1. PURPOSE

The Veterans Health Administration is evaluating the safety and functionality of a variety of commercially available 3D printed nasal swabs for their use in acquiring samples to test for the SARSCoV-2 virus. This test method aims to characterize the bending properties of nasal swabs. Results of this method will determine compliance of the test specimens with functional performance specifications. Due to the limited forces users can apply to swabs in tension and torsion, these loads were not considered to be likely causes of failure and are not covered under this test protocol. However, swabs are often bent within or external to the nasal passage during routine use, so this protocol focuses on bend characterization. Because rotation of the bent swab during sample collection induces fully reversed bending, this protocol also addresses low cycle fatigue failure. Bend radius and angle limits were chosen based on analysis of swab paths in patient CT scans. This protocol tests each swab at 3 locations: 1) thin, flexible neck at the transition to the handle, 2) break point (if present), 3) handle.

2. SCOPE

In this method, the following measurements will be obtained from quasi-static bend tests:

- 2.1 Swab deflection
- 2.2 Reaction moment

Additionally, the following values will be calculated from quasi-static bend tests:

- 2.3 Peak torque
- 2.4 Angle at peak torque
- 2.5 Angular stiffness
- 2.6 Angle at failure (if applicable)

Finally, the swab will undergo several fully reversed bending loads to examine low cycle fatigue characteristics similar to spinning the swab while bent in a patient's nose. These values will be calculated from low cycle fatigue tests:

- 2.7 Angle at failure (if applicable)
- 2.8 Cycles to failure (if applicable)
- 2.9 Peak torque at 10th cycle / peak torque at 1^{st} cycle

3. DESIGN OF EXPERIMENT

This test method consists of a single clamped cantilever with single bending load applied by a universal testing machine (UTM) at a prescribed distance from the clamp edge. A sample of 3 nasopharyngeal swabs shall be tested in each test. Test swabs shall be in the final form as used clinically, including sterilization via the manufacturer's instructions or user standards.

4. MATERIALS / EQUIPMENT

The following equipment is recommended to carry out this test method.

- 4.1 Universal Testing Machine (UTM) capable of torsional loading
- 4.2 Load fixture with < 1% total deflection relative to test specimen (1% suggested by ASTM D790)
  - 4.2.1. Torsional load cell mounted to base
  - 4.2.2. Rigid clamp to secure test specimen to load cell
- 4.3 Load end effector exhibiting < 1% total deflection relative to test specimen
  - 4.3.1. Applied bidirectional load to test specimen through radius load nose
    - 4.3.1.1. Load nose radius no more than 4x specimen depth (ASTM D790)
  - 4.3.2. Prescribed bending radius of specimen fixed by geometry of load end effector

5. PROCEDURE

5.1 Setup

Referring to Figure 1 below, fasten the load cell adapter (1) to the torsional load cell (3) using screws (11). Fix the load cell adapter (1) to the UTM using screws (10). Fasten the lower clamp (4) and the upper clamp (5) to the torsional load cell (3) using screws (9). Fasten the alignment guide (7) to the end effector (6) using screws (12). Secure the end effector (6) to the UTM actuator using screws (10).

Clamp the test specimen (8) in between upper and lower clamps, making sure it is located in the groove in both clamps and parallel with the alignment guide. The test specimen will be positioned in three different ways relative to the edge of the clamp in order to test three different sections of the specimen: the thin distal section, the thick handle section, and the neck transition between these two. This is described in more detail in section 5.2 below.

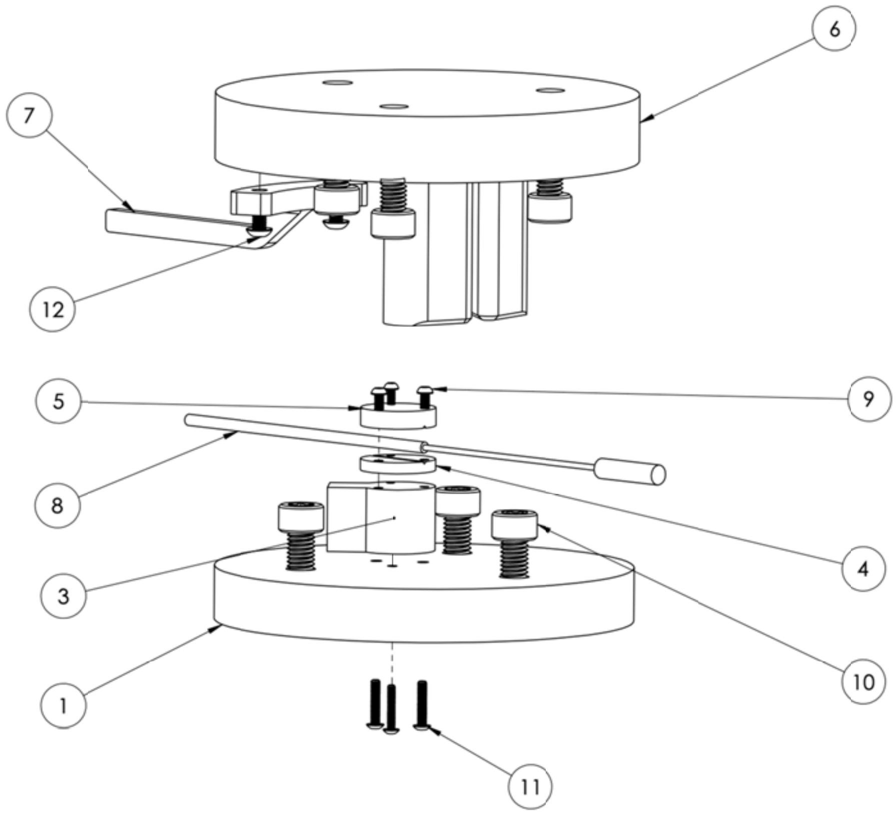

Figure 1. Swab Load Test Fixture

5.2 **Swab Location**

The loading protocol described in section 5.3 is to be applied to the specimen in three distinct locations along the length of the swab. This is intended to characterize the three distinct regions of the swab geometry:

5.2.1. Thin distal section near the swab head, with the end of the thin section at the edge of the cantilever clamp (any thick to thin transition will be just inside the clamp)

5.2.2. Specimen tube break point at the edge of the cantilever clamp. If there is no break point designed into the swab, this step is ignored.

5.2.3. Thick handle region

The swab specimen will be fixed in the clamp as shown in Figure 2 below, which depicts the three different clamping positions. When the first swab is tested for each location, a measurement from the swab tip to the clamp edge shall be recorded and used for reference in subsequent tests at the same location to ensure consistent placement.

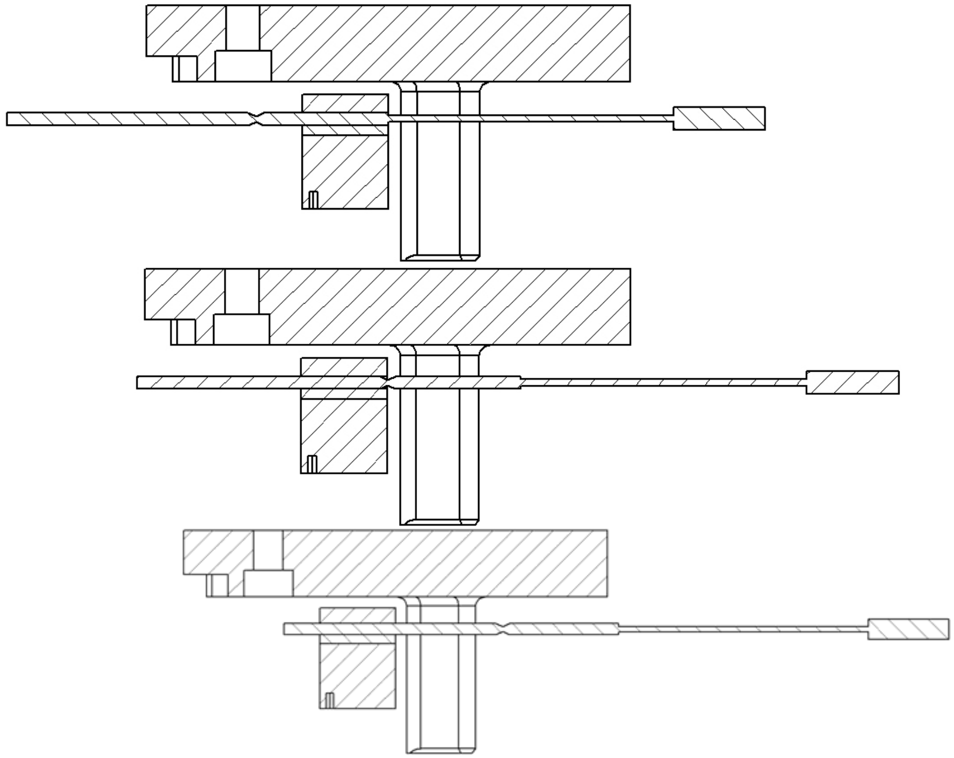

Figure 2. Figure 2a-c. Swab Locations in Clamp (thin section, break point, thick section)

5.3 **Loading Protocol**

The UTM testing protocol involves two distinct steps, the first being a “slow” unidirectional loading and the second being a “fast” bidirectional loading of equal magnitude in either direction. The purpose of the first step is to determine the torque / displacement characteristics of the test specimen, with the loading rate sufficiently slow to record the swab quasi-static characteristics. The purpose of the second step is to apply cyclic loading to mimic the procedure use case wherein the swab is inserted into the nasopharyngeal space, thereby undergoing a bend in the thin distal section, and twisted. This effectively produces a fully reversed bending displacement in the swab of constant peak magnitude up to the bend radius.

The actuator should be zeroed / centered so that the indicator is parallel to the shaft of the swab.

During the first step, the UTM actuator is rotated at a rate of 1.8 degrees/sec (0.01 Hz) in a clockwise direction up to a magnitude of 45°. The UTM actuator displacement and reaction moments are recorded at a sampling rate of 100 Hz.

During the second loading step, after returning the actuator to the neutral position, the UTM actuator rotation rate is increased to 180 degrees/sec (1 Hz) in both clockwise and counterclockwise directions up to the magnitude of 45°. Reaction loads and moments, as well as actuator displacements, are recorded as described above.

5.4 **Data processing**

Data is processed to extract the following information at each test location. The average result is reported along with the standard deviation across all swab samples.

- Peak torque (quasi-static cycle)
- Angle at peak torque (quasi-static cycle)
- Angular stiffness (quasi-static cycle)
- Angle at failure (if applicable)

- Cycles to failure (if applicable)
- Peak torque at 10th cycle / peak torque at 1st cycle

6. ACCEPTANCE CRITERIA

To be Determined

7. REFERENCES

ASTM International. (2017). *ASTM D790-17: Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.* https://doi.org/10.1520/D0790-17

8. ATTACHMENTS

None

Revision History

Revision	CHANGE DESCRIPTION	AUTHOR	APPROVAL	DATE
1.0	Start revision management	Yuri Hudak	pending	7.10.2020