positive (25<Ct<30)
Detected Positive	30	28
Total	30	30
Positive agreement	100%	93.3%

A limited number of patients who presented with symptom onset greater than seven days and also the asymptomatic patients were enrolled in the clinical study (n = 25). the sample size was relatively small, the positive agreement was 61.5% (8/13) and negative agreement was 91.6% (11/12). Therefore, negative results in patients with symptom onset greater than seven days should be treated as presumptive and confirmed with a molecular assay if needed for clinical management, and the test is for professional used.

2. Limit of Detection

When the virus culture concentration was 100 $TCID_{50}$/mL and above, the positive rate was greater than or equal to 95%. At virus culture concentration of 50 $TCID_{50}$/mL and below, the positive rate is not higher than 95%, so the minimum detection limit of the 2019-nCoV Ag Rapid Test Kit (Immunochromatography) is 100 $TCID_{50}$/mL.

3. Cross-reactivity

Cross-reactivity of the Kit was evaluated. The results showed no cross reactivity with the following specimen.

No.	Specimen type	Conc.
1	HCoV-HKU1	10^5 $TCID_{50}$/mL
2	Staphylococcus aureus	10^6 CFU / mL
3	Streptococcus pyogenes	10^6 CFU / mL
4	Measles virus	10^5 $TCID_{50}$/mL

5	Paramyxovirus parotitis	10^5 $TCID_{50}$/mL
6	Adenovirus 3	10^5 $TCID_{50}$/mL
7	Mycoplasma pneumoniae	10^6 CFU / mL
8	Parainfluenza virus 2	10^5 $TCID_{50}$/mL
9	Human Metapneumovirus (hMPV)	10^5 $TCID_{50}$/mL
10	Human coronavirus OC43	10^5 $TCID_{50}$/mL
11	Human coronavirus 229E	10^5 $TCID_{50}$/mL
12	Bordetella parapertussia	10^6 CFU / mL
13	Influenza B (Victoria strain)	10^5 $TCID_{50}$/mL
14	Influenza B (Y strain)	10^5 $TCID_{50}$/mL
15	Influenza A (H1N1 2009)	10^5 $TCID_{50}$/mL
16	Influenza A (H3N2)	10^5 $TCID_{50}$/mL
17	Avian influenza virus (H7N9)	10^5 $TCID_{50}$/mL
18	Avian influenza virus (H5N1)	10^5 $TCID_{50}$/mL
19	Epstein-Barr virus	10^5 $TCID_{50}$/mL
20	Enterovirus CA16	10^5 $TCID_{50}$/mL
21	Rhinovirus	10^5 $TCID_{50}$/mL
22	Respiratory syncytial virus	10^5 $TCID_{50}$/mL
23	Streptococcus pneumoniae	10^6 CFU / mL
24	Candida albicans	10^6 CFU / mL
25	Chlamydia pneumoniae	10^6 CFU / mL
26	Bordetella pertussis	10^6 CFU / mL

27	Pneumocystis jirovecii	10^6 CFU / mL
28	Mycobacterium tuberculosis	10^6 CFU / mL
29	Legionella pneumophila	10^6 CFU / mL

4. Interference Substances

The test results do not be interfered with the substance at the following concentration:

No.	Interference substances	Conc.
1	Whole Blood	4%
2	Ibuprofen	1mg / mL
3	Tetracycline	3μg / mL
4	Chloramphenicol	3μg / mL
5	Erythromycin	3μg / mL
6	Tobramycin	5%
7	Throat spray (Menthol)	15%
8	Mupirocin	10mg/mL
9	Throat lozenge (Menthol)	1.5mg/mL
10	Tamiflu (Oseltamivir)	5mg/mL
11	Naphthoxoline hydrochloride nasal drops	15%
12	Mucin	0.50%
13	Fisherman's Friend	1.5mg/mL
14	Compound Benzocain Gel	1.5mg/mL
15	Cromoglycate	15%

16	Sinex (Phenylephrine Hydrochloride)	15%
17	Afrin (Oxymetazoline)	15%
18	Fluticasone propionate spray	15%

Reference

1.WHO, 09.11.2020. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays: Interim guidance. WHO/2019-nCoV/Antigen_Detection/2020.1

2.FDA, 16.07.2020. Coronavirus testing basics: www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics

3.Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR.2020

PRECAUTIONS

1. For in vitro diagnostic use.
2. Do not use the kit contents beyond the expiration date printed on the outside of the box.
3. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kitcontents.
4. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
5. Do not reuse the used Test Card, Reagent Tubes or Swabs.
6. The user should never open the foil pouch of the Test Card exposing it to the ambient environment until the Test Card is ready for immediate use.
7. Discard and do not use any damaged or dropped Test Card or material.
8. The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
9. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
10. Sample collection and handling procedures require specific training and guidance.
11. Use the appropriate Fixed Volume Pipette in accordance with test procedures.
12. To obtain accurate results, do not use visually bloody or overly viscous samples.

13. To obtain accurate results, an opened and exposed Test Card should not be used.
14. Testing should be performed in an area with adequate ventilation.
15. Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
16. Wash hands thoroughly after handling.

INDEX OF SYMBOL

COMPONENT	Materials Included	DROPPER	Dropper with Sample Buffe
CASSETTE	Test Cassette	SWAB	Swab
TUBE	Tube	HOLDER	Tube Holder
IFU	Instructions for Use		Date of Manufacturer
	Consult Instructions For Use		Do Not Reuse
2°C~30°C	Store at 2°C~30°C	REF	Catalogue Number
	Expiration Date		Keep away from Sunlight
	Manufacturer		Tests per Kit
LOT	Lot Number		Keep Dry In Vitro Diagnostic Medical Device
EC REP	Authorized Representative	IVD	

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