

Test Results for Variants of SARS-CoV-2

We, Asan Pharmaceutical Co., Ltd., are a manufacturer for the rapid diagnosis test kits for the products related to COVID-19 virus and would like to confirm the detection ability to SARS-CoV-2 mutation variants with Asan East Test COVID-19 Ag kit in this letter.

1. Purpose of the test

: In order to check the detection ability of Asan Easy Test COVID-19 Ag for SARS-CoV-2 variants, tests were internally conducted using inactivated SARS-CoV-2 culture medium and recombinant antigens for various variants.

2. Used reagents

- Asan Easy Test COVID-19 Ag
- Asan Easy Test Flu/COVID-19 Ag Combo.

3. Used specimens

- 1) Inactivated SARS-CoV-2 variants viral culture : From ZeptoMatrix

SARS-CoV-2 variant B.1.1.7 culture fluid (Heat Inactivated) Isolate : USA/CA_CDC_5574/2020	1.26x10 ⁶ TCID ₅₀ /ml
SARS-CoV-2 variant B.1.1.7 culture fluid (Heat Inactivated) Isolate : England/204820464/2020	4.57x10 ⁶ TCID ₅₀ /ml
SARS-CoV-2 variant B.1.357 culture fluid (Heat Inactivated) South_Africa/KRISP-K005325/2020	4.57x10 ⁶ TCID ₅₀ /ml

- 2) Recombinant SARS-CoV-2 Nucleocapsid protein of Variants

Category	N protein mutation sites	WHO label	Pango lineage	GISAID clade/lineage	First recorded
Variants of Concern (VOCs)	D3L+S235F+ RG203KR	Alpha	B.1.1.7	GRY(formerly)GR/501Y.V1	Britain
	T205I	Beta	B.1.351	GH/501Y.V2	South Africa
	D63G+D377Y+R203M	Delta	B.1.617.2	G/452R.V3	India
Variants of Interest (VOIs)	A119S+M234I+RG203KR	Zeta	P.2	GR	Brazil
	A12G+T205I	Eta	B.1.525	G/484K.V3	multinational
	RG203KR	Theta	P.3	GR	Philippines
	M234I+P199L	Iota	B.1.526	GH	America
	R203M+D377Y	Kappa	B.1.617.1	G/452R.V3	India
	G204R+G214C+P13L+R203K	Lambda	C.37	GR/452Q.V1	Peru

3) Negative

- ATM(Asan Transport Medium)

4. Test Method

: To test the reactivity to SARS-CoV-2 variants of Asan Easy Test COVID-19 Ag, the lowest detectable concentration was confirmed using an inactivated SARS-CoV-2 virus culture medium. In addition, the lowest concentration that can be detected using the recombinant antigen for various

mutation strains was confirmed.

Each antigen was diluted to a detectable concentration with ATM (Asan Transport Medium), and the diluted antigen was applied to the swab, and then tested according to the “use and capacity” (use method) of the reagent.

5. Test results

1) Inactivated Viral culture

First Recorded	Pango lineage	Isolate	Concentration of LoD (TCID ₅₀ /ml)
Britian	B.1.1.7	USA	4.92 x 10 ²
Britian	B.1.1.7	England	8.93 x 10 ²
South Africa	B.1.357	-	4.46 x 10 ²

2) Recombinant SARS-CoV-2 Nucleocapsid protein of Variants

First Record	Pango lineage	WHO Label	N protein mutation sites	Concentration of LoD(ng/ml)
Britain	B.1.1.7	Alpha	D3L+S235F+ RG203KR	0.313
South Africa	B.1.351	Beta	T205I	0.313
India	B.1.617.2	Delta	D63G+D377Y+R203M	0.313
Brazil	P.2	Zeta	A119S+M234I+RG203KR	0.313
multinational	B.1.525	Eta	A12G+T205I	0.313
Philippines	P.3	Theta	RG203KR	0.313
America	B.1.526	Iota	M234I+P199L	0.313
India	B.1.617.1	Kappa	R203M+D377Y	0.313
Peru	C.37	Lambda	G204R+G214C+P13L+R203K	0.313

6. Conclusion

: Based on the above test results, it is confirmed that there is no problem on detection to SARS-CoV-2 variants which are currently found with Asan Easy Test COVID-19 Ag.

Sincerely,



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President

Asan Pharmaceutical Co., Ltd.