

## COVID-19 Antigen Rapid Test



DETECTION  
TIME  
**10 min**

VISUAL DETECTION  
**NO MACHINE NEEDED**

USA-WA1/2020  
 **$3.13 \times 10^2$  TCID<sub>50</sub>/ml**  
LIMIT OF DETECTION

**15-30°C**  
STORAGE



### INTENDED USE

In vitro immunochromatographic assay for rapid detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal secretions from individuals suspected of COVID-19 within the first 5 days of the onset of symptoms.

### NO CROSS REACTIVITY

No cross-reactivity or interference was seen when tested at the 15 viruses and 12 bacteria.

### NO INTERFERENCE

29 nasal spray products and common chemicals were evaluated and no interference.

### NO HOOK EFFECT

SARS-CoV-2 strain ( $2.8 \times 10^5$  TCID<sub>50</sub>/ml)

### VARIANT DETECTION

Proven and predictive detection for SARS-CoV-2 variants



	WHO Label	PANGOLIN Lineage	Method	Detection Conc.	Detection
1	Alpha	B.1.1.7	Wet Test	$3.16 \times 10^1$	+
2	-	B.1.2	Wet Test	$3.16 \times 10^1$	+
3	Beta	B.1.351	In Silico	NA	+
4	Gamma	P.1	In Silico	NA	+
5	Delta	B.1.617.2	In Silico	NA	+

TCID<sub>50</sub>/ml

### VIRUS INACTIVATION

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



### CLINICAL SPECIMEN COMPARISON

Validated clinical performance of anterior nasal cavity and posterior nasopharynx specimen provides flexibility for specimen collection.

		Comparator Nasopharyngeal Swab		
		+	-	Total
Nasal Swab	+	8	0	8
	-	1	28	29
	Total	9	28	37
Performance		88.9% (8/9) Sensitivity (PPA)	100% (28/28) Specificity (NPA)	97.3% (36/37) Accuracy



### CLINICAL PERFORMANCE

The performance of the Vstrip COVID-19 Antigen Rapid Test for detection of SARS-CoV-2 was established with 162 nasopharyngeal specimens from 148 patients who were suspected of COVID-19 using a US FDA Emergency Use Authorized comparator molecular (RT-PCR) test. As with all antigen tests, performance may decrease as days since symptom onset increases.

		Reference RT-PCR Positive Subjects			
		CT<25	CT<34	<=5 Days	6-10 Days
Vstrip	+	21	29	20	9
	-	1	3	1	2
	Total	22	32	21	11
PPA		95.5% (21/22)	90.6% (29/32)	95.2% (20/21)	81.8% (9/11)

PPA comparison of CT values and symptom onset days

A sensitivity of 95.2% for individuals suspected of COVID-19 within the first 5 days of the onset of symptom.

		Comparator RT-PCR (by Subject)			Comparator RT-PCR (by Specimen)		
		+	-	Total	+	-	Total
Vstrip	+	29	1	30	43	1	44
	-	3	115	118	3	115	118
	Total	32	116	148	46	116	162
Performance		90.6% (29/32) Sensitivity (PPA)	99.1% (115/116) Specificity (NPA)	97.3% (144/148) Accuracy	93.5% (43/46) Sensitivity (PPA)	99.1% (115/116) Specificity (NPA)	97.5% (158/162) Accuracy

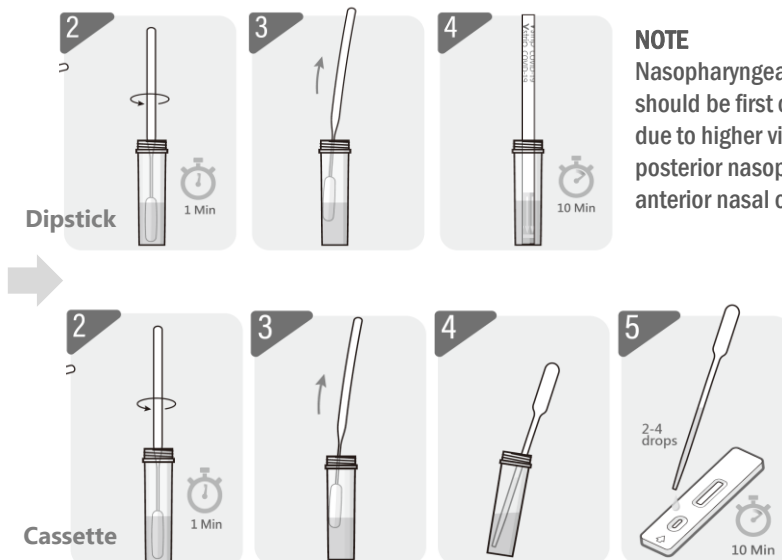
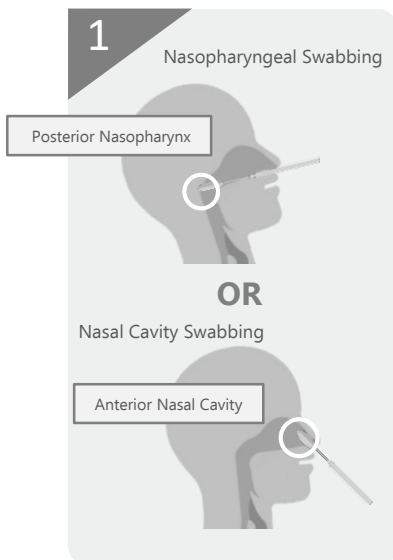
Anterior nasal cavity swabbing provides an easier solution for self or home testing, which reduces loading of the first line medical personnel and cross infection when going out for testing.

## SPECIMEN COLLECTION

## ASSAY PROCEDURE

### NOTE

Nasopharyngeal swabbing should be first considered due to higher virus titer in posterior nasopharynx than anterior nasal cavity.



## INTERPRETATION OF RESULT

### Positive Result

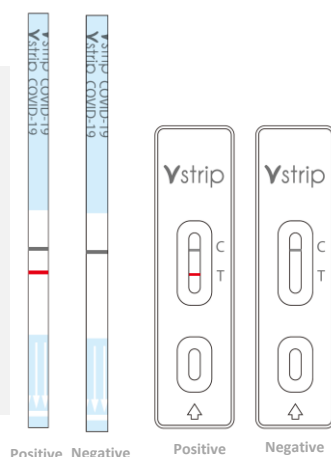
Appearance of RED Test Line below the PURPLE BLACK Control Line indicates a positive result for the presence of SARS-CoV-2 viral antigen.

### Negative Result

Appearance of ONLY the PURPLE BLACK Control Line indicates SARS-CoV-2 viral antigen were not detected.

### Invalid Result

The purple black procedural Control Line does not appear, even if a Red Test Line appears, the result is considered invalid.



For training video and latest information, please visit Vstrip.  
<https://www.vstriptechnology.com/>



## SHIPPING INFORMATION

FORMAT	CAT. NO.	PACK	Box /CTN	G.W./CTN	Carton Size
DIPSTICK	IG10020S01	20 TEST/BOX	35	7.4kg (700 TEST)	L54.5*W35*H34cm
	IG10050S01	50 TEST/BOX	18	7.9kg (900 TEST)	L30*W49*H36cm
	IG10080S01	80 TEST/BOX (no swab)	18	9.4kg (1440 TEST)	L30*W49*H36cm
	IG10020S02	20 TEST/BOX	36	7.9kg (720 TEST)	L30*W49*H36cm
	IG10050S02	50 TEST/BOX	18	7.9kg (900 TEST)	L30*W49*H36cm
CASSETTE	IG10025C02	25 TEST/BOX	18	7.0kg (450 TEST)	L30*W49*H36cm

## AVAILABLE TERRITORIES

TERRITORY	CAT. NO.	PACK
TAIWAN	IG10020S	20 TEST/BOX (DIPSTICK)
INDIA	IG10020S01	20 TEST/BOX (DIPSTICK)
SINGAPORE	IG10050S01	50 TEST/BOX (DIPSTICK)
PHILIPPINES	IG10080S01	80 TEST/BOX (DIPSTICK)
THAILAND		
EUROPEAN UNION	IG10020S02	20 TEST/BOX (DIPSTICK)
	IG10050S02	50 TEST/BOX (DIPSTICK)
	IG10025C02	25 TEST/BOX (CASSETTE)



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### TECHNICAL SUPPORT

For questions, or to report a problem, please call +886-2-2691-9895.  
If outside Taiwan contact your local distributor or [xizhi@pbf.com.tw](mailto:xizhi@pbf.com.tw).



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