
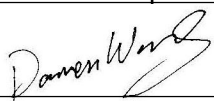


Variant SARS-CoV-2 Report of COVID-19 Antigen Rapid Test (Oral Fluid)

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1. Background

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus in 2019 causes coronavirus disease COVID-19.^[1] The new coronavirus is called 2019-nCoV or SARS-CoV-2. Due to the rapid spread of SARS-CoV-2, COVID-19 is now a pandemic affecting many countries globally. As of May 24th, there were 5.2 million confirmed cases worldwide and 337 000 reported deaths^[2]. The clinical presentation of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.^[3]

2. Objective

The subject of this consultancy will be the evaluation of the analytical performance of the AllTEST COVID-19 Antigen rapid test (Oral fluid). The evaluation will be performed on spiked saliva samples obtained from healthy subjects: each specimens will be spiked with different concentrations of SARS CoV-2 variant recombinant N proteins obtained from variant recombinant N proteins. The following virus lineages will be included: UK variant(B.1.1.7), South African Variant (B.1.351), Brazilian variant (P1/B.1.1.28), Indian variant(B.1.617.2 and B.1.617.3), South African Variant (B.1.1.529).

3. Material and methods

3.1 Materials

- COVID-19 Antigen Rapid Test (Oral Fluid)

SARS CoV-2 variant:

WHO Label	Pango Lineages	Lot No.
Alpha	B.1.1.7	21011801
Beta	B.1.351	21021001
VUI-21ARP-03	B.1.617.3	21070901
Gamma	B.1.1.28	21021001
Delta	B.1.617.2	21070901
Omicron	B.1.1.529	20211201-2

3.2 Method

Totally 30 saliva specimens were obtained from healthy donor (whose identity will be anonymised upon the collection of the sample) showing no symptoms of COVID-19. These 30 specimens will be pooled in order to achieve a large volume of sample.

6 series of saliva specimen were spiked with scalar log₁₀ dilution of variant recombinant N proteins. Each individual spiked specimen was tested in triplicate with the AllTEST COVID-19 Antigen Rapid Test (Oral Fluid).

One aliquot of sample not spiked with the variant recombinant N protein was tested as a negative

control in parallel with the spiked specimens.

3.3 Operation Method

Operation method can be referred to package insert provided in the kits.

3.4 Test Results

No.	Rapid Test Result			Variant
	1	2	3	
1	POSITIVE	POSITIVE	POSITIVE	UK B.1.1.7 not dil
2	POSITIVE	POSITIVE	POSITIVE	UK B.1.1.7-1
3	POSITIVE	POSITIVE	POSITIVE	UK B.1.1.7-2
4	POSITIVE	POSITIVE	POSITIVE	UK B.1.1.7-3
5	POSITIVE	POSITIVE	POSITIVE	UK B.1.1.7-4
6	POSITIVE	POSITIVE	POSITIVE	UK B.1.1.7-5
7	WEAK POSITIVE	WEAK POSITIVE	WEAK POSITIVE	UK B.1.1.7-6
8	NEGATIVE	NEGATIVE	NEGATIVE	UK B.1.1.7-7
9	POSITIVE	POSITIVE	POSITIVE	South African B.1.351 not dil
10	POSITIVE	POSITIVE	POSITIVE	South African B.1.351-1
11	POSITIVE	POSITIVE	POSITIVE	South African B.1.351-2
12	POSITIVE	POSITIVE	POSITIVE	South African B.1.351-3
13	POSITIVE	POSITIVE	POSITIVE	South African B.1.351-4
14	POSITIVE	POSITIVE	POSITIVE	South African B.1.351-5
15	POSITIVE	POSITIVE	POSITIVE	South African B.1.351-6
16	POSITIVE	POSITIVE	POSITIVE	South African B.1.351-7
17	POSITIVE	POSITIVE	POSITIVE	South African B.1.351-8
18	NEGATIVE	NEGATIVE	NEGATIVE	South African B.1.351-9
19	POSITIVE	POSITIVE	POSITIVE	Brazilian B.1.1.28 not dil
20	POSITIVE	POSITIVE	POSITIVE	Brazilian B.1.1.28-1
21	POSITIVE	POSITIVE	POSITIVE	Brazilian B.1.1.28-2
22	POSITIVE	POSITIVE	POSITIVE	Brazilian B.1.1.28-3
23	POSITIVE	POSITIVE	POSITIVE	Brazilian B.1.1.28-4
24	POSITIVE	POSITIVE	POSITIVE	Brazilian B.1.1.28-5
25	POSITIVE	POSITIVE	POSITIVE	Brazilian B.1.1.28-6
26	POSITIVE	POSITIVE	POSITIVE	Brazilian B.1.1.28-7
27	WEAK POSITIVE	WEAK POSITIVE	WEAK POSITIVE	Brazilian B.1.1.28-8
28	NEGATIVE	NEGATIVE	NEGATIVE	Brazilian B.1.1.28-9
29	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.2 not dil
30	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.2 -1
31	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.2 -2
32	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.2 -3
33	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.2 -4

34	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.2 -5
35	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.2 -6
36	WEAK POSITIVE	WEAK POSITIVE	WEAK POSITIVE	Indian B.1.617.2 -7
37	NEGATIVE	NEGATIVE	NEGATIVE	Indian B.1.617.2 -8
38	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.3 not dil
39	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.3 -1
40	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.3 -2
41	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.3 -3
42	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.3 -4
43	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.3 -5
44	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.3 -6
45	POSITIVE	POSITIVE	POSITIVE	Indian B.1.617.3 -7
46	NEGATIVE	NEGATIVE	NEGATIVE	Indian B.1.617.3 -8
47	NEGATIVE	NEGATIVE	NEGATIVE	Negative Control
48	POSITIVE	POSITIVE	POSITIVE	South African B.1.1.529 not dil
49	POSITIVE	POSITIVE	POSITIVE	South African B.1.1.529-1
50	POSITIVE	POSITIVE	POSITIVE	South African B.1.1.529-2
51	POSITIVE	POSITIVE	POSITIVE	South African B.1.1.529-3
52	POSITIVE	POSITIVE	POSITIVE	South African B.1.1.529-4
53	POSITIVE	POSITIVE	POSITIVE	South African B.1.1.529-5
54	POSITIVE	POSITIVE	POSITIVE	South African B.1.1.529-6
55	POSITIVE	POSITIVE	POSITIVE	South African B.1.1.529-7
56	NEGATIVE	NEGATIVE	NEGATIVE	South African B.1.1.529-8
57	NEGATIVE	NEGATIVE	NEGATIVE	Negative Control

3.5 Conclusion

According to the data above, Result above variant SARS-CoV-2 recombinant N proteins can be detected out with the COVID-19 Antigen Rapid Test (Oral Fluid). COVID-19 Antigen Rapid Test (Oral Fluid) can detected out recombinant SARS-CoV-2 variants including B.1.1.7, B.1.351, B.1.617.3, B.1.1.28, B.1.617.2, B.1.1.529 as low as following dilution rate.

WHO Label	Pango Lineages	LOD
Alpha	B.1.1.7	1:1X10 ⁶
Beta	B.1.351	1:1X10 ⁸
VUI-21ARP-03	B.1.617.3	1:1X10 ⁷
Gamma	B.1.1.28	1:1X10 ⁸
Delta	B.1.617.2	1:1X10 ⁷
Omicron	B.1.1.529	1:1X10 ⁷

4. References

1. Q&A on coronaviruses (COVID-19).
<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses>
2. WHO. Coronavirus disease 2019 (COVID-19) Situation Report.

https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200524-covid-19-sitrep-125.pdf?sfvrsn=80e7d7f0_2

3. World Health Organization (WHO). Coronavirus. <https://www.who.int/health-topics/coronavirus>