Letter of Notification

Date: Sep 8th, 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 method was in silico assay method.

In conclusion, in silico assay showed the Omicron subvariants BA.2.75, BA.4, and BA.5 contain four or five mutation sites and three deletion sites in the nucleocapsid protein of SAR-CoV-2, however, these mutations and deletions are outsiders of the epitope of key antibodies used in the CareStart™ Antigen Home Test. This indicates that the Omicron subvariants BA.2.75, BA.4, and BA.5 may not affect the performance of the CareStart™ Antigen Home Test and on/go™ COVID-19 Antigen Self-Test.

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Signature: