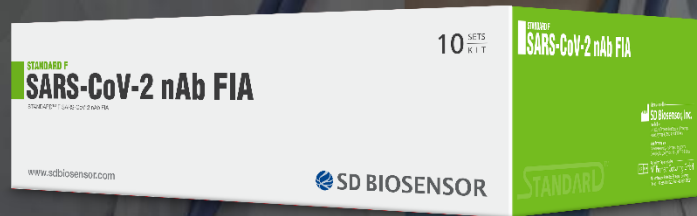




STANDARD F SARS-CoV-2 nAb FIA Test procedure

STANDARD F
SD BIOSENSOR



STANDARD F SARS-CoV-2 nAb

Test procedure

STANDARD F SARS-CoV-2 nAb FIA

STANDARD F SARS-CoV-2 nAb FIA

- Simple testing procedure
- High correlation with other VNT methods
- Available for detecting nAbs produced by different variants group.
(Wuhan/U.K, South Africa/Brazil)

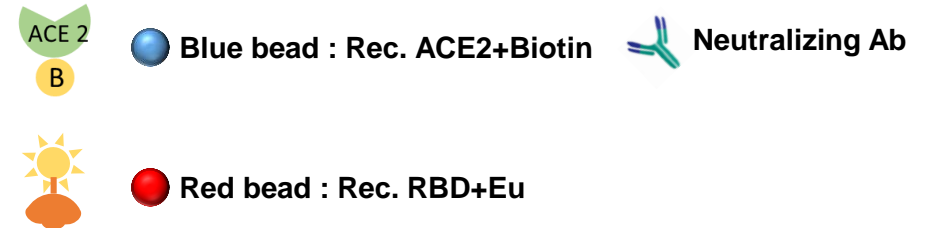


Specimen type	Serum, Plasma (EDTA)
Cut-Off	PI 20% ★ Inhibition rate = $\left(1 - \frac{\text{T peak of Test Sample}}{\text{Designated T peak of Negative sample}}\right) \times 100$
Sensitivity	100% (36/36)
Specificity	<ul style="list-style-type: none"> • Serum : 99.0% (1,089/1,100) • Plasma : 98.8% (494/500)
Specimen volume	100ul of each Variant Group test
Testing time	35 mins (20 mins for incubation/ 15 mins for reading)
Storage condition	Room temperature
Sets/Kit	10 SETS/KIT
Ordering information (CAT#)	10COV80B

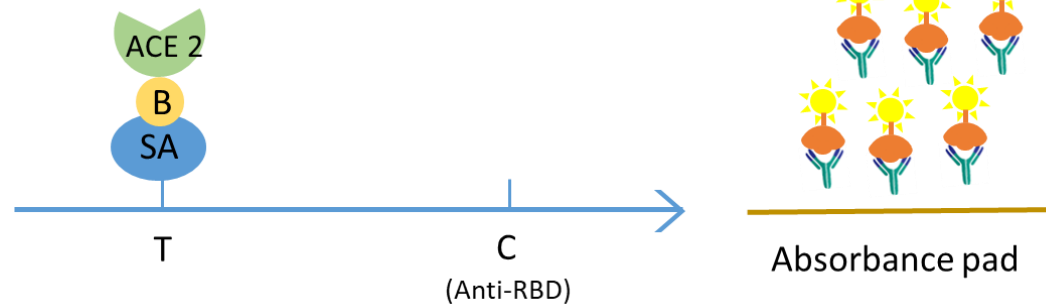
Test principle

Principle of SARS-CoV-2 nAb FIA

- ✓ Surrogate virus neutralization test (sVNT)
 - Recombinant SARS-CoV-2 RBD & recombinant human ACE2



1. Neutralizing Ab Positive

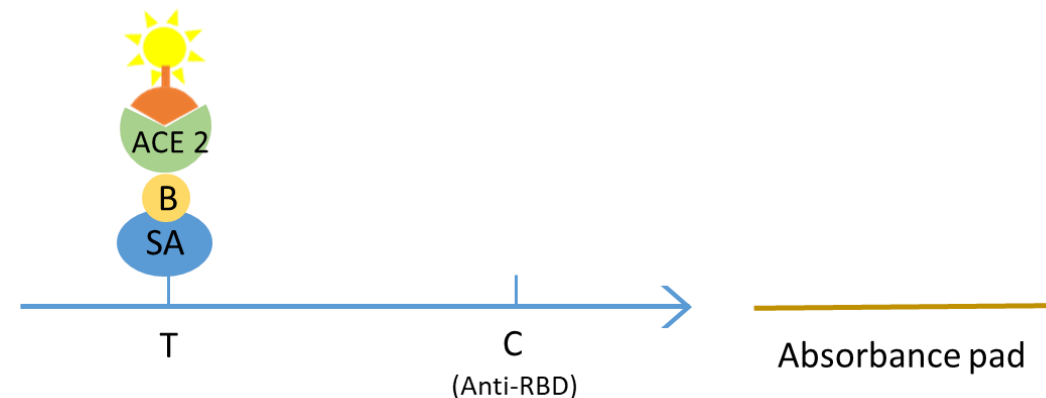


Inhibition of fluorescence intensity increases



: $\geq 20\%$ inhibition = **Positive**

2. Neutralizing Ab Negative



Inhibition of fluorescence intensity decreases



: $< 20\%$ Inhibition = **Negative**

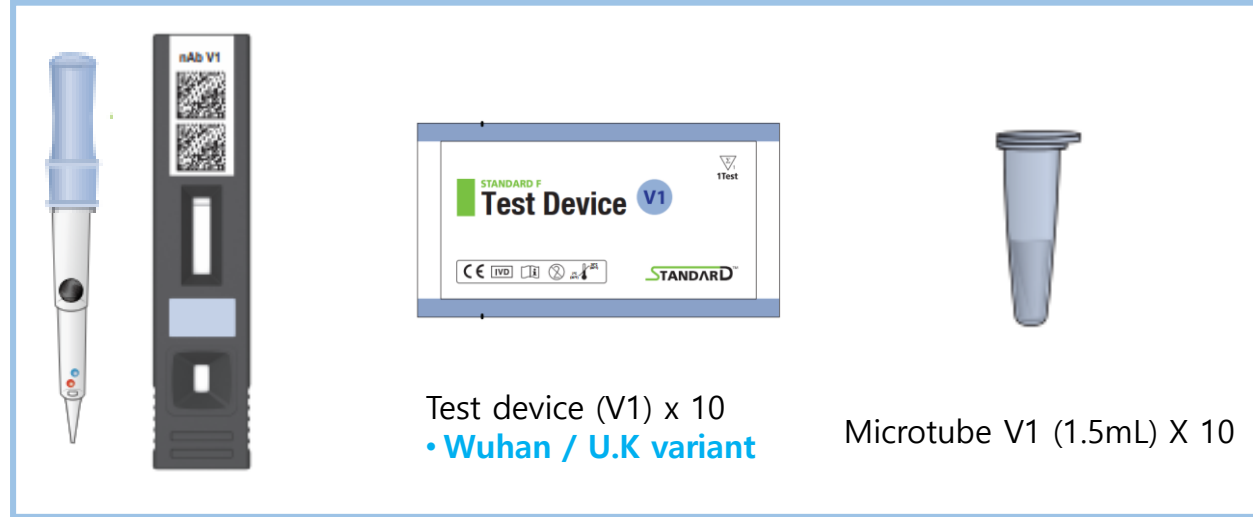
STANDARD d-BLOCK Incubator

STANDARD d-Block Incubator

Dimension	220*184*73 mm
Initial time	15 minutes
Temperature range	35~40°C (95°F ~104°F)
Environment condition	10~30°C (50°F ~86°F)
Cat. No.	12INC10



Kit contents



This section shows the components for the Wuhan / U.K. variant test. It includes a blue pipette, a black test device labeled 'nAb V1', a 'STANDARD F Test Device V1' box, and a blue microtube.

Test device (V1) x 10
• **Wuhan / U.K variant**

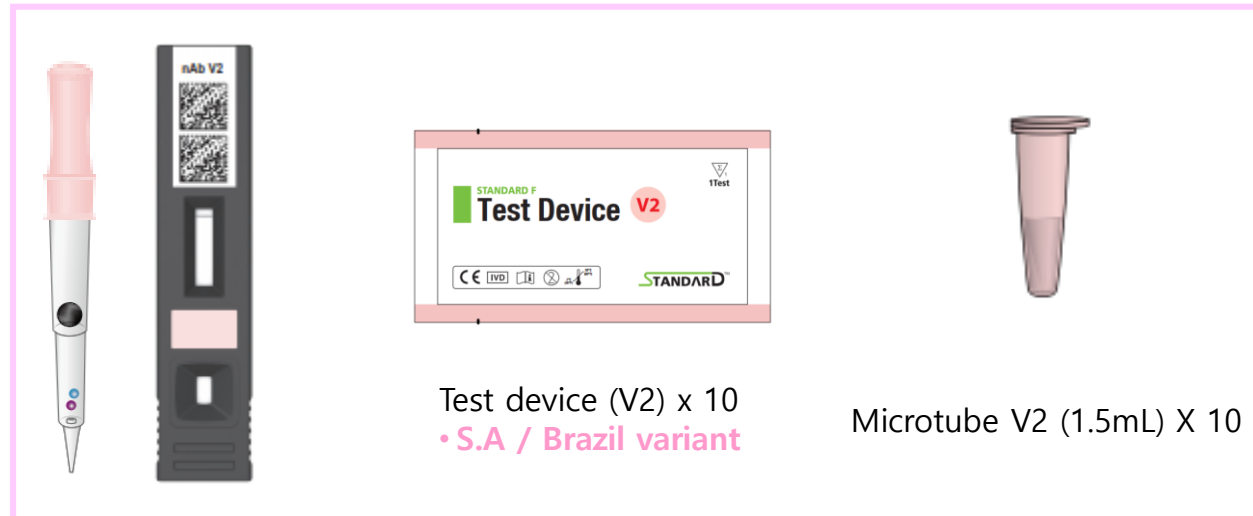
Microtube V1 (1.5mL) X 10



This section shows the positive control and buffer. It includes a 'STANDARD F SARS-CoV-2 nAb Positive Control' card, a red pipette, and a 'Buffer bottle'.

Positive control x 2

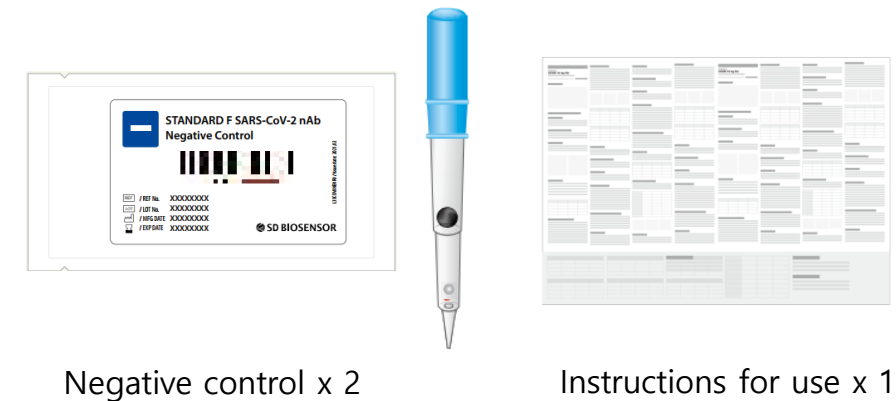
Buffer (6ml) x 1



This section shows the components for the S.A / Brazil variant test. It includes a pink pipette, a black test device labeled 'nAb V2', a 'STANDARD F Test Device V2' box, and a pink microtube.

Test device (V2) x 10
• **S.A / Brazil variant**

Microtube V2 (1.5mL) X 10

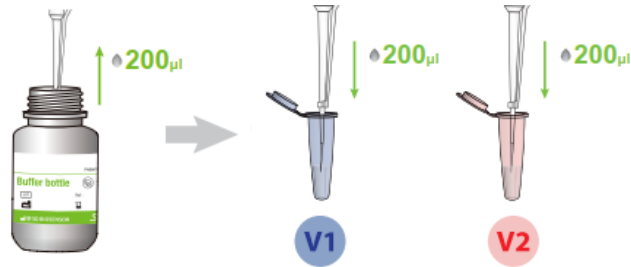


This section shows the negative control and instructions. It includes a 'STANDARD F SARS-CoV-2 nAb Negative Control' card, a blue pipette, and a document titled 'Instructions for use'.

Negative control x 2

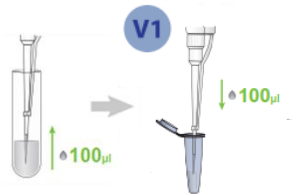
Instructions for use x 1

1. Buffer dispensing



Collect 200ul of buffer from the buffer bottle, and transfer it into each V1,V2 microtube.

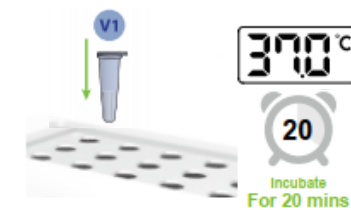
2. V1 mixture preparation (Complete the preparation of V1 mixture at once)



Add 100ul of specimen into microtube.



Dissolve two tablets in the V1 Spot.

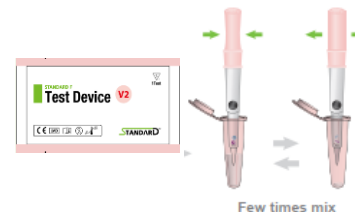


Incubate V1 mixture for 20 minutes.

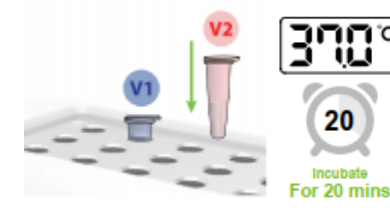
3. V2 mixture preparation (Complete the preparation of V2 mixture at once)



Add 100ul of specimen into microtube.



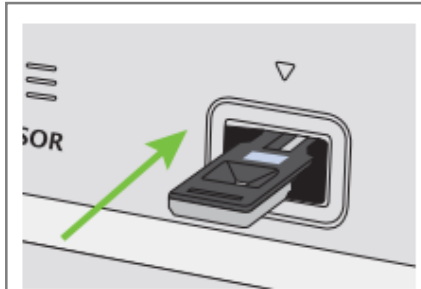
Dissolve two tablets in the V2 Spot.



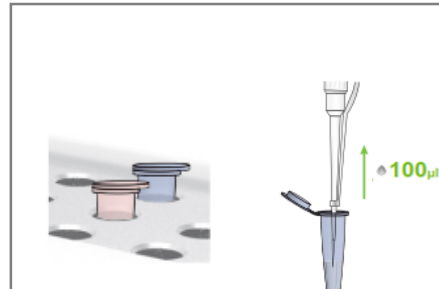
Incubate V2 mixture for 20 minutes.

Test procedure

< **Standard mode** > Repeat for V2 mixture



Insert the test device to the test slot of the analyzer



Prepare 100ul of the incubated specimen mixture



Apply 100ul of the specimen mixture into the specimen well

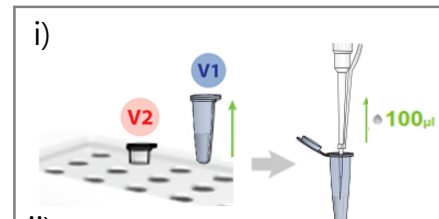


Result After 15 mins
The analyzer will automatically display the test result after 15 minutes

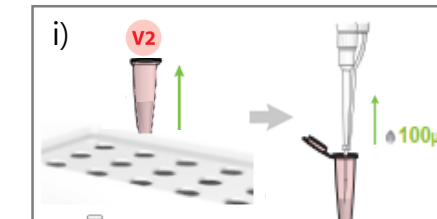
< **Read only mode** >



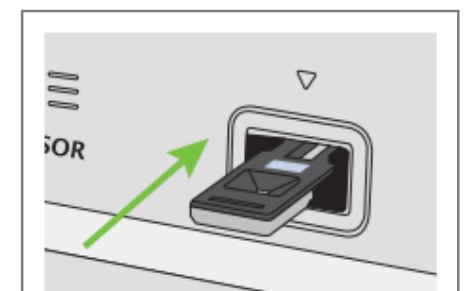
Take the test device out and write specimen information on the label



Apply 100ul of the specimen mixture to the specimen well and incubate for 15 minutes



Apply 100ul of the specimen mixture to the specimen well and incubate for 15 minutes



Insert the test device and the analyzer will immediately display the test result

Evaluation Result in South Korea

- 10 recovered patients showed positive results for STANDARD F SARS-CoV-2 nAb FIA test

	Sample collected at hospitalization						Sample at release						Days from symptom onset to sample collection
	M		G		Neutralizing Ab		M		G		Neutralizing Ab		
	COI	Result	COI	Result	PI	Result	COI	Result	COI	Result	PI	Result	
1	2.26	Positive	0.03	Negative	40.2	Positive	1.17	Positive	4.23	Positive	24.7	Positive	33
2	0.04	Negative	0.01	Negative			2.07	Positive	4.42	Positive	44	Positive	28
3	0.13	Negative	0.05	Negative			0.34	Negative	7.21	Positive	41.3	Positive	27
4	0.04	Negative	0.01	Negative			3.48	Positive	7.31	Positive	83.5	Positive	20
5	1.61	Positive	0.01	Negative	28.3	Positive	5.12	Positive	7.29	Positive	97.7	Positive	17
6	0.21	Negative	0.01	Negative			4.22	Positive	7.3	Positive	96.4	Positive	15
7	0.46	Negative	0.01	Negative			3.6	Positive	7.32	Positive	98	Positive	14
8	0.35	Negative	0.02	Negative			1.82	Positive	7.41	Positive	98.2	Positive	13
9	0.02	Negative	0.02	Negative			4.44	Positive	7.32	Positive	90.8	Positive	13
10	1.95	Positive	0.96	Negative	40.6	Positive	1.94	Positive	7.32	Positive	96.9	Positive	12

- Test results of two vaccinated people

조건		V1 Group 우한 RBD		V2 Group 남아공 RBD	
검체종류	검체 번호	PI value	Result (cut-off : PI 20)	PI value	Result (cut-off : PI 20)
3/5 Az 접 종	전*	75.6	Pos.	-5.0	-
	이*	46.4	Pos.	-16.3	-

Although the vaccine was given, it was found that the immunity to the mutation of the South Africa virus (RBD for Group 2) was negative

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