

Letter of Notification

Date: July 21, 2021

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 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, recombinant antigen method.

In conclusion, in-house performance evaluation using the recombinant nucleocapsid proteins of variants demonstrated 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) did not affect the performance of the *CareStart*[™] COVID-19 Antigen test.

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Signature:

