

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.



VARIANT DETECTION

Proven detection for variants of concern currently circulating the globe.

FEATURES

DETECTION TIME
10 min

VISUAL DETECTION
NO MACHINE NEEDED

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

15-30°C
STORAGE

WHO Label	PANGOLIN Lineages	Isolate	Type	Homology	Virus Detection Titer	Evaluation Result	
Alpha	B.1.1.7	Taiwan/NTU49	Live Virus	99.4%	3.16x10 ⁹ TCID ₅₀ /mL	Detectable	
		USA/CA_CDC_5574/2020	Inactivated Virus		2.80x10 ¹ TCID ₅₀ /mL	Detectable	
		England/204820464/2020	Inactivated Virus		8.80x10 ¹ TCID ₅₀ /mL	Detectable	
VOC Beta	B.1.351	South_Africa/KRISP-005325/2020	Inactivated Virus	100%	1.60x10 ³ TCID ₅₀ /mL	Detectable	
		Hong Kong/VM20001061/2020	Inactivated Virus		1.60x10 ³ TCID ₅₀ /mL	Detectable	
		Italy-INMI1	Inactivated Virus		3.39x10 ³ TCID ₅₀ /mL	Detectable	
		Japan/TY7-503/2021	Inactivated Virus		2.80x10 ³ TCID ₅₀ /mL	Detectable	
Delta	B.1.617.2	USA/PHC658/2021	Inactivated Virus	99.4%	1.51x10 ³ TCID ₅₀ /mL	Detectable	
		Taiwan NTU Strain	Live Virus	97.8%	3.13x10 ⁴ TCID ₅₀ /mL	Detectable	
VOI Lambda	C.37	-	N/A	99.4%	N/A	Detectable	
N/A	B.1.2	Taiwan/NTU55	Live Virus	99.4%	3.16x10 ² TCID ₅₀ /mL	Detectable	
Epsilon	B.1.427	-	N/A	100%	N/A	Detectable	
Lota	B.1.526	-	N/A	100%	N/A	Detectable	
Others	B.1.617.1	USA/CA-Stanford-15_S02/2021	Inactivated Virus	100%	3.39x10 ³ TCID ₅₀ /mL	Detectable	
		B.1.1.7	-	N/A	99.4%	N/A	Detectable
		+E484K	-	N/A	99.4%	N/A	Detectable
Delta Plus	B.1.617.2 (AY lineages)	-	N/A	99.4%	N/A	Detectable	

PACK / REF NO.

- 1 Test /Box IG13001S01
- 2 Tests/Box IG13002S01
- 4 Tests/Box IG13004S01
- 20 Tests/Box IG13020S02



TECH SUPPORT

+886-2-2691-9896
xizhi@pbf.com.tw

VOC = Variants of Concern ; VOI = Variants of Interest

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).

		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

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.

VIRUS INACTIVATION

60 SECS

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

No cross-reactivity

12 Bacteria and 20 viruses tested

No interference

30 interference substances tested

PROCEDURE

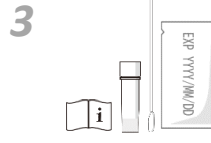
BEFORE USE



Wash or sanitize your hands. Make sure hands are dry before starting.



Check the expiration date. Do not use the kit contents beyond the expiration date.



Confirm the components of kit are complete.

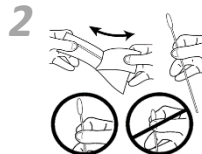


Prepare a timer.

SPECIMEN COLLECTION



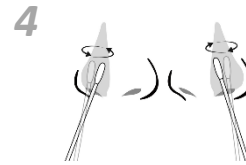
Blow your nose before collecting the specimen. When blowing, use tissue to cover to avoid spreading of the nasal secretion. Do not clean out nose with tissue to avoid the amount of virus being too low to be collected.



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

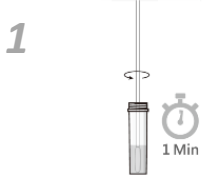


Insert the swab about 2 cm deep into one nostril. Rub the swab around the inside wall of nostril at least 4 times for a total of 15 seconds.



Repeat the above step in the other nostril with the same swab.

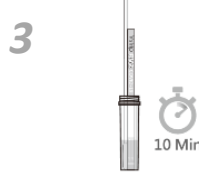
ASSAY PROCEDURE



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.



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.

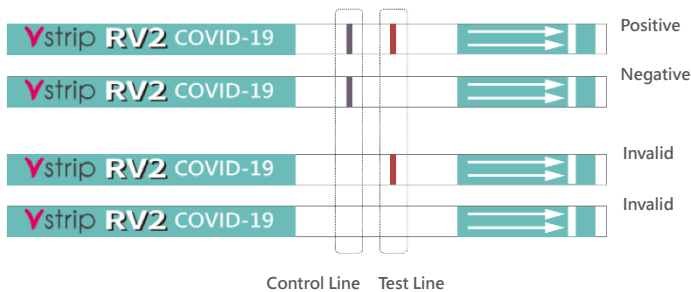


Leave the tube still for 10 minutes. Read the result at 10 minutes and do not read the result after 20 minutes.



Take the picture of test result.

INTERPRETATION OF RESULT



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

