GENEDIA W COVID-19 Ag

REF 643G IVD

INTENDED USE

The GENEDIA W COVID-19 Ag is an in vitro diagnostic single-use test and qualitative immunoassay to detect SARS-CoV-2 antigen in nasopharyngeal swab and sputum specimen from human. This assay is designed for professional personnel in laboratory and at point-of-care as an aid in screening patients suspected of being infected and asymptomatic patients.

SUMMARY AND EXPLANATION OF THE TEST

A novel coronavirus (2019-nCoV) also known as SARS-CoV-2 (COVID-19) was first identified in Wuhan, Hubei Province, China in December 2019. This virus, as with the novel coronavirus SARS-1 and MERS, is thought to have originated in bats, however the SARS-CoV-2 may have had an intermediary host such as pangolins, pigs or civets. The WHO declared that COVID-19 was a pandemic on March 11, 2020, and human infection has spread globally, with hundreds of thousands of confirmed infections and deaths. The median incubation time is estimated to be approximately 5.1 days with symptoms expected to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough, and shortness of breath.

PRINCIPLE OF THE TEST

The GENEDIA W COVID-19 Ag is an immunochromatographic assay kit for rapid and qualitative determination of SARS-CoV-2 infection from nasopharyngeal swab and sputum specimens.
Test kit contains a membrane strip, which is immobilized with the anti-SARS-CoV-2 monoclonal antibody on the test line (T) and Goat-anti mouse IgG on the control line (C) respectively.
And the strip is assembled in the test device. When the sample and the extraction solution are applied to the sample well, the sample is moved to the gold conjugated pad and reacts with anti-SARS-CoV-2 monoclonal antibody-coupled gold conjugate followed by reaction with anti-SARS-CoV-2 monoclonal antibody immobilized in the test line. When the sample contains SARS-CoV-2 antigens, a visible line appears in the test region on the membrane. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing another band in the control region. The GENEDIA W COVID-19 Ag is also very useful to directly detect SARS-CoV-2 antigens from nasopharyngeal swab and sputum samples.

MATERIALS PROVIDED

The GENEDIA W COVID-19 Ag is available in the following packaging configuration:

Configuration \ Kit Size	20 Tests
Test device	20 EA
Extraction solution	20 EA
Sample developing filter cap	20 EA
Sterilized swabs for sample collection	20 EA
Instructions for use	1 EA

WARNINGS

1) This test kit is for in vitro diagnostic and professional use only.
2) Do not re-use test kit.
3) Read the package insert completely before using this product.
Follow the instructions carefully. Not doing so may result in inaccurate test results.
4) Do not use the kit after the expiration date and do not freeze.

PRECAUTIONS

1) Safety precautions
(1) Handle specimens and materials contacting specimens with caution as if capable of transmitting infectious agents.
(2) Do not drink, eat or smoke in areas where specimens are being handled or testing is being performed.
- Do not eat the desiccant in the foil pouch.
- Do not drink extraction solution.
(3) Wear disposable gloves while handling specimens and performing testing of specimens. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.
(4) Dispose of all test specimens and materials used in the test procedure in a biohazard waste container. The recommended of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121 ℃. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (1% solution of sodium hypochlorite) is recommended. Allow to rest 1 hour for effective decontamination.
- Do not autoclave solutions that contain bleach.
(5) Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant. Bleach solutions should be made fresh each day.
(6) When solution contacts with skin or enters the eyes, immediately flush the skin or eyes with running water. If there is any irritation on your skin or eyes, consult a physician immediately.
(7) Avoid splashing or aerosol formation.

2) Handling precautions
(1) This test should be undertaken by trained laboratory personnel. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
(2) Use all test components only once and dispose of them properly (See Safety Precautions). Do not reuse.
(3) The presence of humidity may decrease the stability of the kit. Thus, please carry out the test immediately after removing the test from the aluminum pouch.
(4) Do not use the test kit if the pouch is damaged or the seal is broken.
(5) Do not interchange test devices and extraction solution vials from kits with different lot numbers.
(6) Do not mix and interchange different specimen.
(7) Avoid microbial contamination and exercise care in handling the kit components.
(8) Use of microbial contaminated sample or other transport media can lead to impair the test result.
(9) Extraction solution contains a proprietary anti-microbial agent which presents no hazard to the user if normal laboratory safety precautions are followed.

KIT STORAGE AND STABILITY

1) The GENEDIA W COVID-19 Ag kit and kit components must be stored at 2~30℃ (35.6~86℉) until the expiry date.
2) The test kit is stable for 12 months (while sealed in the original aluminum foil pouch) from the date of manufacture when stored at 2~30℃.
3) Allow kit to come to room temperature (15~30℃ ; 59~86℉) before use.
4) Do not open the aluminum pouch until you are ready to perform a test. After the device pouch is opened, the test should be performed immediately.

LIMITATIONS

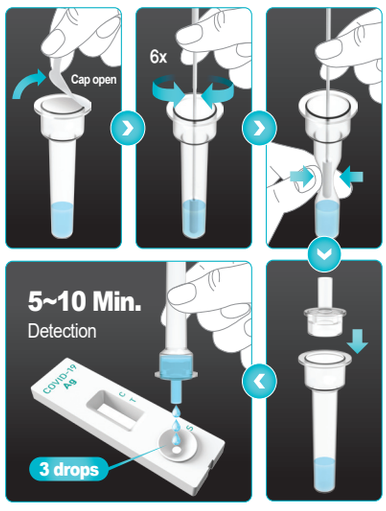
1) The GENEDIA W COVID-19 Ag is designed for primary screening test. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility or false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test result, and doctor's view, collectively.
2) Positive test results do not rule out co-infections with other pathogens.
3) A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
4) The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.

SPECIMEN COLLECTION AND HANDLING

* Because unknown sample have a possibility as source of infection, sample collection were performed by trained or professional person.
1) Collection
(1) Nasopharyngeal swab specimens
- Carefully insert sample collection swab into the nostril that presents the most secretion under visual inspection.
- Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx.
- Rotate the swab several times then remove it from the nasopharynx.
- Samples should be tested as soon as possible after collection.
(2) Sputum specimens
- Sterile container is prepared to collect sputum samples. (Sterile containers are not provided in this kit.)
- Collect the sputum sample in a sterile container by deep coughing.
- Put the swab for sample collection enclosed with this kit into the sterile container containing the sputum sample, turn it several times and soak it sufficiently.
- Samples should be tested as soon as possible after collection.
2) Extraction
(1) Insert swab into the extraction solution tube and swirl the swab 6 times inside the tube to well mix up and extract.
(2) After the extraction, pull out the swab from the tube along the tube wall. Dispose the used swab safely as infectious waste.
(3) After the specimen collection, test immediately.
3) Storage and stability
(1) All specimens should be tested immediately.

TEST PROCEDURE

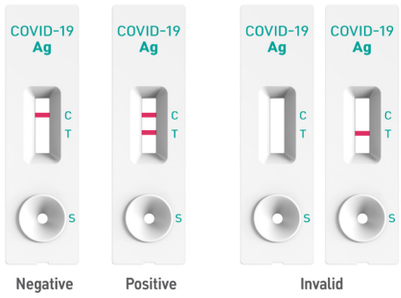
1) Preparation before use
If the test kit is refrigerated(2~8℃), keep it at room temperature(15~30℃) for 15~30 minutes prior to testing. If test kit is stored at room temperature, it could be used immediately.
2) Test procedure
(1) Open the extraction solution tube and insert the patient swab sample into the extraction solution tube. Then, swirl swab 6 times while pressing the head against the bottom and side of the tube.
(2) Roll the swab head against the inside of the tube as you remove it. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
(3) Bind the sample developing filter cap with the extraction tube.
(4) Remove the test device from an aluminum pouch and place it on a flat and dry surface.
(5) Add 3 drops of the extraction solution with specimen into the sample well. Inaccurate drops of the extraction solution can result in reverse migration phenomenon and/or overall a little reddish unclear background.
(6) Interpret the test result in 10 minutes. Some positive results may appear sooner in 5 minutes. Do not read after 15 minutes.
(7) Refer to the test result and interpretation of test result section in this package insert. Since the red color band of the test line may identified clearly, interpret the test result after appearing the clearly identified control line.



INTERPRETATION OF TEST RESULT

The GENEDIA W COVID-19 Ag kit qualitatively interprets positive and negative by examining the presence or absence of color bands on the test line (T) and control line (C).
The control line (C) always shows a band regardless of the presence or absence of COVID-19 specific

antigen in the sample, which is for acknowledging the presence or absence of an abnormality in the reaction. If the control line does not appear, because of an error in the experimental method or a problem with the reagent, retest is required.
In the test line, a band appears or does not appear depending on the presence or absence of COVID-19 specific antigen in the sample. Positive and negative are determined depending on the presence or absence of the test line.



1) Negative result: Only one band in the control line (C)
2) Positive result:
Two bands are appeared in the test line (T) and control line (C).
3) Invalid result:
If the red color band does not appear in the control line (C) at 10 minutes, the result is considered invalid regardless of any shade of a pink-to-red test line (T) appears. If the test is invalid, a new test should be performed with a new patient sample and a new test device.

INTERNAL QUALITY CONTROL

1) The control line should appear on all valid tests, whether the sample is positive or negative. The control line indicates that a specimen was added and that the fluid migrated appropriately through the test device.
2) If the test does not meet the criteria, retest is performed.
3) Control materials are not provided with GENEDIA W COVID-19 Ag.

PERFORMANCE CHARACTERISTICS

1) Analytical sensitivity
(1) Limit of Detection (LOD)
LOD of Heat-Inactivated SARS-CoV-2 is $7.50X10^2$ $TCID_{50}$/mL.

Limit of Detection (LOD)	No. Positive/Total	% Positive
$7.50X10^2$ $TCID_{50}$/mL	20/20	100%

(2) Hook effect
No high dose hook effect was observed up to $1.60X10^4$ $TCID_{50}$/mL of Heat-Inactivated SARS-CoV-2.
(3) Reactivity/Inclusivity
The target nucleocapsid sequence used for GENEDIA W COVID-19 Ag is "2019-nCoV/USA-WA1/2020". In silico analysis of the sequence is performed with other strains as follows. It showed high homology more than 99%.

No.	Strain	NCBI Accession No.	% Homology
1	Wuhan-Hu-1	MN908947.3	99.99 %
2	2019-nCoV_HKU-SZ-002a_2020	MN938384.1	99.99 %
3	SARS-CoV-2/human/USA/CA-CDC-CA1/2020	MN994467.1	99.98 %
4	SARS-CoV-2/human/USA/CA-CDC-CA2/2020	MN994468.1	99.98 %
5	BetaCoV/Korea/SNU01/2020	MT039890.1	99.96 %
6	2019-nCoV_HKU-SZ-005b_2020	MN975262.1	99.99 %
7	SARS-CoV-2/human/USA/AZ-CDC-AZ1/2020	MN997409.1	99.99 %
8	2019-nCoV WHU01	MN988668.1	99.99 %
9	2019-nCoV WHU02	MN988669.1	99.99 %
10	SARS-CoV-2/human/USA/IL-CDC-IL1/2020	MN988713.1	99.97 %
11	SARS-CoV-2/human/USA/WA-S1476/2020	MT821795.1	99.96 %
12	SARS-CoV-2/human/USA/CA-QDX-185/2020	MT786799.1	99.94 %
13	SARS-CoV-2/human/USA/SEARCH-0725-IPL/2020	MT811339.1	99.96 %
14	SARS-CoV-2/human/USA/SEARCH-0713-SAN/2020	MT811332.1	99.97 %

2) Analytical specificity
(1) Cross-reactivity
There was no significant cross-reactivities.

Cross-reactivity material	Concentration
Legionella pneumoniae	$>0.5X10^3$ CFU/mL
Mycoplasma pneumonia	$1.50X10^6$ CFU/mL
Human Coronavirus NL63	1/40 dilution
Human Coronavirus NL63 (Heat-inactivated)	$0.85X10^4$ $TCID_{50}$/mL
Human Coronavirus 229E	$0.50X10^4$ PFU/mL
Betacoronavirus (OC43)	$3.40X10^5$ PFU/mL
MERS-CoV (Heat-inactivated)	$0.85X10^4$ $TCID_{50}$/mL
Coronavirus-SARS Stock	1/20 dilution
Influenza A_H1N1_A/PR/8/34	$1.95X10^5$ PFU/mL
Influenza A_H3N2_A/Aichi/2/68	$1.55X10^5$ PFU/mL
Influenza B (Yamagata)_B/Florida/4/2006	$0.55X10^8$ $CEID_{50}$/mL
Influenza B (Victoria)_B/HongKong/5/72	$0.50X10^8$ $CEID_{50}$/mL
Rhinovirus 14	$0.6X10^4$ PFU/mL
Enterovirus 70	$4.40X10^6$ PFU/mL
Enterovirus 71	$0.70X10^4$ PFU/mL
RSV A_Long	$1.20X10^5$ PFU/mL
RSV B_9320	$2.30X10^4$ PFU/mL
Parainfluenza 1	$1.95X10^4$ PFU/mL
Parainfluenza 2	$1.00X10^6$ PFU/mL
Parainfluenza 3	$0.80X10^5$ PFU/mL
Parainfluenza 4a	$2.30X10^7$ PFU/mL
Parainfluenza 4b	$1.20X10^7$ PFU/mL
Metapneumovirus	$0.70X10^4$ PFU/mL
Adenovirus 1	$2.00X10^7$ PFU/mL
Adenovirus 3	$2.00X10^4$ PFU/mL
Streptococcus pneumonia	$>0.5X10^3$ CFU/mL
Haemophilus influenza	$>0.5X10^3$ CFU/mL
Candida albicands gu5	1/20 dilution
Bordetella pertussis 18323	$0.55X10^8$ CFU/mL
Streptococcus pyogenes strain Type 1	$>0.5X10^3$ CFU/mL
Chlamydophila pneumonia 2023	$2.00X10^6$ IFU/mL

(2) Interference
There was no significant interference.

Interference material	Concentration
Conjugated Bilirubin	5 mg/mL
Cholesterol	15 mg/mL
Triglyceride mixture	20 mg/mL
Sodium Heparin	30 mg/mL
Sodium Citrate	10 mg/mL
K3-EDTA	20 mg/mL
Albumin	30 mg/mL
Hemoglobin	40 mg/mL
(R)-(-)-Phenylephrine hydrochloride	1 mg/ml
Beclomethasone	500 ng/ml
Benzocaine	1 mg/ml
Dexamethasone	10 mg/ml
Flunisolide	500 ng/ml
Menthol	10 mg/ml
Mucin	1 mg/ml
Mupirocin	500 ng/ml
Oxymetazoline Hydrochloride	0.05 mg/ml
Tobramycin	500 ng/ml
Oseltamivir Phosphate	500 ng/ml
Acetaminophen	30 µg/mL
Acetylsalicylic acid	652 µg/mL
Ibuprofen	500 µg/mL
Zanamivir	1 mg/mL

3) Precision
(1) Between lot
One person tested three different lots of GENEDIA W COVID-19 Ag; three times at each concentration of the control standard.
(2) Between person
Three different person tested GENEDIA W COVID-19 Ag; three times at each concentration of the control standard.
(3) Between day
One person tested GENEDIA W COVID-19 Ag during five days; four times at each concentration of the control standard.
(4) Between site
One person tested GENEDIA W COVID-19 Ag at three different sites; five times at each concentration of the control standard for 5 days.
(5) Repeatability
One person tested GENEDIA W COVID-19 Ag; four times at each concentration of the control standard for 20 days.

4) Clinical evaluation
For the evaluation of diagnostic performance, COVID-19 positive samples from 102 individuals and COVID-19 negative samples from 129 individuals were introduced in this study.

		Real-Time PCR		Total
		Positive	Negative	
GENEDIA W COVID-19 Ag	Positive	89	0	89
	Negative	13	129	142
Total		102	129	231

- Clinical sensitivity : 87.25% (95% CI : 79.2% - 93.0%)
- Clinical specificity : 100% (95% CI : 97.2% - 100%)
- Total Agreement Ratio : 94.4%

Positive results broken down by days since symptom onset :

Days Since Symptom Onset	RT-PCR	GENEDIA W COVID-19 Ag	PPA
	Positive (+)	Positive (+)	
≤7	49	48	98% (95% CI : 89.1% - 100%)
8 to 14	22	17	77%(95% CI : 54.6% - 92.2%)
≥15	7	6	86%(95% CI : 42.1% - 99.6%)
Asymptomatic	24	18	75%(95% CI : 53.3% - 90.2%)

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