Summary of Nasal Swab abrasion assessment test

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Background
Nasopharyngeal (NP) swabs are an important part of the diagnostic testing procedures for the SARS-CoV-2 virus which causes the current pandemic Coronavirus disease (COVID-19). The expanded demand for testing has increased the need for swabs and 3D printing has emerged as a method to meet the demand. There are a variety of 3D printed swabs currently available with different designs and printing methods. VAPSHCS is evaluating the safety and functionality of a variety of commercially available 3D printed NP swabs for their use in acquiring samples for Covid-19 diagnostic tests.

Purpose
A nasal swab must be able to collect sufficient sample material from a patient for accurate PCR testing. Therefore, the design of the nasal swab head must have a sufficient surface area and absorption capability. However, these design features should not come at the cost of creating nasal mucosal abrasions that cause bleeding (epistaxis). Clinical analysis estimates that the likelihood of abrasion injury during normal use occurs when the swab is rotated during sample collection. This method provides an objective measure of the potential nasal swab abrasion resulting from swabbing. The test method consists of rotating a single nasal swab against a foam block under constant load, comparable to the pressure required for clinical swabbing. It is not intended to be an indicator of a safe or unsafe nasal swab, but rather to provide feedback on the abrasive quality of the swab. Data obtained from this test is intended to be followed up with a formal clinical trial during less critical times to establish safety and efficacy.

Summary
The nasal swab is inserted into the abrasion testing fixture with the handle supported outside of the testing area. A block of impression foam is inserted on top of the swab and weighted to evenly distribute 36 grams onto the swab. The swab is rotated for five (5) complete revolutions, the impression foam is removed, and the foam is measured for depth and volume of foam removed.