One Step Novel Coronavirus（SARS-CoV-2）
IgM / IgG Test Kit

(For Professional Use Only)　(For COVID-19)

CE

INTERPRETATION OF THE SYMLIOS ON THE PACKAGE

for "Do not reuse"

IVD for "In vitro diagnostic medical device"

for "Temperature limitation"

for "Consult instructions for use"

for "Use by"

LOT for "Batch code"

for "Keep dry"

for "Attention, see instructions for use"

for "Keep away from sunlight"

Σ n for "Contains sufficient for <n> tests"

for "Manufacturer"

for "Do not use if package is damaged"

EC REP for "Authorized representative in the European community"

WARNING

FOR IN VITRO DIAGNOSITC USE ONLY

1. Read directions for use carefully before performing this test. Pay attention to the position of the C and T line.
2. Do not use beyond the labelled expiration date.
3. Do not reuse the test devices.
4. Do not use if pouch is damaged or opened.
5. Do not touch the membrane on the strip.
6. Once open the pouch, the test device should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.
7. It is recommended that all specimens be used as if they are potentially infectious and handled in accordance with Biosafety Level 2 practices as described in the CDC NIH Publication: Biosafety in Microbiological and Biomedical laboratories, or other equivalent guidelines.
8. Devices used for the assay should be sterilized before being disposed.

INTENDED USE

This kit is used for the in vitro qualitative detection of novel coronavirus (SARS-CoV-2) IgM / IgG antibodies in human serum, plasma and whole blood samples, it is intended to detect antibodies to SARS-CoV-2 to help identify people who may have been exposed to the SARS-CoV-2 virus or have recovered from the COVID-19 infection.

It is only used as a supplementary detection indicator for suspected cases with negative nucleic acid detection of novel coronavirus or used in conjunction with nucleic acid detection in the diagnosis of suspected cases. This product is limited to medical institutions.

SUMMARY

The novel coronaviruses.belong to the β genus. COVID-19 is an acute respiratory infection disease. People are generally susceptible.Currently, the patients infected by 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

One Step Novel Coronavirus（SARS-CoV-2） is a chromatographic lateral flow immunoassay. A recombinant SARS-CoV-2 antigen conjugated to colloidal gold embedded in the sample pad reacts with the SARS-CoV-2 antibody present in serum/plasma/whole blood forming conjugate-SARS-CoV-2 antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate-SARS-CoV-2 antibody complex is captured by mouse anti human IgM-μ chain (M) or mouse anti human IgG (G) immobilized on a membrane forming a colored test line in the test region. A negative sample does not produce a test line due to the absence of colloidal gold conjugate-SARS-CoV-2 antibody complex. A colored control line in the control region appears at the end of test procedure regardless of test result. This control line is the result of colloidal gold conjugate binding to the mouse anti-goat antibody immobilized on the membrane, and it indicates that the colloidal gold conjugate is functional.

REAGENTS

The test contains recombinant SARS-CoV-2 antigens and goat IgG coupled colloidal gold particles; mouse anti human IgM-μ chain coated in the M region of the membrane; mouse anti human IgG in the G region of the membrane;mouse anti-goat antibody in the control region of the membrane.

MATERIALS PROVIDED

Each pouch contains

1. test cassette
2. Desiccant (do not eat)

Each box contains

1. Individually wrapped Test Cassettes
2. Test diluents (buffer)
3. Package insert
4. Disposable plastic dropper for serum /plasma /whole blood

Other equipment or reagents needed

1. Timer
2. Positive and Negative controls

STORAGE AND STABILITY

The test kit can be stored at temperature 4°C to 30°C (39°F-86°F) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat.

ASSAY PROCEDURE

Specimen collection and preparation

1.The test works best on fresh samples. It can be performed using either serum/plasma/whole blood. Collect serum/plasma/whole blood specimens following regular clinical laboratory procedures.

2.Only those specimens that are clean, clear and with good fluidity can be used for the assay. Avoid using hemolyzed, extremely thickened specimens.

3. The test works best on fresh samples. But if specimens cannot be tested on the day of collection, store in a refrigerator or freezer. Bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE

1.Bring the specimen and test components to room temperature if refrigerated or frozen. Place the test device on a clean, flat surface and label specimen number.

2.Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 1 drop (about 10 μL) of serum, plasma or 2 drop (about 20 μL) of whole blood (include finger blood), into the sample well,making sure that there are no air bubbles. Then add 2drops (about 60 μL) of Sample Diluent immediately.

3.Set up timer. Wait for 15 minutes and read results.

4.Do not read results after 30 minutes.

INTERPRETATION OF RESULTS

Negative

Only the control line appears on the membrane. The absence of a test line indicates a negative result.

Positive

Control line and at least one test line appear on the membrane. The appearing of M test line indicates a SARS-CoV-2 IgM positive result, the appearing of G test line indicates a SARS-CoV-2 IgG positive result, the appearing of both M and G test lines indicate both SARS-CoV-2 IgM & IgG positive result. The lower the antibody concentration is, the weaker the test line is.

Invalid

There should always be a control line in the control region regardless of test result. If control line is not seen, the test is considered invalid. Repeat the test using a new test device.

C-Control line　　**M-IgM**　　**G-IgG**

QUALITY CONTROL

A procedural control is built into each test strip, indicating that the reagents are present and sample is migrating properly. It is good laboratory practice to use quality control material to ensure proper performance. When using these control materials, use the same procedures as with clinical specimen. Positive and negative controls are suggested to be used to test each shipment of

product upon receipt.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity

The analytical sensitivity of One Step Novel Coronavirus（SARS-CoV-2）IgM / IgG is 1:16/1:8.

2.Analytical Specificity

A cross-reactivity study was conducted to prove that the test did not react with the relevant pathogens, high-epidemic pathogens, and normal or pathogenic bacteria that may be encountered in clinical samples, but with Human coronavirus HKU1, NL63, OC43, 229E, SARS -coronavirus, or MERS-coronavirus has a cross reaction. The following table provides a list of recommended computer analysis organisms.

Other high priority pathogens from the same genetic family	High priority organisms likely in the circulating area
Human coronavirus 229E	Adenovirus (e.g. C1 Ad. 71)
Human coronavirus OC43	Human Metapneumovirus (hMPV)
Human coronavirus HKU1	Parainfluenza virus 1-4
Human coronavirus NL63	Influenza A & B
SARS-coronavirus	Enterovirus (e.g. EV68)
MERS-coronavirus	Respiratory syncytial virus
others	Rhinovirus
	Chlamydia pneumoniae
	Haemophilus influenzae
	Legionella pneumophila
	Mycobacterium tuberculosis
	Streptococcus pneumoniae
	Streptococcus pyogenes
	Bordetella pertussis
	Mycoplasma pneumoniae
	Pneumocystis jirovecii (PJP)
	Pooled human nasal wash - to represent diverse microbial flora in the human respiratory tract
	Candida albicans
	Pseudomonas aeruginosa
	Staphylococcus epidermis
	Staphylococcus salivarius

3. Diagnostic Sensitivity and Specificity

By comparing with Wantai and Livzon ELISA test reagents, the clinical performance, diagnostic sensitivity and diagnostic specificity of the one-step SARS-CoV-2 test are confirmed. A total of 389 clinical specimens were tested, including 60 IgM-positive, 323 IgM-negative and 6 IgM-positive other high-priority pathogens of the same gene family, including 132 IgG-positive, 251 IgG-negative and 6 IgG-positive others High priority pathogens. The following table summarizes the results:

Clinical Accuracy of SARS-CoV-2 IgM Test

	Predicate Test (Positive)	Predicate Test (Negative)	Total
SARS-CoV-2 IgM positive	44(a)	17(b)	61
SARS-CoV-2 IgM Negative	16 (c)	312(d)	328
Total	60	329	389

Diagnostic Sensitivity (Positive agreement):
= a / (a+c) = 44/60= 73.3%
Diagnostic Specificity (Negative agreement):
= d/ (b+d) = 312/329= 94.8%
Total agreement
= (a+d)/ (a+b+c+d) = (44+312)/389 = 91.5%

Clinical Accuracy of SARS-CoV-2 IgG Test

	Predicate Test (Positive)	Predicate Test (Negative)	Total
SARS-CoV-2 IgG positive	122(a)	12 (b)	134
SARS-CoV-2 IgG Negative	10 (c)	245(d)	255
Total	132	257	389

Diagnostic Sensitivity (Positive agreement):
= a / (a+c) = 122/132= 92.4%
Diagnostic Specificity (Negative agreement):
= d/ (b+d) = 245/257 = 95.3%
Total agreement
= (a+d)/ (a+b+c+d) = (122+245)/389 = 94.3%

4. Repeatability and Reproducibility

Three lots of One Step Novel Coronavirus（SARS-CoV-2）IgM / IgG Test were used and 10 cassettes of each lot were tested with SARS-CoV-2 IgG and IgM antibodies enterprise reference. Result is summarized in the following table.

Concentration	Lot 1		Lot 2		Lot 3		Precision
	P	N	P	N	P	N	
0	0	10	0	10	0	10	10/10
Con.of SARS-CoV-2 IgG 1:8	10	0	10	0	10	0	10/10
Con.of SARS-CoV-2 IgM 1:16	10	0	10	0	10	0	10/10

P: positive N: negative

LIMITATION OF THE PROCEDURE

1.For in vitro diagnostic use only.
2.Keep the foil pouch sealed until just before use.
3.Patient samples and test devices should be handled as though they are potentially infectious.
4.When interpreting test results, use a bright, unfiltered light.
5.For samples that are positive by this test, a more specific confirmatory test should be done. A clinical evaluation of the patient's information should be made and considered before a diagnosis is established. The use of a rapid test alone is not sufficient for any clinical diagnosis.
6.Do not use test kit beyond expiry date.
7.The test device should not be reused.
8.This test has not been reviewed by the CE and FDA.
9.Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
10.Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
11.Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.