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 during the pandemic, we have assessed InteliSwab® performance with a number of these variants. Specifically, OraSure has tested InteliSwab® with the past and present **CDC Variants of Concern*** listed below:

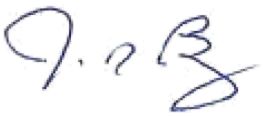
We have shown the ability to detect:

- **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, BA.3, and BA.5**

InteliSwab® was tested using recombinant proteins containing the relevant mutations as well as live viral isolates of the relevant strains. Testing was conducted at OraSure and by third party laboratories including a recent collaborative study with NIH demonstrating that InteliSwab® detects the Omicron Variant. This data has been shared with the FDA.

Name: Jody D Berry

Job Title: Chief Science Officer

Signature: 

*As of April 26, 2022: https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#Consequence

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.