3. Hook Effect
No high dose hook effect was observed when tested with up to a concentration of $2.0\times10^{5.0}$ $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus.

4. Cross Reactivity

Virus/Bacteria/Parasite	Concentration	Results
Adenovirus	$1.0\times10^{5.0}$ $TCID_{50}$/mL	Negative
Influenza A	$1.0\times10^{5.0}$ $TCID_{50}$/mL	Negative
Influenza B	$1.0\times10^{5.0}$ $TCID_{50}$/mL	Negative
Human parainfluenza virus 2	$1.0\times10^{5.0}$ $TCID_{50}$/mL	Negative
Human Metapneumovirus	$1.0\times10^{5.0}$ $TCID_{50}$/mL	Negative
Human coronavirus OC43	$1.0\times10^{5.0}$ $TCID_{50}$/mL	Negative
Human coronavirus 229E	$1.0\times10^{5.0}$ $TCID_{50}$/mL	Negative
Bordetella parapertussis	$1.0\times10^{6.0}$cells/mL	Negative
Rhinovirus	$1.0\times10^{6.0}$cells/mL	Negative
Parainfluenza	$1.0\times10^{6.0}$cells/mL	Negative
Respiratory Syncytial Virus	$1.0\times10^{6.0}$cells/mL	Negative
varicella-zoster virus	$1.0\times10^{6.0}$cells/mL	Negative
Streptococcus pneumonia	$1.0\times10^{6.0}$cells/mL	Negative
Mycoplasma pneumoniae virus	$1.0\times10^{6.0}$cells/mL	Negative

5. Endogenous/Exogenous Interference Substances Studies

Substance	Active Ingredient	Concentration
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
OTC Homeopathic Nasal Spray 1	Benflin	10% v/v
OTC Homeopathic Nasal Spray 2	hydroxymetazoline	10% v/v
OTC Homeopathic Nasal Spray 3	sodium chloride	10% v/v
Antibacterial, Systemic	Tobramycin	0.0005% w/v

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SYMBOL	DESCRIPTION
	Manufacturer
EC REP	Authorized representative in the European Community
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch Code
	Use-by date
	Temperature Limitation
CE	CE Mark
REF	Catalogue number
	Biological risks
	Do not re-use
	Contains Sufficient for <n> Tests
	Date of manufacture
	Keep Away From Sunlight
	Consult instructions for use
	Keep Dry

COVID-19 Ag Test Kit

(For Medical Professional Use Only)

[Version No] 0003

[Issued Date] 2020-11-09

[Packaging Specifications]

1 test/kit, 20 tests/kit.

[Intended Use]

The COVID-19 Ag Test Kit is used for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in human nasopharyngeal or nasal swab specimens and is designed to assist the diagnosis of COVID-19.

[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]

This kit is based on the principle of lateral flow colloidal gold immunoassay and detects the nucleocapsid protein from SARS-CoV-2 in specimen via immuno-sandwich methodology. When the sample is added to the sample well, the nucleocapsid protein in the sample reacts with the gold labeled antibody and forms an immuno-complex, which will flow onto the nitrocellulose membrane. When the immuno-complex reaches the test band, it will react with the COVID-19 antibody pre-coated on the nitrocellulose membrane and will be fixed on the test band and develop color, which indicates a positive result. When the rest of immuno-complex reaches the control band, it will react with the control band antibody pre-coated on the nitrocellulose membrane and will be fixed on the control band and develop color.

[Supplied Kit Components]

Component	1 test/kit		20 tests/kit	
	Quantity	Specification	Quantity	Specification
Test Cassette	1	Individual package	20	Individual package
Specimen Collection Swab	1	-----	21	21 per bag
Lysis Buffer	1	0.6 mL per tube	21	0.6 mL per tube
Nozzle Cap with Protective Cover	1	-----	21	21 per bag
Product Insert	1 Copy	-----	1 Copy	-----

Note: Timer is needed but not provided. Various components of different batches of reagents cannot be used interchangeably in order to avoid false results.

[Warnings and Precautions]

1. This kit is for *in vitro* diagnostic use.
2. This kit is for medical professional use only.
3. Do not use cassettes which are damaged, or have an unclear label or expired.
4. Samples with invalid results must be retested.
5. The cassette is for one time use only. Used cassettes and samples should be treated as potential bio-hazardous materials.
6. Do not eat the desiccant in the foil pouch.
7. Do not reuse the used Test Cassette, fixed Lysis buffer, used Nozzle and used Specimen Collection Swab.

[Kit Storage and Product Shelf Life]

Store at room temperature (2 -30°C or 35.6-86°F) in a dry shady place. Avoid direct sunlight.
18 months of shelf life (production date to expiration date).

[Specimen Requirements]

1. Only nasopharyngeal or nasal swab, or non-inactivated viral transport media can be tested.
2. Colorless viral transport media is preferred.
3. Contaminated samples should not be used.
4. Test specimens immediately after collection for optimal test performance.
5. Stability of nasopharyngeal or nasal swab, or viral transport media:

Storage temperature	Shelf time
2~8°C	4 hours
15~25°C	1 hour

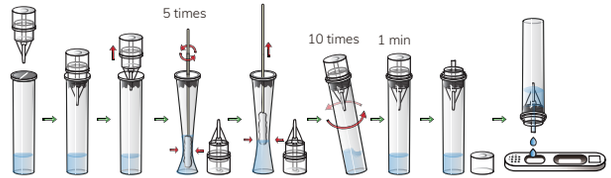
6. Samples should be tested within 1 hour at room temperature (15-25°C) or 4 hours at 2-8°C after collection.
7. Do not freeze samples.
8. Improper sample collection, handling, storage, or transportation may cause false results.

[Test Procedure]

Caution: Please read the product insert of the kit carefully.

Nasopharyngeal or Nasal Swab

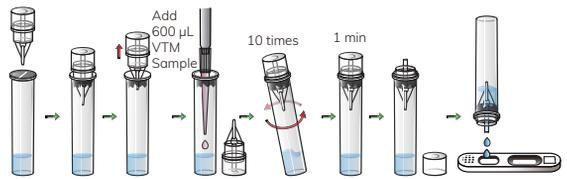
1. Collect nasal or nasopharyngeal swab from the patient in accordance with standard operating procedure.
2. Pierce the sealing membrane of lysis buffer tube with the tip of nozzle cap.
3. Unplug the nozzle cap from the tube and place it on the workbench with the protective cover facing down. Be careful not to touch the nozzle tip to avoid contamination.
4. Insert the swab into the lysis buffer tube. Squeeze the tube and stir the swab for 5 times.
5. Keep squeezing the tube and remove the swab. Make sure all the liquid from the swab is removed.
6. Install the nozzle cap with the protective cover facing up. Mix the tube by gently shaking for 10 times. Let stand for 1 minute.
7. Remove the protective cover. Squeeze the tube and discard the first two drops of processed specimen.
8. Add three drops of processed specimen vertically into the sample well, and then let stand for 15 minutes.
9. Read the test result immediately, the test result will be invalid after 30 minutes.



Viral Transport Media (Non-inactivated)

1. Mix the specimen received in viral transport media (VTM) by vortexing for 5 seconds.
2. Pierce the sealing membrane of lysis buffer tube with the tip of nozzle cap.
3. Unplug the nozzle cap from the tube and place it on the workbench with the protective cover facing down. Be careful not to touch the nozzle tip to avoid contamination.
4. Add 600μL VTM sample into the lysis buffer tube. Alternatively, users can reduce the volume of VTM sample to a minimum of ≥100μL according to the actual situation, and dilute it with lysis buffer at a ratio of 1:1.
5. Install the nozzle cap with the protective cover facing up. Mix the tube by gently shaking for 10 times. Let stand for 1 minute.
6. Remove the protective cover. Squeeze the tube and discard the first two drops of processed specimen.
7. Add three drops of processed specimen vertically into the sample well, and then let stand for 15 minutes.
8. Read the test result immediately, the test result will be invalid after 30 minutes.

Note: Considering the different brands of the VTM in different countries, we suggest our customers to send us the instruction and composition of the VTM. We can check the composition of the VTM you use and we recommend our customers to test the cassette directly without dilution. Samples that are stored in PBS or UTM may also be a better choice.



Caution: Keep the WESAIL COVID-19 Ag Test Kit cassette in sealed foil pouch prior to use. The cassette should be used within 30 minutes once the foil pouch is opened. If the temperature is higher than 30°C or under conditions of high humidity, it should be used immediately after the foil pouch is opened.

[Disposal]

Disposal of biohazardous materials should follow the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all federal, state, and local regulations.

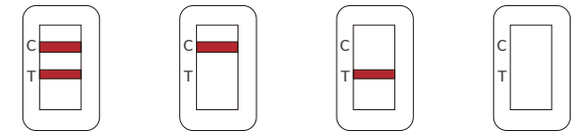
[Result Interpretation]

Positive: colored bands appear at both test band (T) and control band (C).

Negative: colored band appears at control band (C) only.

Invalid: no visible colored band appear at control band. The test procedures may not be followed correctly, or the cassette is deteriorated. It is recommended to retest the specimen.

Note: The color intensity of the test band (T) may vary according to the concentration of antigen in the sample. The lower the concentration, the weaker the intensity. The determination of a positive result should be based on the presence of the test band (T) and control band (C), regardless of whether the test band (T) is weaker than the control band (C).



[Limitations of the Procedure]

1. The test results of this product are for diagnostic aid only and cannot be used as the sole basis for confirming or excluding diagnosis. To achieve diagnostic purposes, the results should always be assessed in combination with clinical examination, medical history, and other laboratory data.
2. This product is only used for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in human nasopharyngeal or nasal swab, but not for quantitative detection.
3. This product is only for the initial screening test. The disease diagnosis should be made in conjunction with clinical observations, patient history, epidemiological information, and other laboratory evidence.
4. Subject to the limitations of the assay methodology, the questionable results should be verified with other test methodology.

[Performance Characteristics]

1. Limit of detection (LOD)

LOD : $8.0\times10^{2.0}$ $TCID_{50}$/mL

The LOD was determined as the lowest virus concentration that was detected ≥ 95% of the time.

(i.e., concentration at which at least 19 out of 20 replicates tested positive).

Stock SARS-CoV-2 Titer	$1.6\times10^{5.0}$ $TCID_{50}$/mL				
Dilution	10×	100×	200×	400×	800×
Concentration in Dilution tested ($TCID_{50}$/mL)	$1.6\times10^{4.0}$ $TCID_{50}$/mL	$1.6\times10^{3.0}$ $TCID_{50}$/mL	$8.0\times10^{2.0}$ $TCID_{50}$/mL	$4.0\times10^{2.0}$ $TCID_{50}$/mL	$2.0\times10^{2.0}$ $TCID_{50}$/mL
Number positive/Total of 20 replicates	100% (20/20)	100% (20/20)	100% (20/20)	35% (7/20)	0% (0/20)
LOD	$8.0\times10^{2.0}$ $TCID_{50}$/mL				

2. Positive and Negative coincidence rate

COVID-19 Ag Test Kit	PCR		
	Positive	Negative	Total
Positive	45	4	49
Negative	5	496	501
Total	50	500	550
Sensitivity	90.0%(45/50)		
Specificity	99.2%(496/500)		
Overall percent agreement	98.4%(541/550)		