

1. PURPOSE

The 'Go / No-Go gauge' aims to complement the more quantitative results from the mechanical bending test protocol and dimensional analysis report by providing a 'sanity check' that the swab has appropriate geometric and mechanical characteristics to reach either the nasopharyngeal or mid-turbinate sampling site. The gauge is not intended to be an absolute indicator for the safety of a swab, but rather to provide feedback on the swab design's mechanical and dimensional properties in a form that is more obviously related to its clinical application than a mechanical testing machine. Data obtained from the gauge is intended to be followed up with a formal clinical trial during less critical times to establish safety and efficacy more rigorously.

2. SIGNIFICANCE AND USE

2.1 Assesses the flexibility and geometric characteristics of the swab

3. MATERIALS / EQUIPMENT

3.1 3D printable files can be found on the NIH 3D Print Exchange (3Dprint.nih.gov)

3.2 The gauge can be 3D-printed from any rigid material, although transparent materials are preferred to better visualize the motion of the swab. Formlabs 'Surgical Guide' resin has been found to work well.

3.3 M3 sized fasteners or glue

4. PROCEDURE

1. Print the Nasopharyngeal (NP) or Mid-turbinate (MT) 'go no-go gauge' in a rigid material using your desired printing method. It is recommended to lie the outer surface flat on the build platform to eliminate any support material being required on the inside of the gauge.
2. Adhere the two halves using fasteners or glue. The print is designed to support M3 sized nuts and socket head cap screws.
3. Insert an unused swab into the gauge, with the tip reaching the end of the cavity.



- With the swab tip all the way inserted and holding the gauge in one hand if necessary, lightly press the swab handle to the nub located on the end of the lower flange with a finger and thumb.



- Repeat this, instead lightly pressing the handle to the nub of the top flange rather than the bottom.



5. RESULTS

Remove the swab and inspect for signs of failure, including breakage or cracking.

6. SUPPLEMENTARY MATERIALS

- 3D printable files for the nasopharyngeal and mid-turbinate Go / No-Go Gauges (.stl)
- Design rationale documentation (.pdf)
- 'Go / No-Go Gauge' Simple Instructions (.pdf)

Revision History

Revision	CHANGE DESCRIPTION	AUTHOR	APPROVAL	DATE
1.0	Start revision management	Alex Hotz	pending	7.10.2020