MediDia COVID-19 Ag

※ Please read the instructions for use carefully

▶INTENDED PURPOSE

MediDia COVID-19 Ag is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to Coronavirus (SARS-CoV-2) in nasopharyngeal specimens.

▶EXPLANATION OF THE TEST

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by 2019-nCoV, a new strain of coronavirus that has not been previously identified in humans. The disease is primarily spread via respiratory droplets from infected individuals when they cough or sneeze. Time from exposure to onset of symptoms is generally between 2 and 14 days. The disease may initially present with few or no symptoms, or may develop into fever, coughing, shortness of breath, pain in the muscles and tiredness. Further development may include pneumonia and acute respiratory distress syndrome.

MediDia COVID-19 Ag is a chromatographic immunoassay kit for rapid qualitative determination for coronavirus infection.

▶PRINCIPLE OF THE METHOD

MediDia COVID-19 Ag is a qualitative, lateral flow immunoassay for the detection of specific antigens in nasopharyngeal specimens. In this test, antibody specific to the SARS-CoV-2 antigen is separately coated on the test line regions of the test device. During testing, the extracted specimen reacts with the antibody to SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to SARS-CoV-2 on the membrane and generates a colored line in the test region. If SARS-CoV-2 antigens are present in the specimen a colored test line will be visible in the result window. If SARS-CoV-2 antigens are not present in the specimen, then no color will appear in the test line.

▶COMPOSITION

MediDia COVID-19 Ag contains the following items to perform the test.

1) Test devices sealed in a foil pouch with desiccant
2) Extraction buffer tube
3) Filter cap
4) Sterile swab
5) Instruction for use

▶SPECIMEN COLLECTION AND PREPARATION

Nasopharyngeal swab specimens

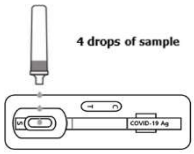
Insert a sterilized swab into the nasal cavity securely through a nostril and collect specimen by wiping the nasopharyngeal mucosa several times.

※ Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assay.

▶TEST PROCEDURE

1. This test should be conducted at room temperature, so if the test reagent was stored in a cold environment then the reagent must be kept at room temperature for approximately 15~30 minutes before testing.
2. Remove the cap of an extraction buffer tube. Immerse the swab tip into extraction buffer, then swirl the swab 5~10 times while pressing the head against the bottom and side of the collection tube.
3. Withdraw the swab while pinching and squeezing and remove it. The swab shall be regarded as biohazardous waste and shall be disposed of accordingly.
4. Close the test tube with a filter cap securely, and then take a test device out from the foil pouch.

5. Place the test device on a flat surface. Invert the test tube and gently squeeze it to draw 4 drops into the sample well on the device
6. Interpret the result between 15~20 minutes.



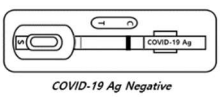
※ Please do not interpret after 20 minutes.

▶READING AND INTERPRETATION OF RESULT

1. Control (C) band means the test is working properly.
2. Test (T) band indicates the test result.

NEGATIVE:

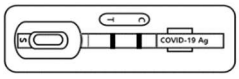
The presence of only 'C' band indicates a negative result



COVID-19 Ag Negative

POSITIVE:

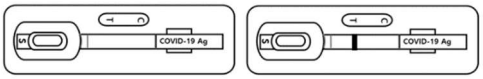
The presence of Test band (T) with Control ('C') band indicates a positive result.



COVID-19 Ag Positive

INVALID:

If the Control (C) band does not appear in the result window after performing test, the result is considered invalid.



※ It is possible that directions may not have been followed correctly or the test device may have been deteriorated. In such cases, it is recommended that specimens be re-tested with a new device.

▶ PERFORMANCE CHARACTERISTICS

1. Clinical evaluation

Samples taken from patients were used to evaluate how accurate MediDia COVID-19 Ag is at identifying the presence of SARS-CoV-2 as compared to RT-PCR testing.

Sensitivity: 97.37%, Specificity: 100%

		RT-PCR		Total
		Positive	Negative	
MediDia COVID-19 Ag	Positive	111	0	111
	Negative	3	334	337
Total		114	334	448

▶FOLLOW-UP MEASURES

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by a physician after all clinical and laboratory findings have been evaluated.

▶LIMITATIONS OF THE METHOD

1. The test is for in vitro diagnostic use only.
2. This test detects the presence of SARS-CoV-2 antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate anti-SARS-CoV-2 antigens concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
7. A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.

▶WARNING AND PRECATIONS

1. For professional *in vitro* diagnostic use only
2. Do not re-use the test device
3. Do not eat or smoke while handling specimens.
4. Wear protective gloves while handling specimens. Wash hands thoroughly afterward.
5. Do not use test kit if the packing is damaged or the seal is broken.
6. Do not use the kit beyond the expiration date.
7. Avoid splashing or aerosol formation while handling specimens.
8. Clean up spilled specimens thoroughly using an appropriate disinfectant.
9. The test device is sensitive to humidity. Pull out the test device from the foil pouch right before use.
10. This test kit contains a little of sodium azide. Avoid contact with skin, eyes. If you get the solution on your body, immediately wash thoroughly with flushing water. And contact a doctor if you need to.
11. Decontaminate and dispose of all specimens, tested kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
12. Since the test may give you the false positive or false negative result, final diagnosis should not be made only by this product's test result.

▶STORAGE AND SHELF LIFE

MediDia COVID-19 Ag should be stored at 2~30℃ (36~86℉). The test device is sensitive to humidity as well as to heat. Do not use it beyond the expiration date, 24 months from manufacturing date.

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