COVID-19 Antigen Rapid Test Cassette

（Fluorescence Immunochromatography）

Package Insert

CLA-COV19AG	English

A rapid test for the qualitative detection of Novel Coronavirus SARS-CoV-2 antigen in Nasopharyngeal swab. For professional in vitro diagnostic use only.

INTENDED USE

The Clarity COVID-19 Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Novel Coronavirus SARS-CoV-2 antigen in Nasopharyngeal swab.

SUMMARY

The new coronavirus belongs to the coronavirus of the genus β. It has an envelope and the particles are round or elliptical. They are often polymorphic and have a diameter of 60-140 nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current research shows that the homology with bat SARS-like corona virus (bat-SL-CoVZC45) is more than 85%. When isolated and cultured in vitro, the new coronavirus can be found in human respiratory epithelial cells in about 96 hours, while it takes about 6 days to separate and culture in VeroE6 and Huh-7 cell lines.

The new coronavirus (SARS-COV-2) antigen detection method can effectively reduce the false negatives of RT-PCR and false positives of antibody detection methods. The diagnosis is fast, accurate and requires low equipment and personnel, suitable for rapid investigation of suspected cases of novel coronavirus infection on a large scale. The rapid investigation of suspected cases is effective during outbreaks and also can be used as a supplementary test for nucleic acid testing to avoid the risk of new transmission caused by the discharge of false negative patients.

PRINCIPLE

This cassette adopts an immunofluorescence double antibody sandwich method. The new coronavirus SARS-CoV-2 antigen (hereinafter referred to as "SARS-CoV-2") in the sample reacts with the fluorescent labeled anti-SARS-CoV-2 monoclonal antibody on the conjugated pad to form a complex. The complex, via capillary action, travels along the nitrocellulose membrane to the SARS-CoV-2 detection line (T line). The reaction complex is then captured by the anti-SARS-CoV-2 monoclonal antibody coated on the detection line to complete the final reaction. The detection line (T line), under the action of excitation light, will form a red band of radiant light. The test cassette needs to be used with the Immunofluorescence analyzer to determine whether SARS-CoV-2 is present in the sample.

REAGENTS

The test cassette contains anti-Novel Coronavirus SARS-CoV-2 antibody coated particles and anti-Novel Coronavirus SARS-CoV-2 antibody coated on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test. Reliability of assay results cannot be guaranteed if there is any deviation from the instructions in this package insert.

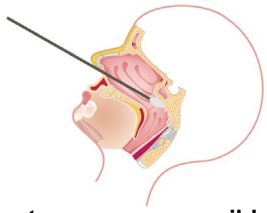
1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection before testing.
5. The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not store this kit in frozen condition.
8. Do not use the product if package is damaged.
9. Do not re-use the product.
10. Use only the extraction solution provided with the kit.
11. Read and interpret the results within 15 minutes.
12. Do not eat, drink or smoke in the area where the specimens or kits are handled.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated 2°C – 30°C (36°F – 86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Insert a sterile swab into the nasopharyngeal cavity firmly from the nostril perpendicular to the face and collect the mucus epidermis and swirl the swab several times.



Please perform the test as soon as possible after collection of samples.

MATERIALS

Materials provided

25 Test cassettes 25 Sterile Swabs Package Insert Workstation

ID card 25 Extraction Buffer Vials (NaCl + DSP + Tris + Proclin 300)

MATERIALS REQUIRED BUT NOT PROVIDED

Timer Gloves

ANALYZER REQUIRED

Clarity Fluorescence immunoassay analyzer: CLA-IFARDR

DIRECTIONS FOR USE

Allow the test cassette, specimen, extraction buffer to equilibrate to room temperature (15°C – 30°C (59°F – 86°F) prior to testing.

1. Put on the gloves, take out the ID card and confirm the batch number of the ID card and the test are the same. After this, insert the ID card into the ID card port of the immunofluorescence analyzer. Do not touch the insertion end of the ID card. The immunofluorescence analyzer will emit a "beep" sound if the ID card has been inserted correctly.

2. Select “Quick Test” mode or “Standard Test” mode on the main interface of the Clarity immunofluorescence analyzer (the operation method of the instrument is mentioned in the User’s Manual)

2.1 **"Quick test"** mode: after adding the sample, use a timer to count the time, insert the test cassette into the immunofluorescence analyzer at 15 minutes. The immunofluorescence analyzer will complete the test and display the results automatically.

2.2 **"Standard test"** mode: after adding the sample, insert the test cassette into the immunofluorescence analyzer. The immunofluorescence analyzer will complete the test and display the result automatically.

3. Remove the test cassette from the sealed foil pouch and use it within 30 minutes. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

4. Unscrew cap 1 (See illustration 1) and put the swab sample into the extraction buffer. Rotate the swab for approximately 10 seconds while pressing the swab head against the inside of the tube to release the antigen in the swab (See illustration 2). Leave the swab in the Extraction Tube for 1 minute.

5. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol (See illustration 3).

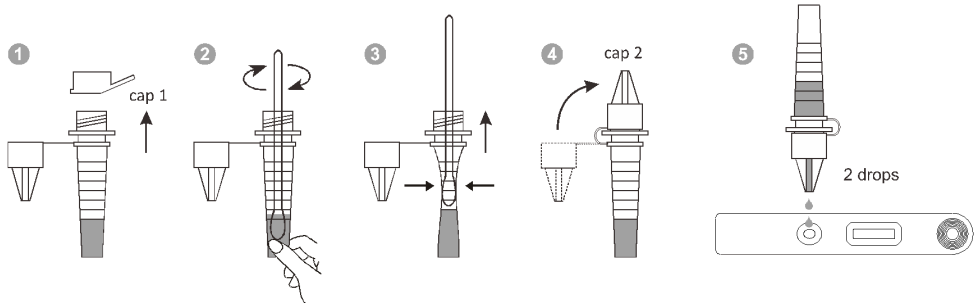
6. Tighten cap 1 and then unscrew cap 2 (See illustration 4). Place the test cassette on a clean and level surface.

7. Add 2 drops of solution to the sample well (See illustration 5).

7.1 **"Quick test"** mode: after adding sample, use a timer to count the time, insert the test cassette into the immunofluorescence analyzer at 15 minutes and the reading will be performed automatically.

7.2 **"Standard test"** mode: insert the test card into the immunofluorescence analyzer and the reading will be performed automatically after 15 minutes.

8. The immunofluorescence analyzer will read/print test results.



INTERPRETATION OF RESULTS

1. The result of this device is displayed as "negative", "positive" and/or "invalid".

2. The test results of this device are interpreted by the programming on the Clarity immunofluorescence analyzer. If the instrument displays the result as "invalid", the test should be considered invalid. Please note that an invalid result is an indication of incorrect operation procedure or the device is deteriorated and/or damaged. In this case, you should carefully read the instructions again and retest with a new device. If the problem persists, stop using this batch of device immediately and contact the Clarity Diagnostics Technical Support at 1-877-485-7877

3. Other factors can also cause incorrect test results. These factors include technical reasons, operational errors, and other sample related factors.

QUALITY CONTROL

An internal procedural control is included in the test. A line appearing in the control line region (C) is an internal valid procedural control, it confirms adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. This device is a qualitative detection device and cannot determine the SARS-CoV-2 virus quantity in the sample.
2. This device should only be used for testing human nasopharyngeal swab specimens.
3. The test results of this device can only be used by a healthcare provider. The test results need to be combined with other clinical and laboratory data. If the test results are inconsistent with the clinical evaluation, further examination is required.
4. False positive results may be due to the following reasons: non-specific components in the sample may have similar antigenic determinants to capture fluorescent labeled antibodies.
5. False negative results may be due to the following reasons: unknown components may prevent the antigenic determinants from binding to the antibody; unstable SARS-CoV-2 virus antigen gradually degenerates with time and temperature, and cannot be recognized by the antibody. Effective test result depends on a properly functioning device and sample storage environment.

PERFORMANCE CHARACTERISTICS

Limit of Detection - LOD

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) replicates test positive. The LoD was established using limiting dilutions of a heat inactivated viral sample. The material was supplied at a concentration of 1.58 x 10^7TCID$_{50}$/mL.

SARS-CoV-2 tested(TCID$_{50}$/mL)	Test Result
7900	5/5 Positive
3950	5/5 Positive
1975	5/5 Positive
1580	5/5 Positive
987.5	5/5 Negative

The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates in the same way.

Starting Material Concentration	Estimated LoD	Positive/Total	%Positive
1.58 x 10^7 TCID$_{50}$/mL.	1.58×10^3 TCID$_{50}$/mL.	20/20	100%

POSITIVE AGREEMENT

Positive agreement of the SARS-CoV-2 antigen rapid test was evaluated using clinical samples collected from symptomatic subjects. All subjects were confirmed positive for SARS-CoV-2 by Nucleic Acid Test (RT-PCR) or clinical diagnosis.

NEGATIVE AGREEMENT

Negative agreement of the SARS-CoV-2 antigen rapid test was evaluated using clinical samples. Samples were collected during the SARS-CoV-2 pandemic and all were excluded for SARS-CoV-2 by Nucleic Acid Test (RT-PCR) or clinical diagnosis.

Clarity COVID19 Ag Test Cassette	PCR Positive (Confirmed Cases)	PCR Negative (Excluded Cases)	Total
Positive	24	1	25
Negative	1	64	65
Total	25	65	90
Positive Agreement	24/25	96.00% (95%CI:79.65%～99.90%)	
Negative Agreement	64/65	98.46% (95%CI:91.72%～99.96%)	
Overall Agreement	88/90	97.78% (95%CI:92.20%～99.73%)	

CROSS-REACTIVITY

The following potentially cross-reactive substances were added to SARS-CoV-2 negative and spiked positive specimens. Test results showed that the organisms or viruses do not cross-react with the Clarity COVID-19 Antigen Test Cassette at the below listed concentrations.

Potential Cross-Reactant	Concentration	Result	
		Negative Specimen	Spiked with Positive Specimen
Adenovirus (e.g. C1 Ad. 71)-Type 7A	1.41×10^5 U/ml	Negative	Positive
Enterovirus (e.g. EV68)	5.01×10^5 TCID$_{50}$/ml	Negative	Positive
Human Metapneumovirus (hMPV)	3.80×10^6 TCID$_{50}$/ml	Negative	Positive
Influenza A H1N1 (New Cal/20/99)	1.15×10^7 U/ml	Negative	Positive
Influenza B (Florida/02/06)	1.41×10^5 U/ml	Negative	Positive

Parainfluenza virus 1	9.12×10^{8} $TCID_{50}$/ml	Negative	Positive
Parainfluenza virus 2	1.15×10^{7} U/ml	Negative	Positive
Parainfluenza virus 3	6.61×10^{6} U/ml	Negative	Positive
Parainfluenza virus 4	2.82×10^{7} U/ml	Negative	Positive
Respiratory syncytial virus-Type A	3.80×10^{6} U/ml	Negative	Positive
Rhinovirus (Type 1A)	3.55×10^{5} U/ml	Negative	Positive
Bordetella pertussis	1.13×10^{10} CFU/ml	Negative	Positive
Candida albicans	6.27×10^{8} CFU/ml	Negative	Positive
Haemophilus influenzae	5.43×10^{8} CFU/ml	Negative	Positive
Legionella pneumophila	1.88×10^{10} CFU/ml	Negative	Positive
Mycobacterium tuberculosis	6.86×10^{7} CFU/ml	Negative	Positive
Mycoplasma pneumoniae	3.16×10^{8} CCU/ml	Negative	Positive
Pneumocystis jirovecii (PJP)-S. cerevisiae Recombinant	3.45×10^{8} CFU/ml	Negative	Positive
Pseudomonas aeruginosa	8.44×10^{9} CFU/ml	Negative	Positive
Staphylococcus epidermis	1.21×10^{10} CFU/ml	Negative	Positive
Streptococcus pneumoniae	2.26×10^{9} CFU/ml	Negative	Positive
Streptococcus pyogenes	1.64×10^{9} CFU/ml	Negative	Positive
Streptococcus salivarius	8.17×10^{8} CFU/ml	Negative	Positive
Human coronavirus 229E	4.17×10^{5} $TCID_{50}$/ml	Negative	Positive
Human coronavirus OC43	1.05×10^{6} $TCID_{50}$/ml	Negative	Positive
Human coronavirus NL63	1.70×10^{5} $TCID_{50}$/ml	Negative	Positive
MERS-coronavirus	3.16×10^{6} $TCID_{50}$/ml	Negative	Positive
Influenza A Virus H3N2	1.6×10^{5}CEID/ml	Negative	Positive

INTERFERING SUBSTANCES

The following potentially interfering substances were added to SARS-CoV-2 negative and spiked positive specimens. Test results showed that the interfering substances do not interfere with the Clarity COVID-19 Antigen Rapid Test Cassette at the below listed concentrations.

Interfering reaction substance	Concentration	Result	
		Negative Specimen	Spiked with Positive Specimen
Whole Blood	4%	Negative	Positive
Mucin	0.50%	Negative	Positive
Mometasone Furoate Nasal Spray	0.05% g/g	Negative	Positive
Dextromethorphan Hydrobromide Oral Solution	1.5mg/ml	Negative	Positive
Ambroxol Hydrochloride Tablets	7.5mg/ml	Negative	Positive
Fluticasone Propionate	5% v/v	Negative	Positive
Nasal Cleasing Solution	5g/L	Negative	Positive
Compound Gargle Solution Chlorhexidine Gluconatie	0.2mg/ml	Negative	Positive
Throat Lozenge	3mg/mL	Negative	Positive
Tamiflu Oseltamivir Phosphate Capsules	5 mg/mL	Negative	Positive

HIGH DOSE HOOK EFFECT

No high dose hook effect was observed up to $1.58\times10^{6}TCID_{50}$/mL of heat-inactivated SARS-CoV-2 stock.

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9. US Food and Drug Administration (FDA). Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff. Issued March 16, 2020. Docket Number FDA-2020-D-0987.

Index of Symbols

IVD	For in vitro diagnostic use		Use by		Contents sufficient for n tests
REF	Catalogue number		Do not use if package is damaged		Do not re-use
LOT	Batch code		Consult instruction for use		Keep dry
	Manufacturer	2°C 30°C	Consult instruction for use		Protect from direct sunlight
	Date of manufacture	Σ n	Temperature limit at 2°C – 30°C.	CE	CE Mark

Manufactured By:

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REF: CLA-COV19AG

Version 01, Sep 22nd, 2020

CE

Version 1, 22nd September 2020

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