

1. 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.

2. MATERIALS / EQUIPMENT

- 2.1 Impression foam cut into a 2" x 2" square (for example, BioFoam Impression Foam No. 4000)
- 2.2 Abrasion testing box (see associated drawing for pattern)
- 2.3 36-gram weight (equivalent to two 2" x 2" x 0.25" acrylic sheets)
- 2.4 3D laser scanner (resolution $\pm 0.005"$)
- 2.5 Tape
- 2.6 Sterilized nasal swabs

3. PRODECURE

3.1 Set-up

Place a small piece of tape around the handle of the swab and join the tape ends (Figure 1). This tape "flag" will be used as a rotational position indicator during the test.

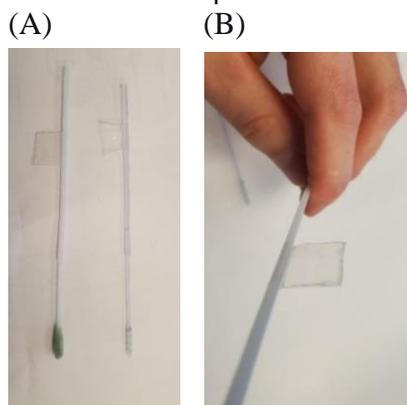
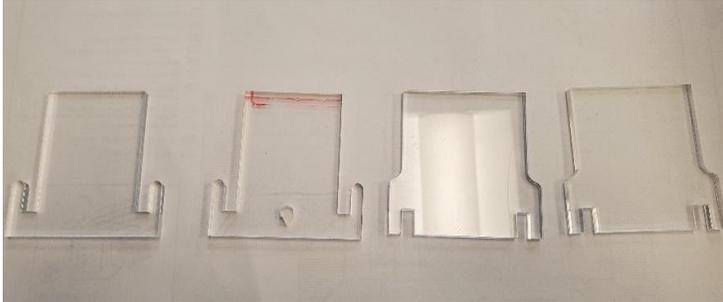


Figure 1: Tape flag position indicator on nasal swabs. (A) Flags are located on the swab handle at a sufficient distance from the swab end to (B) allow room to grasp the swab.

The abrasion testing box is assembled by locking the base corners together (Figure 2).

(A)



(B)



Figure 2: Abrasion testing box is shown (A) unassembled and (B) fully assembled.

Acrylic is recommended for the box material because it is clear and makes alignment easier during the test. Transparent tape can be used at the top of the box to secure the walls, if necessary. Impression foam is cut into a 2 x 2 inch square using a knife or saw. It is important not to disrupt or damage the surface of the foam during this step.

3.2 Testing protocol

Place the nasal swab in the abrasion testing box and confirm that the head is just past the inner wall, and the handle of the swab is supported outside of the box. Next, the impression foam is loaded into the top of the box and weighted with an even distribution of 36 grams to ensure that the foam maintains contact with the swab head (Figure 3). In clinical use, the swab is lightly pressed against the tissue and rotated. This allows it to maintain contact while collecting the sample. A force of 36g was estimated to be appropriate based on bench measurements and clinical expertise. It also allowed the swab to make a measurable impression on the foam block with a minimum number of rotations.

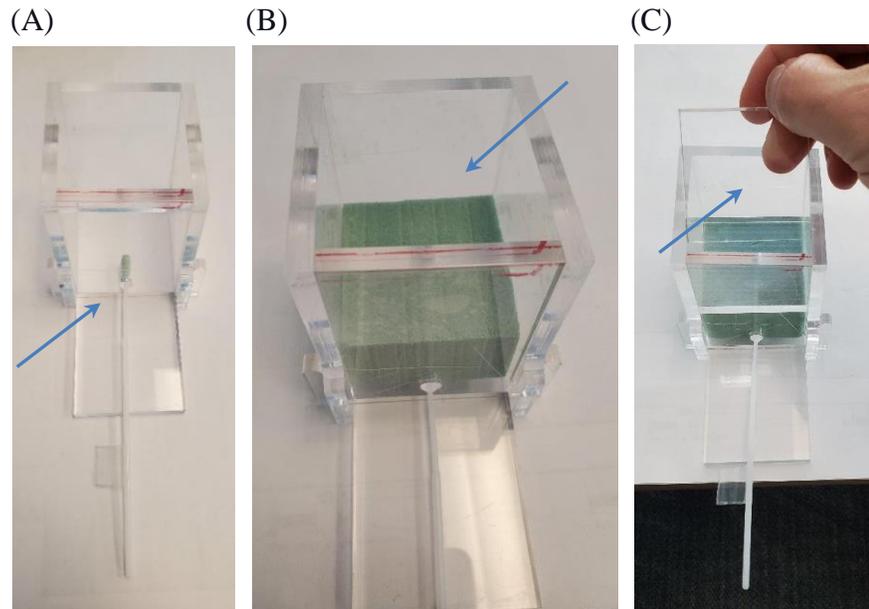


Figure 3: Abrasion testing box set-up. (A) The swab head is inserted just inside the box (blue arrow) with the handle supported. (B) Next, the foam is inserted from the top (indicated by blue arrow), and (C) a 36-gram weight (in this case, a piece of acrylic, blue arrow) is placed on top of the foam to maintain a constant force.

Once the weighted foam has contacted the swab, note the location of the tape on the swab handle. Rotate the swab continuously in one direction for five full rotations. Carefully turn the testing jig over to unload the weighted impression foam from the swab (Figure 4).

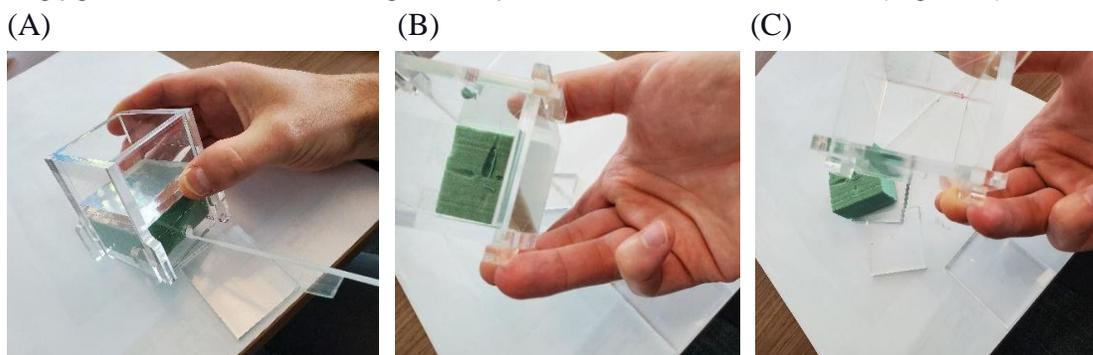


Figure 4: Removing the foam impression after an abrasion test. (A) Pick up the jig and (B) carefully invert it to let the weight fall out, followed by the foam (C). Note, foam can be used up to 4 times (B) if it is carefully labeled so that each impression is correctly correlated to the test swab that made it.

Set the foam aside for later measurements and inspect the swab head to assess the amount of foam collected. Foam collected within the head to an extent that it obscures the swab head features could affect the accuracy of abrasion test results, and should be considered when analyzing results.

4. DATA PROCESSING

It is challenging to take contact-based measurements of the impression foam due to its highly deformable nature. Therefore, laser or light scanning is recommended for measuring the extent of foam surface removal produced from abrasion (depth and volume of foam material removed). Results from 3D printed nasal swabs can be compared to those from standard of care swabs. Ten swabs should be tested for each design type (e.g., 3D printed swab, standard of care).

The average and standard deviation is reported across all swab samples for the following measures:

- Max depth of foam impression
- Volume of removed foam

5. SUPPLEMENTARY MATERIALS

- 6.1 Video demonstrating technique (.mp4)
- 6.2 Cutting guides for creation of acrylic jig fixture (.DWG, .SLDPRT)

Revision History

Revision	CHANGE DESCRIPTION	AUTHOR	APPROVAL	DATE
1.0	Start revision management	Alex Berardo-Cates	pending	7.10.2020