Statement on the monitoring of SARS-CoV-2 variants

Recently, the SARS-CoV-2 has been discovered the newest SARS-CoV-2 Omicron strain subvariants **FLiRT**.

Sejoy SARS-CoV-2 Antigen Rapid Test Cassette (Ref.: **COVG-602**、**COVG-602ST**), SARS-CoV-2 Antigen Saliva Lolly Test (Ref.: **COVG-603**) and SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette (Ref.: **COIF-522**) are designated to detect the nucleocapsid protein (NP) of SARS-CoV-2 virus. Epitope of capture antibody and detection antibody used are not in the mutation area. Thus, abovementioned SARS-CoV-2 variants with spike protein mutation and nucleocapsid protein mutation of table do not affect the detection performance of Sejoy Test.

The Sejoy urgently established a special verification team to monitor and analyze the genetic data of the newly discovered SARS-CoV-2 variant. By the Peptide probe sequence comparison results of the marketed products and by verifying the inactivated virus culture of these mutant strains (The virus culture solution was inactivated with β- propiolactone. β-Propiolactone can bind to the genetic material of pathogenic microorganisms and inactivate them without affecting the properties of the protein. Therefore, the virus culture medium after inactivation by this method will not have any impact on the performance evaluation of SARS-CoV-2 Antigen Rapid Test Cassette, SARS-CoV-2 Antigen Saliva Lolly Test and SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette), the results confirmed that SARS-CoV-2 Antigen Rapid Test Cassette (Ref.:**COVG-602**、**COVG-602ST**), SARS-CoV-2 Antigen Saliva Lolly Test (Ref.:**COVG-603**) and SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette (Ref.:**COIF-522**) that has been marketed by Sejoy Biomedical Co.,Ltd. has no missed detection against the above-mentioned variant and still ensure the accuracy and sensitivity of the detection reagents.

Clinical performance of SARS-CoV-2 Antigen Rapid Test Cassette, SARS-CoV-2 Antigen Saliva Lolly Test and SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette has been determined by testing specimens of SARS-CoV-2 antigen, after verification of the latest Omicron strain subvariant and SARS-CoV-2 variant, the sensitivity is not affected.

Up to now, our company has monitored and analyzed the genetic data of major epidemic SARS-CoV-2 variants, including：

NO.	WHO Label	Pango Lineage	Time
1	Alpha	B.1.1.7	Dec-2020
2	Beta	B.1.351	Dec-2020
3	Delta	B.1.617.2	May-2021
4	Eta	B.1.525	Mar-2021
5	Gamma	P.1	Jan-2021
6	Kappa	B.1.617.1	Jun-2021
7	Lambda	C.37	Aug-2021
8	Lota	B.1.526	Feb-2021
9	Theta	P.3	Mar-2021
10	Zeta	P.2	Mar-2021
11	Omicron	B.1.1.529	Nov-2021
12		B.1.640	Nov-2021
13		BA.1	Nov-2021
14		XE	Jan-2022
15		BA.2	Feb-2022
16		BA.2.12.1	Feb-2022
17		BA.3	Feb-2022
18		BA.4	Jan-2022
19		BA.5	Jan-2022
20		BF.7	Mar-2022
21		BA.2.75	May-2022
22		BQ.1.1	Aug-2022
23		XBB	Sep-2022
24		BQ.1	Sep-2022
25		EG.5	Feb-2023
26		EU.1.1	Apr-2023
27		BA.2.86	Aug-2023
28		FL.1.5.1	Aug-2023
29		JN.1	Dec-2023
30		KP.2	May-2024
31		LB.1	Jul-2024
32		FLiRT	Jul-2024

Our company will continue to pay attention to the variant of the SARS-CoV-2 to ensure that our company's SARS-CoV-2 Antigen Rapid Test Cassette (Ref.:**COVG-602** 、 **COVG-602ST**), SARS-CoV-2 Antigen Saliva Lolly Test (Ref.:**COVG-603**) and SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette (Ref.:**COIF-522**) will not miss detection and ensure the sensitivity, accuracy and specificity are not affected.

Sejoy Biomedical Co., Ltd.

浙江世佳生物医疗有限公司
SEJOY BIOMEDICAL CO.,LTD.

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