SARS-CoV-2 Antigen Rapid Test

REF: ABH-IC05-CoVAg

INTENDED USE:

The novel Coronavirus antigen (SARS-CoV-2 Ag) Rapid Test is an in vitro immunochromatographic assay for qualitative detection of Nucleocapsid protein antigen of the SARS-CoV-2 virus in nasopharyngeal (NP) directly.

TEST PRINCIPLE:

The SARS-CoV-2 Ag Rapid Test is a lateral flow chromatographic immunoassay that uses highly sensitive monoclonal antibodies to detect SARS-CoV-2 Nucleocapsid (N) protein Ag in NP swab specimens. Anti-SARS-CoV-2 antibody is pre-coated in test (T) line region. During testing, the specimen reacts with SARS-CoV-2 antibody conjugates in the conjugated pad. The immune complex of Ag and conjugates then move upward on the membrane chromatographically and reacts with the anti-SARS-CoV-2 antibody in T line region. If the specimen contains SARS-CoV-2 antigens, a colored line will appear in T line region. If the specimen does not contain SARS-CoV-2 Ag, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control (C) line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

COMPONENTS:

The kit component configurations are provided below:
Test Cassette (10), Extraction Buffer (10×0.4 mL), Nasopharyngeal swab (10 Pcs), and IFU.

STORAGE AND STABILITY:

-Store the kit at 2-30˚C. If stored at 2-8˚C, ensure that the test device is brought to 15-30˚C before opening. Test kit is valid for 18 months.
- Do not freeze the kit or store the kit over 30˚C.

SPECIMEN COLLECTION AND PREPARATION:

1. Tip the patient's head back and carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx.
2. Rotate the swab several times (move gently to avoid traumatic bleeding). Withdraw the swab from the nasal cavity.
3. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
4. Label an extraction tube. Make sure that the tube is standing firm.
5. Insert the swab into the extraction tube which contains the extraction buffer.
6. Roll the swab at least 8 times while pressing the head against the bottom and side of the extraction tube.
7. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.
8. Sample should be tested as soon as possible after collection. Be careful of contamination.

TEST PROCEDURE:

1. Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
2. Place the nozzle cap into the sample extraction tube tightly.
3. Reverse the sample extraction tube, and add 3-4 drops (100 µL) of test sample by squeezing the extracted solution tube into the sample window.
4. Wait for the colored band(s) to appear. The result should be read in 15-20 minutes. Do not interpret the result after 20 minutes.

SPECIMENT STORAG:

Specimens should be tested as soon as possible. If the sample has to be stored, store the swab sample at 2-8 ˚C, up to 4 hours prior to testing.

INTERPRETATION OF ASSAY RESULTS:

- Negative: When only the C line develops, the test result indicates the absence of SARS-CoV-2 virus antigen in the sample and hence likely no infection.
- Positive: When both the C and T line develop, the test result indicates the presence of SARS-CoV-2 virus Ag in the sample and hence likely infection.
- Invalid: If the C Line does not develop, the assay is invalid regardless whether the color of T line is present. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS:

Clinical Sensitivity and Specificity

The SARS-CoV-2 Ag Rapid Test has been valuated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the SARS-CoV-2 Ag Rapid Test has a high overall accuracy.
Relative Sensitivity: 95%
Relative Specificity: 98%
Accuracy: 96.9%

Table 1: The SARS-CoV-2 Ag Rapid Test vs RT-PCR

Method		RT-PCR		Total
SARS-CoV-2 Antigen Rapid Test	Results	Positive	Negative	
	Positive	57	2	59
	Negative	3	98	101
Total Results		60	100	160

Cross-reactivity and Interference

*Interferences: Benzocaine (150 mg/dL), Human Blood (5%), Mucin (5 mg/mL), Naso GEL (NeilMed)(5%), CVS Nasal Drops (phenylephrine15%), Afrin (Oxymetazoline) (15%), CVS Nasal Spray (Cromolyn) (15%), Mupirocin (0.15mg/dL), Fluticasone(0.000126mg/dL), Budenoside (0.00063 mg/dL), Biotin (0.35mg/dL), Methanol 150mg/dL.
*Cross-reactivity: Human coronavirus 229E (1x105 PFU/mL), Human coronavirus OC43 (1x105PFU/mL), Human coronavirus NL63 (9.87x103 PFU/mL), Adenovirus (e.g. C1 Ad. 71) (1x105 PFU/mL), Parainfluenza virus Type 1-4 (1x105 PFU/mL), Influenza A H3N2 (8.82x104 PFU/mL), Influenza A H1N1(1x105 PFU/mL), Influenza B (3.24x104 PFU/mL), Rhinovirus (3.95x105PFU/mL)

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WARNINGS:

1. This instructions of use (IFU) must be read completely before performing the test. Failure to follow directions in IFU may yield inaccurate test results.
2. Test results should be read between 15 and 20 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results.
3. Do not open the sealed pouch until you are ready to conduct the assay. Once opened, the cassettes should be used within 15 min.
4. Do not use expired devices.
5. Bring all reagents to room temperature (15-30°C) before use.
6. Do not use the components of any other type of test kit as a substitute for the components in this kit.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Dispose of all specimens and materials used to perform the test as biohazardous waste.

LIMITATIONS OF THE PROCEDURE:

1. The etiology of respiratory infection caused by microorganisms other than SARSCoV-2 will not be established with this test. The SARS-CoV-2 Ag Rapid Test is capable of detecting both viable and non-viable SARS-CoV-2. The performance of the SARS-CoV-2 Ag Rapid Test depends on antigen load and may not correlate with viral culture results performed on the same specimen.
2. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of SARS-CoV-2 antigens in specimen, as they may be present below the minimum detection level of the test or if the sample was collected or transported improperly.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. Positive test results do not rule out co-infections with other pathogens.
5. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management, including infection control.

REFERENCES:

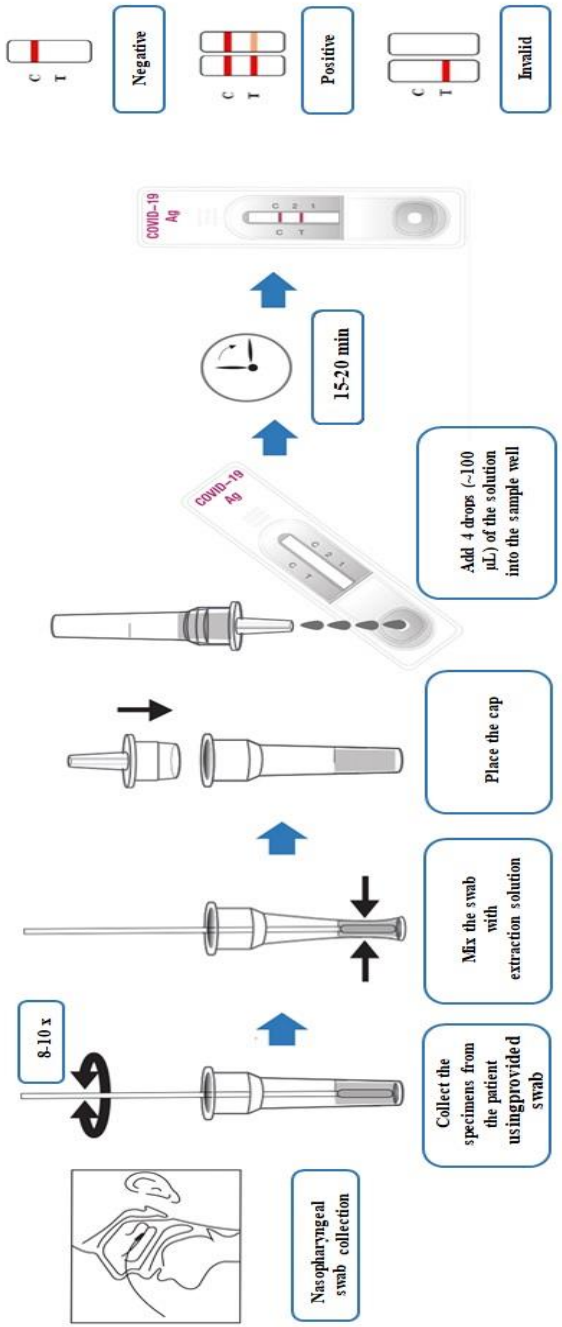
1.Li M, Jin R, Peng Y, et al. Generation of antibodies against COVID-19 virus for development of diagnostic tools{J}. medRxiv. https://doi. org/10. 1101/2020. 02. 20. 20025999.

2.Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version VII), National Health Office Medical Letter [2020] No.184, 2020.3.3.

3. Laboratory Biosafety Guidance Related to Coronavirus Disease (COVID-19) (Edition II), National Health Office Science and Education Letter [2020] No. 70, 2020.1.23.

Index of CE Symbols:

	Use by date		Consult instructions for use
	Contains sufficient for tests		Caution
	Date of Manufacture		Manufacturer
IVD	In vitro diagnostic medical device		Temperature limit
LOT	Batch Code		Do not re use
REF	Catalog Number		Do not use if package is damaged
	Keep dry		Keep away from sunlight



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