Vstrip RV2 COVID-19 Antigen Rapid Test Home Use

IVD REF

IG13002S01 (2 Tests/Kit)
IG13004S01 (4 Tests/Kit)
IG13020S02 (20 Tests/Kit)

2021/07 V01
IP13018IN

- **For use under Emergency Use Authorization (EUA) Only.**
- **Test result should not be used as the sole basis for treatment or patient management decisions.**

MATERIALS PROVIDED

All provided materials should be stored and handled at 15-30℃.

Test Dipstick	(2/4/20 pcs/KIT)	Each test houses a strip in individual foil pouch.
Extraction Buffer	(2/4/20 pcs/KIT)	Sodium Azide (<0.1%); Sodium Hydroxide (<0.5%); Albumin Bovine Serum (<1%)
Anterior Nasal Swab	(2/4/20 pcs/KIT)	Sterile
Package Insert	(1pcs/KIT)	

MATERIALS NOT PROVIDED

Timer、Camera

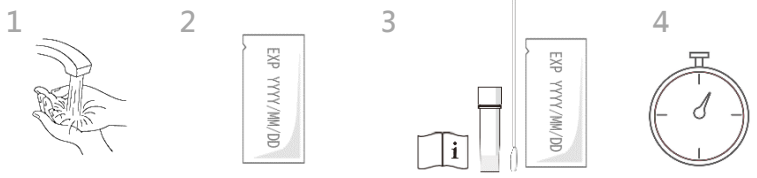
INTENDED USE

Vstrip RV2 COVID-19 Antigen Rapid Test Home Use is an in vitro immunochromatographic assay intended for the qualitative detection of nucleocapsid protein antigen of SARS-CoV-2 in anterior nasal secretion from individuals who are suspected of COVID-19. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not rule out SARS-CoV-2 infection. Test result should not be used as the sole basis for treatment or patient management decisions.

STORAGE INSTRUCTION

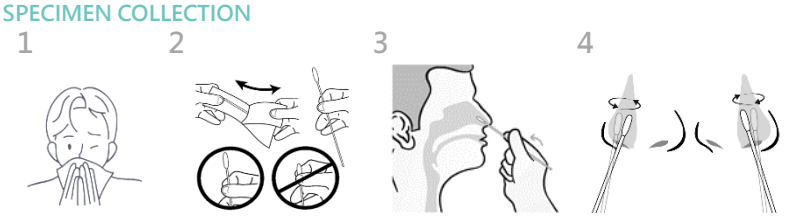
The product should be stored at 15-30 °C. Do not refrigerate or freeze.

BEFORE USE



1. Wash or sanitize your hands. Make sure hands are dry before starting.
2. Check the expiration date. Do not use the kit contents beyond the expiration date.
3. Confirm the components of kit are complete.
4. Prepare a timer.

SPECIMEN COLLECTION



Specimens should be tested immediately after collection.

1. Blow your nose before collecting the specimen. When blowing, use tissue to cover to avoid spreading of the nasal secretion. Do not clean out nose with tissue to avoid the amount of virus being too low to be collected.
2. Open the swab package. Make sure the swab head does not touch anything until sample collection.
3. Insert the swab about 2 cm deep into one nostril. Rub the swab around the inside wall of nostril at least 4 times for a total of 15 seconds.
4. Repeat the above step in the other nostril with the same swab.

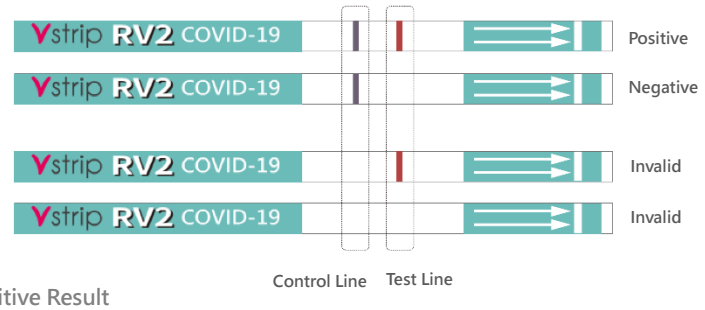
ASSAY PROCEDURE

Open the foil pouch right before test to minimize the problem caused by humidity.

1. Put the specimen collected swab into the extraction buffer tube. Roll the swab 3-5 times. Leave the swab in extraction buffer for 1 minute.
2. Keep the swab in tube. Then open foil pouch to get the test dipstick, place the test dipstick into the extraction buffer tube with the arrow sign down.
3. Leave the tube still for 10 minutes. Read the result at 10 minutes and do not read the result after 20 minutes.
4. Take the picture of test results.

INTERPRETATION OF RESULTS

Please compare the test dipstick directly with the figure.



Positive Result

At 10-20 minutes, if both Test Line and Control Line position show a line individually, it means a positive result of the presence of SARS-CoV-2 viral antigen.

A positive test result means it is very likely that you have COVID-19, and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

Negative Result

At 10-20 minutes, if only Control Line position shows a line, it means a negative result. A negative result indicates that the presence of antigen is negative in the specimen, or the antigen level is below the detection limit.

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. Negative results may require additional molecular test to confirm that you do not have COVID-19. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If your test result is negative, please consult your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Invalid Result

At 10-20 minutes, if both Test Line and Control Line position do not show a line respectively, or only Test Line position shows a line, the result is considered invalid. When invalid, a new test performed with a freshly collected specimen is suggested.

GENERAL TEST CLEAN-UP

Dispose of the used test materials in a biohazard waste container. All equipment and biohazardous waste should be discarded in accordance with country, state, and local law, and policies.

WARNINGS AND PRECAUTIONS

1. Do not insert the test dipstick directly into the nasal area, and inappropriate specimen collection, storage, and transport may yield false test results. Disregard test results beyond specified time (20 min).
2. This test has been authorized only for the detection of proteins from SARSCoV-2, not for any other viruses or pathogens. The results must be interpreted together with other clinical information available to the physician. Therefore, negative result does not exclude SARS-CoV-2 viral infection, and positive result does not rule out co-infection with other viruses or bacteria.
3. Negative test result may occur if the level of antigen in specimen is below the detection limit of the test.
4. Antibodies may fail to detect, or detect with less sensitivity when SARS-CoV-2 viruses have undergone minor amino acid changes in the target epitope region.
5. To obtain accurate results, follow the instruction for use. Do not reuse kit components and interchange or mix different lots of tests.
6. Check the expiration date, integrity of package and test dipstick pouch before use. Do not use if components beyond the expiration date or package damage.
7. When collecting an anterior nasal specimen, use the anterior nasal swab supplied in the kit. Use of alternative swabs may result in incorrect results. Seek specific training or guidance if you are not experienced with specimen collection and procedures.
8. Use of protective tools is recommended when collecting, handling, storing, and disposing of the components within process.
9. If the extraction buffer contacts the skin or eyes, flush with copious amounts of water. For additional information on hazard symbols, safety, handling, and disposal of the components within this kit, please refer to the Material Safety Data Sheet (MSDS) available at Vstrip official website.

CLINICAL PERFORMANCE

The clinical performance was established with 153 subjects who were suspected of COVID-19. Anterior nasal secretion was collected and handled as described in instruction for use. The clinical test result of the Vstrip RV2 COVID-19 Antigen Rapid Test Home Use was compared to that of molecular test. (RT-PCR, Cobas SARS-CoV-2, Roche)

		Cobas SARS-CoV-2, Roche		
		Positive	Negative	Total
Vstrip RV2 COVID-19 Antigen Rapid Test Home Use	Positive	29	1	30
	Negative	2	121	123
	Total	31	122	153

Sensitivity: 93.55% (29/31, 95%CI: 78.58% - 99.21%)
Specificity: 99.18% (121/122, 95%CI: 95.52%- 99.98%)
Accuracy: 98.04% (150/153, 95%CI: 94.38%-99.59%)

For 10 asymptomatic patients confirmed to be positive by molecular test, all of them were tested positive by Vstrip RV2 COVID-19 Antigen Rapid Test Home Use.

LIMIT OF DETECTION

The limit of detection (LOD) was established using gamma-inactivated SARS-CoV-2 (USA-WA1/2020, NR-52287). The inactivated virus was mixed into the pooled human clinical nasal matrix (CNM) obtained from multiple healthy volunteers previously confirmed to be SARS-CoV-2 negative.
An initial range finding study was performed in triplicate using a 2-fold dilution series. At each dilution, 50 µL samples were spiked to swabs and then tested by Vstrip RV2 COVID-19 Antigen Rapid Test Home Use. The estimated LOD found from the initial 2-fold serial dilution test was confirmed by additional testing 20 replicates.

Type	Strain	Starting Conc.	Estimated LOD	Positive /Total	Positive%
Inactivated SARS-CoV-2, gamma-Irradiated	USA-WA1/2020	2.8×10^5 $TCID_{50}$/mL	1.51×10^2 $TCID_{50}$/mL	20/20	100

INCLUSIVITY

The inclusivity study of SARS-CoV-2 mutant variants was established by wet-testing and in silico protein sequence homology analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI).

The wet-testing was performed in clinical nasal matrix.

PANGOLIN lineages	Concentration	WHO Label
B.1.1.7	3.16×10^1 $TICD_{50}$/mL	Alpha
B.1.2	3.16×10^1 $TICD_{50}$/mL	
B.1.617.2	10^1 $TICD_{50}$/mL	Delta

The Basic Local Alignment Search Tool (BLAST) was used to assess the degree of nucleocapsid protein sequence homology between mutant variants and Wuhan-Hu-1.

PANGOLIN lineages	Homology Analysis	WHO Label
B.1.1.7	99.4%	Alpha
B.1.351	100%	Beta
P.1	99.4%	Gamma
B.1.617.2	99.4%	Delta

INTERFERENCE

Nasal spray products and common chemicals were evaluated and did not interfere with the Vstrip RV2 COVID-19 Antigen Rapid Test Home Use in clinical nasal matrix at the levels tested below.

Interference substances	Testing Conc.	Interference Substances	Testing Conc.
Afrin (Oxymetazoline)	15% v/v	Naso GEL (NeilMed)	5% v/v
Aspirin	20mg/ml	Nasal Ointment	10%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Nasal Washing Salt	20mg/ml
CVS Nasal Drops (Phenylephrine)	15% v/v	NASONEX Aqueous Nasal Spray	10%
CVS Saline Nasal Spray	15% v/v	Oxymetazoline HCl	10mg/ml
Dextromethorphan	10mg/ml	Phenylephrine HCl	100mg/ml
Diphenhydramine HCl	5mg/ml	Postan	20mg/ml
Fisherman's Friend	1.5 mg/mL	Ricola (Menthol)	1.5 mg/mL
Hemoglobin	20mg/ml	Sore Throat Phenol Spray	15% v/v
Hosoon Troches (ROOT)	20mg/ml	Swinin Nasal Sprays	10%
Homeopathic (Alkalol)	1:10 dilution	Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Ibuprofen	20mg/ml	Tobramycin	4 µg/mL
Mupirocin	10 mg/mL	Whole blood	5%
Mucin	4%	Zicam	5% v/v
Nasal Gel (Oxymetazoline)	10% v/v		

HOOK EFFECT

Vstrip RV2 COVID-19 Antigen Rapid Test Home Use was tested up to 2.8×10^5 $TCID_{50}$/ml of gamma-inactivated SARS-CoV-2 (USA- WA1/2020, NR-52287), and no high-dose hook effect was observed.

CROSS REACTIVITY

The cross-reactivity of Vstrip RV2 COVID-19 Antigen Rapid Test Home Use was performed on the positive and negative clinical nasal matrix containing high levels of non-target microorganisms. A total of 12 bacteria was tested at a target concentration between 10^6 and 10^8 cfu/mL and the 18 viruses were tested at concentrations between 10^5 and 10^8 $TCID_{50}$/mL (or pfu/mL). Each organism and virus were tested in triplicate in the absence or presence of 2xLoD ($TCID_{50}$/mL: 3.02×10^2) of gamma inactivated SARS-CoV-2. No cross-reactivity or interference was seen when tested at the potentially interfering concentrations. The bacteria and viruses tested were listed in the below Table.

Bacteria panel	
Bordetella pertussis	*Mycoplasma pneumoniae*
Candida albicans	*Pseudomonas aeruginosa*
Chlamydia pneumoniae	*Staphylococcus aureus*
Escherichia coli	*Staphylococcus epidermidis*
Haemophilus influenzae	*Streptococcus pneumoniae*
Legionella pneumophila	*Streptococcus pyogenes*
Viral panel	(*Unit: pfu/ml)
Adenovirus type 7	Human Parainfluenza Virus (HPIV) Type II*
Adenovirus type 41	Human Parainfluenza Virus (HPIV) Type III*
Enterovirus (EV71)	Influenza A -H1N1
Enterovirus Type 68	Influenza A -H3N2
Human coronavirus 229E*	Influenza B -Vic
Human coronavirus NL63	Influenza B -Yam
Human coronavirus OC43*	MERS-CoV
Human Metapneumovirus (hMPV 3 type B1)	Respiratory syncytial virus (Subgroup B)*
Human Parainfluenza Virus (HPIV) Type I*	Rhinovirus (HRV14)

BLAST is used to analyze the degree of protein homology for high-risk pathogens which cannot be detected directly.

- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid protein is relatively low, at 36.74% across 82% of sequences. And two antibody recognition positions are 0% similarity, so cross-reactivity is excluded.
- For SARS-Coronavirus, homology exists between the SARS-CoV-2 nucleocapsid protein and SARS-Coronavirus. BLAST results showed 90.52% across 100% of sequences, its high similarity. The cross-reactivity with SARS-CoV-2 is likely due to high homology between the two viruses nucleocapsid protein.

REPRODUCIBILITY

An evaluation of reproducibility was conducted at three different locations using 48 samples with SARS-CoV-2 recombinant nucleocapsid protein spiked into clinical nasal matrix. The study panel contained samples with four different levels of inactivated virus categorized as negative, high negative, low positive and moderate positive. Each sample was tested at each site by two operators. The results obtained at each site agreed with the expected. The data analyses support the hypothesis that Vstrip RV2 COVID-19 Antigen Rapid Test Home Use is easily reproducible by different operators and can be performed with little to no difficulty.

TECHNICAL SUPPORT

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ORDERING INFORMATION/ PACKAGING

IG13002S01.....2 Tests/Kit
IG13004S01.....4 Tests/Kit
IG13020S02.....20 Tests/Kit

SCAN FOR INSTRUCTION

SYMBOL LEGEND

REF	Catalog number	LOT	Batch Code
IVD	In vitro diagnostic medical device		Temperature Limit
	Consult Package Insert		Do not reuse
Σ	Contains sufficient for < n > tests		Manufacturer
	Do not use if package is damaged and consult Package Insert		

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