Letter of Notification

Date: April 18, 2022

To Whom It May Concern,

This letter is to inform you regarding the performance study on the effect of the SARS-CoV-2 variants on the performance of the CareStart™ COVID-19 Antigen Home Test (FDA EUA 210314) and authorized distributor brand name on/go™ COVID-19 Antigen Self-Test. This study was intended to evaluate the impact of the SARS-CoV-2 variants on the performance of the test.

The performance evaluation methods were in silico assay method and recombinant antigen method.

In conclusion, in silico assay showed the Omicron variant contains several mutations (4 mutation sites and 3 deletion sites) in the nucleocapsid protein of SAR-CoV-2, but these mutations and deletions may not affect the performance of the CareStart™ Antigen Home Test.

In-house performance evaluation using the recombinant nucleocapsid proteins of variants demonstrated that the B.1.1.7 (Alpha), B.1.351 (Beta), B.1.1.248 (Gamma), B.1.617.1 (Kappa), B.1.617.2 (Delta), B.1.617.3, AY.1 (Delta plus), C.37 (Lambda), AY.2, AY.3, B.1.1.529 (Omicron) and BA.2 (Omicron sublineage) did not affect the performance of the CareStart™ COVID-19 Antigen Home Test and on/go™ COVID-19 Antigen Self-Test.

Name: Seungjae Baek
Job Title: Senior Managing Director
Customer Service

Signature: [signature image]