Letter of Notification

Dear Customer,

This communication addresses the performance of InteliSwab® with SARS-CoV-2 variants.

As part of OraSure's response to the continued emergence of SARS-CoV-2 variants, we have assessed InteliSwab® performance for a number of these variants. Specifically, OraSure has tested InteliSwab® with the past and present **Variants of Concern** listed below:

We have assessed the ability to detect:

- **Alpha, B.1.1.7**
- **Beta, B.1.351**
- **Gamma, P.1**
- **Delta, B.1.617.2**
- **Omicron, B.1.1.529, BA.1, BA.2, BA.2.12.1, BQ.1, BQ.1.1, BA.3, BA.4, BA.4.6, BA.5, XBB.1, XBB.1.5, EG.5, EG.5.1, FL.1.5.1, BA.2.86, JN.1, HV.1 and HK.3**

InteliSwab® performance was assessed by either wet testing and/or *in silico* analysis. Wet testing was done using recombinant proteins containing the relevant mutations as well as live viral isolates of the relevant strains. Wet testing was conducted at OraSure and by third party laboratories including a collaborative study with NIH demonstrating that InteliSwab® detects the Omicron variant in live clinical samples.

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Job Title: VP Science, Innovation and Technology

Signature: *Rafal Iwasiow*

InteliSwab® COVID-19 RAPID TEST

This product has not been FDA cleared or approved, but it has been authorized by the FDA under an EUA. The emergency use of this product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens And, this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.