

Notification Letter

To Whom it may concern,

Thank you for your interest in the BIOCREDIT COVID-19 Ag.

We, Rapigen, Inc., would like to inform you that BIOCREDIT products for SARS-CoV-2 kits are not affected by “Alpha (B.1.1.7), Beta (B.1.351), Epsilon (B.1.429), Eta (B.1.525), Kappa (B.1.617.1), Lambda (C.37), Zeta (P.2), Gamma (P.1), Delta (B.1.617.2), Delta plus (AY.1), Mu (B.1.621), Omicron (B.1.1.529) SARS-CoV-2 variants”.

The list of applicable BIOCREDIT products is as follows.

Product Name	Catalog No.
BIOCREDIT COVID-19 Ag	G61RHA20
	G61RHA20C
BIOCREDIT COVID-19 Ag Test Nasal	G69RHA20
	G69RHA20C
BIOCREDIT COVID-19 Ag Home Test Nasal	G69RHSD1
	G69RHSB1, G69RHSB2
	G69RHSD5
BIOCREDIT COVID-19 CoviFlu Ag Duo	G68RHA20
BIOCREDIT COVID-19 Ag Test Saliva	G63RHA20

Detailed information confirmed through internal test analysis is below.

1. Analytical sensitivity

As a result of evaluating the sensitivity to virus and recombinant for 12 different lineages, the sensitivity was similar to that of NCCP 43326/2020/korea virus and Wuhan-Hu-1 recombinant N protein. Therefore, it was confirmed that the sensitivity of the BIOCREDIT product was not affected by the 14 different lineages.

No.	lineage	Antigen type	Source*	Recombinant protein mutation site	WHO Label
1	B.1.1.7	Inactivated virus	NCCP 43381	-	Alpha
2	B.1.351	Inactivated virus	NCCP 43382	-	Beta
3	P.1	Cell culture-derived virus	NCCP 43388	-	Gamma
		Recombinant protein	Fapon (FPZ0655)	P80R+RG203KR	
4	B.1.617.2	Cell culture-derived virus	NCCP 43390	-	Delta
		Recombinant protein	Fapon (FPZ0694)	D63G+D377Y+R203M	
5	B.1.429	Recombinant protein	Fapon (FPZ0691)	T205I	Epsilon
6	P.2	Cell culture-derived virus	NCCP 43383	-	Zeta
7	B.1.525	Recombinant protein	Fapon (FPZ0695)	A12G+T205I	Eta
8	B.1.617.1	Recombinant protein	Fapon (FPZ0689)	R203M+D377Y	Kappa

9	B.1.617	Recombinant protein	Fapon (FPZ0693)	R203K+D377Y	N/A
10	B.1.617.3	Recombinant protein	Fapon (FPZ0690)	P67S+D377Y+R203M	N/A
11	B.1.618	Recombinant protein	Fapon (FPZ0688)	G18S+A119S+A217S+M234I+E367Q	N/A
12	C.37	Recombinant protein	Fapon (FPZ0740)	P13L+R203K+G204R+G214C	Lambda
13	B.1.1.529	Recombinant protein	Fapon (FPZ0814)	P13L, Δ 31-33, R203K, G204R	Omicron
14	B.1.640	Recombinant protein	Fapon (FPZ0815)	D22Y+E378Q+T205I	N/A

* The National culture collection for pathogens (NCCP): the national pathogen resources bank in Korea.; Fapon: Fapon Biotech Inc.

2. In-silico analysis

Through sequencing of the mutation site, it was confirmed that the region intersected with the target region of our product. Mutation sites of Gamma, Delta, and Zeta were included in the epitope region, but it was confirmed that they did not have an effect when checked through Analytical sensitivity.

No.	Lineage	N protein Mutation site	Mutations within the epitope	WHO Label
1	B.1.1.7, B.1.1.7+E484K, B.1.1.7+L452R, B.1.1.7+S494P, Q.1, Q.2, Q.3, Q.4,	D3L, R203K, G204R, S235F		Alpha
2	B.1.351, B.1.351+E516Q, B.1.351+L18F, B.1.351+P384L, B.1.351.2, B.1.351.3	T205I		Beta
3	P.1, P.1+P681H, P.1.2	P80R, R203K, G204R	○	Gamma
4	P.1.1	P80R	○	
5	B.1.617.2, B.1.617.2+E484Q, B.1.617.2+K417N, B.1.617.2+Q613H	D63G, R203M, D377Y	○	Delta
6	AY.1, AY.2, AY.3, AY.4, AY.6, AY.7, AY.9, AY.12	D63G, R203M, G215C, D377Y	○	
7	AY.5,	D63G, R203M, G215C, S327L, D377Y	○	
8	AY.8, AY.10, Ay.11,	D63G, R203M, D377Y	○	
9	B.1.525	S2Y, Δ 3, A12G, T205I		Eta
10	B.1.526	P199L, M234I		Iota
11	B.1.617.1	R203M, D377Y		Kappa
12	C.37	P13L, R203K, G204R, G214C		Lambda
13	B.1.621	N205I		Mu
14	P.2	A119S, R203K, G204R, M234I	○	Zeta
15	P.3	R203K, G204R		Theta
16	B.1.1.529	P13L, Δ 31-33, R203K, G204R		Omicron
17	A.23.1+E484K	S202N		Other variants of interest
18	A.27	S202N		
19	A.28	A35V, S202N		
20	AT.1	R203K, G204R		
21	B.1.1.318	R203K, G204R, A208G, Δ 209		
22	B.1.1.519	R203K, G204R		
23	B.1.1.523	R203K, G204R, G212C		
24	B.1.214.2	D3L, T205I		

25	B.1.427	T205I	
26	B.1.429	T205I	
27	B.1.466.2	T205I	
28	B.1.616	T325I	
29	B.1.617.3	P67S, R203M, D377Y	
30	B.1.619	P13L, S201I, T205I	
31	B.1.620	N/A	
32	C.1.2	P13L, R203K, G204R	
33	C.16	R203K, G204R	
34	C.36+L452R	R203K, G204R, G212V	
35	C.36.3	R203K, G204R, G212V	
36	R.1	S187L, R203K, G204R, Q418H	

3. Conclusion

As a result of analytical sensitivity and In-silico analysis, it is verified that BIOCREDIT products for SARS-CoV-2 kits are not affected by “Alpha (B.1.1.7), Beta (B.1.351), Epsilon (B.1.429), Eta (B.1.525), Kappa (B.1.617.1), Lambda (C.37), Zeta (P.2), Gamma (P.1), Delta (B.1.617.2), Delta plus (AY.1), Mu (B.1.621), Omicron (B.1.1.529) SARS-CoV-2 variants”.

Rapigen will test various variants and inform you of the results.

Thank you
Sincerely yours,

RapiGEN INCORPORATION



Jae-Ku Park President

Dr. Jae-Ku Park
CEO/President of RapiGEN INC.
December 16th, 2021 (Ver. 01)