MDx COVID-19 Ag Rapid Test

REF MDX-CVD-22 MFDS License No. 20-960 CE IVD

INTRODUCTION

A novel coronavirus infection was identified in December 2019, which confirmed as severe acute respiratory syndrome caused by infection with a new Betacoronavirus. The World Health Organization (WHO) named this new corona-virus as "SARS-CoV-2" and the disease as "COVID-19" that has been causing hundreds of thousands of confirmed human infections worldwide.
MDx COVID-19 Ag Rapid Test is a lateral flow immunochromatography assay for the qualitative detection and diagnosis of SARS-CoV-2 in nasopharyngeal swabs, without using viral transport media. This test can be a supplemental diagnostic assay to real-time PCR assay in advanced laboratory for rapid diagnosis of COVID-19 infection. In addition, this rapid test can be utilized in limited facility by operators with minimum training.

INTENDED USE

MDx COVID-19 Ag Rapid Test is a lateral flow immunochromatography assay to detect SARS-CoV-2 in nasopharyngeal swabs collected from individuals suspected of COVID-19. Positive results in this test indicate the presence of SARS-CoV-2. However, positive results do not rule out co-infection with other viruses or bacteria. The agent detected may not be the definite sole cause of disease manifestation. Laboratories should report all positive results to the appropriate public health authorities. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment, patient management, and infection control. Negative results should be considered in the context of a patient's exposure time, history and the presence of clinical signs and symptoms consistent with COVID-19. **MDx COVID-19 Ag Rapid Test** is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests.

PRINCIPLE OF THE TEST

MDx COVID-19 Ag Rapid Test is a lateral flow based immunochromatography assay for the detection of SARS-CoV-2 in nasopharyngeal swabs with no use of transport media. When the specimen is added into the test device, the specimen is absorbed into the sample pad by capillary reaction, binds to the SARS-CoV-2 specific antibody-gold particle conjugate and the immune complexes move through the membrane to reach pre-coated capture antibody lines. When the SARS-CoV-2 antigen level in the specimen is at or above the cut-off (limit of detection, LoD), the immune complexes (antigen bound to the antibody-gold conjugate particles) are captured by SARS-CoV-2 specific antibody immobilized as the test line (T) in the device, visualizing a colored test band that indicates a positive result.
When the SARS-CoV-2 antigen level in the specimen is below the cut-off or no antigen, no band is visualized in the test line (T) of the device, indicating a negative test result. If the test performed properly, a colored line should always appear at the control line (C).

COMPOSITION OF KIT

No.	Composition	20 Tests/Kit
1	COVID-19 Ag Test Device	20 Tests
2	Sample Dilution Buffer	20 ea
3	* Nasopharyngeal Specimen Collection Swab (NP Swab)	20 ea
4	Dropper Cap	20 ea
5	Instruction Manual	1 book

* NP Swab : MFDS License No. 20-555 / MFDS License No. 21-519, V-SWAB™ NP Swab

SPECIMEN COLLECTION

1. The test should be used for the detection of SARS-CoV-2 in human nasopharyngeal swab specimens that are collected and tested directly (i.e., swabs that have not been placed in transport media are not recommended).
2. Collect the nasopharyngeal swab specimens using a NP Swab.
3. For best performance, NP swab should be tested as soon as possible after collection. If the specimen is kept for longer than 1 hour, the sample is not recommended for testing. A new fresh sample must be collected for testing.

STORAGE AND EXPIRATION

1. Store the kit at room temperature (2-30°C/36-86°F) avoiding direct sunlight or high humidity.
2. Kit components are stable until the expiration date.
3. Do not freeze the kit.

PRECAUTION

1. This kit is for *in vitro* diagnostic use only.
2. All specimens should be treated as potentially infectious materials. Use appropriate precautions in collection, handling, storage, and disposal of samples and used kit components according to biosafety level 2 or higher guidelines.
3. Wear appropriate personal protective equipment (gown, gloves, mask, eye protection etc.) when handling and testing the specimens.
4. This test has been authorized only for the detection of SARS-CoV-2, not for any other viruses or pathogens.
5. Follow the direction of the instruction manual strictly for an accurate result.
6. Use the device as soon as possible (<10 minutes) after opening the foil pouch. Moisture can negatively affect on the performance of the device.
7. Discard COVID-19 Ag Test Device and NP Swab, Sample Dilution Buffer, Dropper Cap after use. These components cannot be used more than once.
8. Do not use the kit beyond the expiration date.
9. Do not store collected swab specimen in the original paper swab packaging.
10. Do not use transport media, and use the collected specimen immediately.
    * Be careful not to contaminate the specimen.
11. Testing should be performed by professionally trained staff working in certified laboratories or clinics.
12. Test results should be interpreted by the medical doctor along with clinical findings and other laboratory test results.
13. Disposal of the diagnostic device: All specimens and used kit should be treated as bio-hazard wastes. The handling and disposal of all specimens and used kit must follow local, state, and national regulations.
14. Results from this antigen testing should not be used to inform infection stage (such as early stage of infection or recovery stage).
15. This test is only for qualitative assay. Neither the quantitative value nor the concentration of SARS-CoV-2 antigen can be determined by this kit.

LIMITATION OF THE TEST

1. This test detects the presence of SARS-CoV-2 in human nasopharyngeal swab specimens.
2. Neither the quantitative value nor SARS-CoV-2 antigen concentration can be determined by this qualitative test.
3. Failure to follow the test procedure and interpretation of test results may lead to poor test performance and/or invalid results.
4. The result of this test should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection with no consideration on other clinical data available to the physician.
5. For more accurate interpretation on infection status, additional follow-up testing using other laboratory methods is recommended.
6. When interpreting the positive result, cross reactivity against other related viruses such as SARS and common cold coronavirus is possible. Negative result should be interpreted with the consideration on following factors.
   1) Improper collection, delivery or handling of specimens.
   2) Lower concentration of SARS-CoV-2.
   3) Change of antigen recognition motif due to genetic mutation of the virus.
   4) Specimens should be tested within 1 hour after collection.
7. Inactivated virus or VTM specimens that have been N protein denatured can sometimes yield inaccurate test results with this kit.

PERFORMANCE DATA

1. Clinical evaluation

Performance characteristic for the **MDx COVID-19 Ag Rapid Test** for rapid detection of SARS-CoV-2 antigen was conducted at a clinical center during the 2020 SARS-CoV-2 pandemic situation. A total of 115 prospective specimens were tested using the **MDx COVID-19 Ag Rapid Test.** These specimens consisted of nasopharyngeal swabs from patients. The performance of **MDx COVID-19 Ag Rapid Test** was compared to real-time PCR.

MDx COVID-19 Ag Rapid Test had 83.8% (Ct value<35), 93.6% (Ct value <30), and 95.8% (Ct value <25) of diagnostic sensitivity and 100% of diagnostic specificity indicating that this rapid test is user-friendly and reliable for testing of COVID-19 associated clinical specimens.

COVID-19 real-time PCR results		Result of MDx COVID-19 Ag Rapid Test			
		Positive	Negative	Value	95% CI
Positive	Ct value <35 (n=37)	31	6	83.78%	67.99~93.81%
	Ct value <30 (n=31)	29	2	93.55%	78.58~99.21%
	Ct value <25 (n=24)	23	1	95.83%	78.88~99.89%
Negative (n=78)		0	78	100.00%	95.38~100.00%

2. Analytical sensitivity

Limit of Detection (LoD) : $10^{1.7}$ $TCID_{50}$/mL

3. Analytical specificity

1) No cross reaction was observed against 55 different infectious pathogens other than SARS-CoV-2.

No.	Tested Virus List (Strain)	No.	Tested Virus List (Strain)
1	Human coronavirus (NL63)	29	Adenovirus (Type 8)
2	MERS-CoV	30	Adenovirus (Type 11)
3	Human coronavirus (229E)	31	Adenovirus (Type 18)
4	Human coronavirus (OC43)	32	Adenovirus (Type 23)
5	Influenza A (Korea/2785/2009/H1N1)	33	Adenovirus (Type 40)
6	Influenza A (Victoria/361/2011/H3N2)	34	*Haemophilus influenzae*
7	Influenza A (Korea/01/09/H1N1pdm)	35	*Streptococcus pneumoniae*
8	Influenza A (Perth/16/09/H3N2)	36	*Streptococcus pyogenes*
9	Influenza A (California/07/09/H1N1)	37	*Canidida albicans*
10	Influenza B (Busan/1487/2013)	38	*Mycoplasma pneumoniae*
11	Influenza B (Seoul/7/2013)	39	*Legionella pneumophila*
12	Influenza B (Gyeonggi/578/11)	40	*Bordetella pertussis*
13	Influenza B (Gwangju/275/2003)	41	*Chlamydia pneumoniae*
14	Influenza B (Ulsan/602/2011)	42	*Staphylococcus aureus*
15	Rhinovirus (8)	43	*Corynebacterium diphtheriae*
16	Rhinovirus (42)	44	*Staphylococcus epidermidis*
17	Enterovirus (71)	45	*Neisseria gonorrhoeae*
18	Respiratory syncytial virus (Type A)	46	Human betaherpesvirus 5 (Cytomegalovirus)
19	Respiratory syncytial virus (Type B)	47	Herpes Simplex Virus-1
20	Parainfluenza virus (Type 1)	48	Herpes Simplex Virus-2
21	Parainfluenza virus (Type 2)	49	Epstein-Barr Virus (EBV)
22	Parainfluenza virus (Type 3)	50	Varicella Zoster Virus (VZV)
23	Parainfluenza virus (Type 4)	51	Parvovirus B19
24	Human metapneumovirus	52	Human Immunodeficiency Virus-1 (HIV-1)
25	Adenovirus (Type 1)	53	Human Immunodeficiency Virus-2 (HIV-2)
26	Adenovirus (Type 3)	54	Hepatitis C Virus (HCV)
27	Adenovirus (Type 5)	55	Hepatitis B Virus (HBV)
28	Adenovirus (Type 7)		

2) The performance of **MDx COVID-19 Ag Rapid Test** was not affected by any of the 32 potentially interfering materials.

No.	Factor	Pathogens	Conc.	No.	Factor	Pathogens	Conc.
1	Antiviral drugs	Zanamivir	5mg/L	17	Antibiotic	Azithromycin	2.5g/L
2		Doxycycline hyclate(Maralia)	70uM	18		Ceftriaxone	2.5g/L
3		Quinine(Maralia)	150uM	19		Meropenem	500mg/L
4		Lamivudine (Retroviral medication)	1mg/mL	20	Nasal sprays or drops	Choloraseptic (Menthol/Benzocaine)	1.5mg/mL
5		Ribavirin	1mg/L	21		Naso Gel(NeiMed)	5%v/v
6		Oseltamivir phosphate	5mg/mL	22		Phenylephrine	15%v/v
7		Paramivir	750mg/L	23		Alkalol nasal wash	1:10 dilution
8		Lopinavir	500mg/L	24		Afrin(Oxymetazoline)	15%v/v
9		Ritonavir	125mg/L	25	Homeopathic allergy relief medicine	Cromolyn sodium salt	15%v/v
10	Anti-inflammatory medication	Acetaminophen	200uM	26		Olopatadine hydrocholoride	10mg/mL
11		Acetylsalicyclic acid	4mM	27	Others	Blood(human), EDTA anticoagulated	5%
12		Ibuprofen	2.5mM	28		Mucin:bovine submaxillary gland, type I-2	0.50%
13	Antibiotic	Mupirocin	10mg/mL	29		Fluticasone Propionate	5%v/v
14		Tobramycin	5ug/mL	30		Heparin	18U/mL
15		Ciprofloxacin	30uM	31		Hemoglobin human	17.5g/dl
16		Levofloxacin	1.25g/L	32		Histamine	0.25mg/L

3) The performance of **MDx COVID-19 Ag Rapid Test** was not affected by any of five commensal microbes commonly found in nasal cavity.

No.	Substances	Conc.	Agreement of expected result		No.	Substances	Conc.	Agreement of expected result	
			Positive	Negative				Positive	Negative
1	*Staphylococcus epidermidis*	2.4×10^7	100% (3/3+)	100% (3/3-)	4	*Haemophilus influenzae*	4.4×10^6	100% (3/3+)	100% (3/3-)
2	*Streptococcus pneumoniae*	1.7×10^7	100% (3/3+)	100% (3/3-)	5	*Neisseria gonorrhoeae*	1.9×10^5	100% (3/3+)	100% (3/3-)
3	*Corynebacterium diphteriae*	2.8×10^5	100% (3/3+)	100% (3/3-)					

INDEX OF SYMBOLS

IVD *In Vitro* Diagnostics	Consult Instruction Manual	REF Catalog Number	This way up
Do Not Reuse	Contains Sufficient for <n> Tests	LOT Batch Code (LOT)	Recyclable
EXP Expiration Date	Temperature Limitation	Manufacturing Date	Keep dry
Manufacturer	Fragile, handle with care	CE Conformité Européenne Mark	
EC REP Authorized representative in the European Community			

Doc. No.: IFU-CVD22-004_EN (Rev.04_2021-07-30)

MDx COVID-19 Ag Rapid Test

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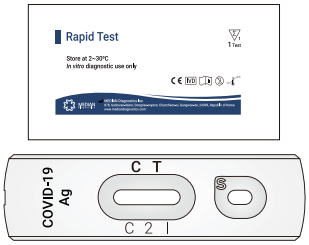
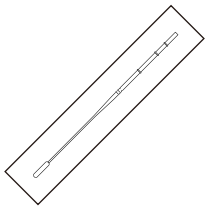
MEDIAN Diagnostics

KIT COMPONENTS



COVID-19 Ag Test Device
(individually in foil pouch with desiccant)

Sample Dilution Buffer



NP Specimen Collection Swab
(NP Swab)

Dropper Cap

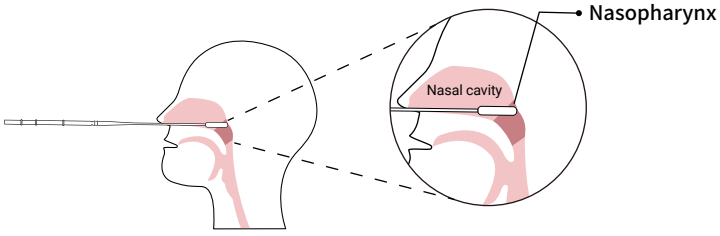
Instruction Manual

Box Appearance

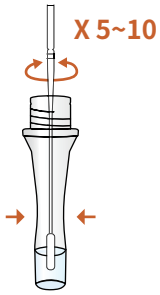
TEST PROCEDURE

1. Insert the NP Swab into the nostril of the patient to reach the surface of the posterior nasopharynx, and then withdraw the NP Swab from nasal cavity.
2. Insert the NP Swab into Sample Dilution Buffer. Stir the NP Swab 5~10 times.
3. Remove the NP Swab after gently squeezing the head of the NP Swab.
4. Securely tighten Dropper Cap on the buffer tube.
5. Add 3 drops of extracted specimen to the sample hole of COVID-19 Ag Test Device.
6. Wait for 15-20 minutes and read the result. Do not wait for longer than 20 minutes before reading the result.

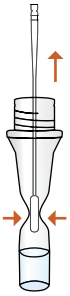
1. Collect the nasopharyngeal swab specimens



2. Sample dilution

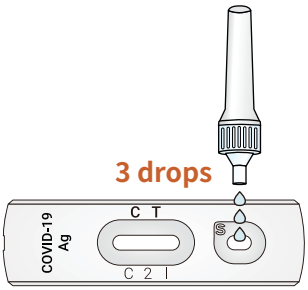


3. Remove the NP swab

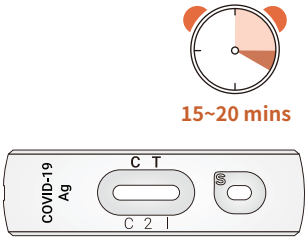


4. Tighten Dropper Cap

5. Add 3 drops of extracted specimen

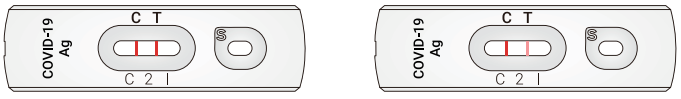


6. Read the result
(in 15~20 minutes)

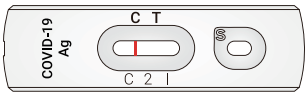


INTERPRETATION

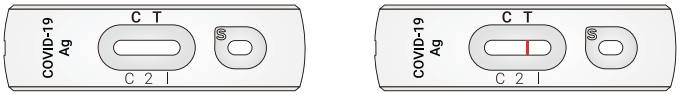
1. **Positive** : Colored bands at T and C



2. **Negative** : Colored band only at C



3. **Invalid** : No colored band at C line regardless of T line's band



* **Note** : A colored band should always be visualized at C line regardless of the results at T line.
If C line is not visualized, it is a no test. The retest is recommended using new Test Device.

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Doc. No.: IFU-CVD22-004_EN (Rev.04_2021-07-30)