

Vstrip RV2

COVID-19 Antigen Rapid Test

HOME USE

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.



CLINICAL PERFORMANCE

The performance of the Vstrip RV2 COVID-19 Antigen Rapid Test HOME USE for detection of SARS-CoV-2 was established with anterior nasal specimens from 153 subjects using a US FDA Emergency Use Authorized comparator molecular (RT-PCR) test (Cobas SARS CoV 2, Roche).

DETECTION TIME
10 min

VISUAL DETECTION
NO MACHINE NEEDED

USA-WA1/2020
1.51x10² TCID₅₀/ml
LIMIT OF DETECTION

15-30°C
STORAGE

		Cobas SARS CoV 2, Roche		
		+	-	Total
Vstrip RV2 Home Use	+	29	1	30
	-	2	121	123
	Total	31	122	153
Performance		93.6% (29/31) Sensitivity (PPA)	99.2% (121/122) Specificity (NPA)	98.0% (150/153) Accuracy

PPA: 93.6% (95%CI: 78.58% - 99.21%)
NPA: 99.2% (95%CI: 95.52% - 99.98%)

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.

VARIANT DETECTION

WHO Label	PANGOLIN lineages	Isolate	Homology	Minimum Virus Detection Titer	Evaluation Result	
		Taiwan/NTU49		3.16x10 ⁶ TCID ₅₀ /mL	Detectable	
Alpha	B.1.1.7	USA/CA_CDC_5574/2020	99.4%	2.80x10 ⁴ TCID ₅₀ /mL	Detectable	
		England/204820464/2020		8.80x10 ⁴ TCID ₅₀ /mL	Detectable	
		South_Africa/KRISP-005325/2020		1.60x10 ³ TCID ₅₀ /mL	Detectable	
VOIC	Beta	B.1.351	100.0%	1.60x10 ³ TCID ₅₀ /mL	Detectable	
		Italy-INMI1		1.60x10 ³ TCID ₅₀ /mL	Detectable	
	Gamma	P.1	99.4%	2.80x10 ³ TCID ₅₀ /mL	Detectable	
	Delta	B.1.617.2	99.4%	1.00x10 ⁴ TCID ₅₀ /mL	Detectable	
VOI	Lambda	C.37	-	N/A	Detectable	
	Epsilon	B.1.427	-	100.0%	N/A	Detectable
Other	Lota	B.1.526	-	100.0%	N/A	Detectable
	N/A	B.1.2	Taiwan/NTU55	N/A	3.16x10 ² TCID ₅₀ /mL	Detectable

VOIC = Variants of Concern ; VOI = Variants of Interest

Proven and predictive detection for major SARS-CoV-2 variants currently circulating the globe.

VIRUS INACTIVATION 60 secs

Proven virus inactivation function of Extraction Buffer in 60 seconds prevents contamination during assay procedure.



TECH SUPPORT
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PACK / REF NO.
2 Tests/Box IG13002S01
4 Tests/Box IG13004S01
20 Tests/Box IG13020S02

PROCEDURE

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.

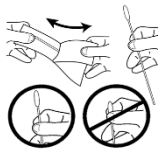
SPECIMEN COLLECTION

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



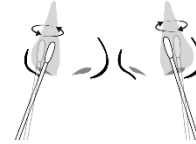
Open the swab package. Make sure the swab head does not touch anything until sample collection.

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.

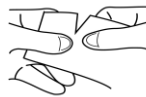
ASSAY PROCEDURE

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



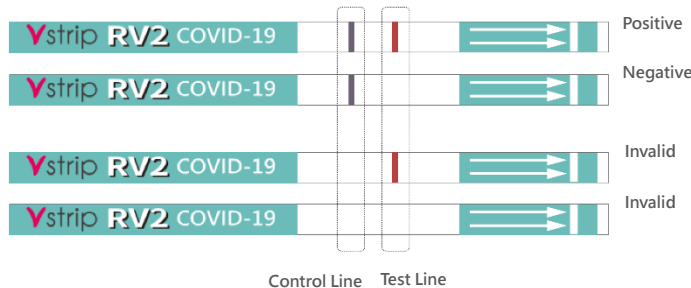
Leave the tube still for 10 minutes. Read the result at 10 minutes and do not read the result after 20 minutes.

4



Take the picture of test result.

INTERPRETATION OF RESULT



For update information, visit Vstrip official website <https://www.vstriptech.com/>

