COVID-19 Antigen Test Cassette
Package Insert

A rapid test for the qualitative detection of COVID-19 antigen in nasopharyngeal swab specimens. For professional medical institutions use only. Not for self testing.

【INTENDED USE】

The COVID-19 Antigen Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in nasopharyngeal swab specimen to aid in the diagnosis of COVID-19 viral infection.

【PRINCIPLE】

The COVID-19 Antigen Test Cassette is a qualitative membrane strip based immunoassay for the detection of COVID-19 antigen in nasopharyngeal swab specimen. In this test procedure, anti-COVID-19-N antibody is immobilized in the test line region of the device. After a nasopharyngeal swab specimen specimen is placed in the specimen well, it reacts with anti-COVID-19-N antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-COVID-19 antibody.

If the specimen contains COVID-19 antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain COVID-19 antigen, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains anti-COVID-19-N antibody as the capture reagent, another anti-COVID-19-N antibody as the detection reagent. A Goat anti-Mouse IgG is employed in the control line system.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30°C). The test is stable to 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】

1. COVID-19 Antigen Rapid Test (Lateral Flow) can be applied to to nasopharyngeal swab.
2. Do not return the nasopharyngeal swab to the original paper packaging.
3. For best performance, direct nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasopharyngeal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to 1 hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.
4. If specimens are to be transported, they should be packed in compliance with local regulations covering the transportation of etiological agents.

【MATERIALS】

Materials provided

Test devices	Extraction buffer	Extraction Tubes
Package insert	Swab	Work station

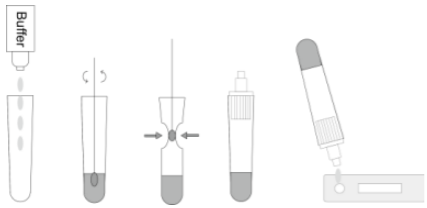
Materials required but not provided

Timer

【DIRECTIONS FOR USE】

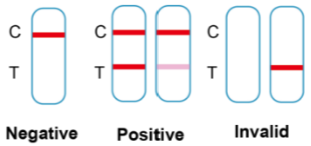
Allow the test, specimen, buffer and/or controls to reach room temperature 15-30℃ (59-86℉) prior to testing.

1. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 10 drops of solution to the Extraction Tube.



2. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
3. 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.
4. Cover the tube with cap,then add 3 drops of the sample into the sample hole vertically.
5. Read the result after 15 minutes. If left unread for 20 minutes or more the results are invalid and a repeat test is recommended.

【INTERPRETATION OF RESULTS】



Positive: Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region.

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of COVID-19 antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

Negative: One colored line appears in the control region(C).No apparent colored line appear in the test line region.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. 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 test detects both viable (live) and non-viable, SARS-CoV and COVID-19. 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.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. The performance of COVID-19 Antigen Test Cassette was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. False negative results may occur if a specimen is improperly collected, transported, or handled.
5. False results may occur if specimens are tested past 1 hour of collection. Specimens should be test as quickly as possible after specimen collection.
6. Positive test results do not rule out co-infections with other pathogens.
7. Positive test results do not differentiate between SARS-CoV and COVID-19.
8. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
9. Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
10. If the differentiation of specific COVID-19 viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The COVID-19 Antigen Test Cassette (nasopharyngeal Swab Specimen) was compared with a commercial PCR(from Oriental gene).

Days post symptom onset	Number of samples	PCR positive	COVID-19 Antigen Test Cassette
≤3	9	9	7/9=77.8%
4~7	33	33	32/33=97.0%
8~14	25	25	23/25=92%
>14	9	9	8/9=88.9%
Total	76	76	70/76=92.1% 95% CI: (87.7%~93.9%)

The total sensitivity of COVID-19 Antigen is 92.1%; 95% CI:(87.7% - 93.9%)

Number of samples	PCR Negative result	COVID-19 Antigen Test Cassette
215	215	211/215=98.1%
Total	N/A	98.1% 95%CI: (95.14%-99.44%)

Total specificity from the above table is 98.1%; 95%CI: (95.14%-99.44%)

Cross-reactivity

The COVID-19 Antigen Test Cassette has been tested for other virus(Table below). The results showed no cross-reactivity.

No cross-reactivity	Human Rhinovirus 14	Arcanobacterium	Staphylococcus aureus subspaureus
Human coronavirus OC43	Human Rhinovirus 16	Candida albicans	Staphylococcus epidermidis
Coronvirus NL63	Measles	Corynebacterium	Streptococcus pneumoniae
Influenza A H1N1	Mumps	Escherichia coli	Streptococcus pygenes
Influenza A H3N2	Parainfluenza virus 2	Moraxella catarrhalis	Streptococcus salivarius
Influenza B	Parainfluenza virus 3	Neisseria lactamica	Streptococcus sp group F
Human Rhinovirus 2	Respiratory syncytial virus	Nesseria subllava	Pseudomonas aeruginosa

Interfering Substances

The following compounds have been tested using the COVID-19 Antigen Test Cassette (nasopharyngeal Swab Specimen) and no interference was observed.

Analytes	**Conc.**	**Analytes**	**Conc.**
Whole Blood	20μl/ml	Oxymetazoline	0.6mg/ml
Mucin	50μg/ml	Phenylephrine	12mg/ml
Budesonide Nasal Spray	200μl/ml	Rebetol	4.5μg/ml
Dexamethasone	0.8mg/ml	Relenza	282ng/ml
Flunisolide	6.8ng/ml	Tamiflu	1.1μg/ml
Mupirocin	12mg/ml	Tobryamycin	2.43mg/ml

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 4-30°C	LOT	Lot Number	**REF**	Catalog #

Swab

EC REP European Authorized Representative info.:
Lotus NL B.V.
T.a.v.de heer X.Wei
Koningin Julianaplein 10
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NO. 20200011 version 00
Effective date: 2020-09-25