

VHA Nasal Swab Testing Protocols and Results

Testing is ongoing; results are up to date of as of August 17, 2020.

OVERVIEW

A nasal swab's simple shape belies its complex function - to safely collect a sample of virus from a patient's nasal passage and deliver that intact viral sample into reagents in a lab for COVID-19 testing. An increased demand for nasal swabs has overwhelmed established swab manufacturers. To meet the need, multiple manufacturers have leveraged 3D printing to design and produce novel nasal swabs. Objective testing of the key functions of novel nasal swabs is required, to ensure that they match the safety and effectiveness set by established products. The Veterans Health Administration (VHA) created a set of 8 protocols to test key functionalities of nasal swabs. These protocols are meant to benchmark novel swabs to established, traditionally manufactured swabs with a long track record of safety and efficacy. Test criteria and protocols can be found [here](#).

Anatomy of a Swab



TESTED SWABS

GOLD STANDARD:

Two of the largest and most established manufacturers of nasal swabs are Puritan Medical Products (Maine, USA) and Copan Diagnostics, Inc. (Brescia, Italy).

For testing, we benchmarked 3D printed swabs against the following:

- BD swab (220531), made by Copan, packaged in the BD Universal Viral Transport for Viruses, Chlamydiae, Mycoplasmas and Ureaplasmas (220531) (Becton, Dickinson and Company, Sparks MD).
- Copan swab (FLOQ swab, 5U088S01) packaged in the Cepheid GeneXpert Xpert Xpress Nasopharyngeal Sample Collection Kit for viruses (SWAB/M-100)

3D-PRINTED SWABS

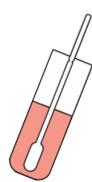
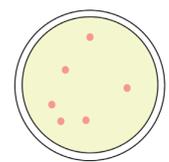
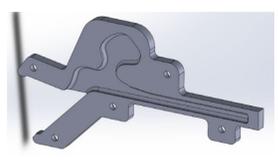
Initial testing included six 3D-printed nasal swabs that were either commercially available and/or had open source files.

- Abiogenix <https://www.abiogenix.com/>
- EnvisionTec <https://envisiontec.com/wp-content/uploads/2020/04/EnvisionTEC-NP-Swabs.pdf>
- Northwell (FormLabs 3D print) <https://formlabs.com/covid-19-response/covid-test-swabs/>
- University of South Florida (USF; FormLabs 3D print) <https://formlabs.com/covid-19-response/covid-test-swabs/>
- Origin <https://www.origin.io/npswab/>
- Resolution Medical <https://www.resolutionmedical.com/latticeswabs>

DISCLAIMER

The results from these tests are not intended to be an absolute indicator of a performant swab, but rather serve as a comparative measure that, when combined with other laboratory testing, can provide a more comprehensive analysis of swab performance in a clinical laboratory environment. The VHA recommends that a follow up study with more rigorous testing of 3D-printable nasal swabs for diagnostic purposes (including, but not limited to, COVID-19) should be conducted when resources allow, either during or after the COVID-19 public health emergency.

PROTOCOL MENU

Bending Protocol 	Break Point Protocol 	Absorption Protocol 	Elution Protocol 
rtPCR Compatibility Protocol TESTING IN PROGRESS	Abrasion Protocol TESTING IN PROGRESS	Indentation Protocol TESTING IN PROGRESS	Go No-Go Gauge Protocol 

ANATOMIC TESTING

Go No-Go Gauge Protocol:

Purpose: Assesses the ability of the swab to fit through the nasal cavity and reach the sampling location (e.g. nasopharynx, mid-turbinate region)

Swab Type	Nasopharynx	Mid-turbinate Region
BD	PASS	PASS
Copan FLOQ	PASS	PASS
Abiogenix	PASS	PASS
Envisiontec	PASS	PASS
Northwell (FormLabs)	PASS	PASS
USF (FormLabs)	PASS	PASS
Origin	PASS	PASS
Resolution	PASS	PASS

MECHANICAL TESTING

Bending Protocol:

Purpose: Assesses the ability of the neck of a swab to withstand repeated bending without breaking.

Gold Standard		3D Printed Swabs					
BD	Copan FLOQ	Abiogenix	EnvisionTec	FormLabs Northwell	FormLabs USF	Origin	Resolution
10	10	10	9	2	3	6	10
10	10	10	9	2	4	6	10
10	10	10	10	2	4	6	10
10	10	10	10	3	4	7	10
10	10	10	10	6	4	7	10
10	10	10	10	8	5	7	10
10	10	10	10	10	5	7	10
10	10	10	10	10	5	8	10
10	10	10	10	10	6	8	10
10	10	10	10	10	8	9	10

N=10 swabs per swab brand. The number signifies the number of bend cycles the swab made it through without breaking, e.g., "6" indicates the swab made it through 6 cycles and broke on the 7th cycle. The number "10" signifies the swab made it through all 10 cycles tested without breaking.

Break Point Protocol:

Assesses the ability of the swab to yield specifically at the break point when placed into a vial.

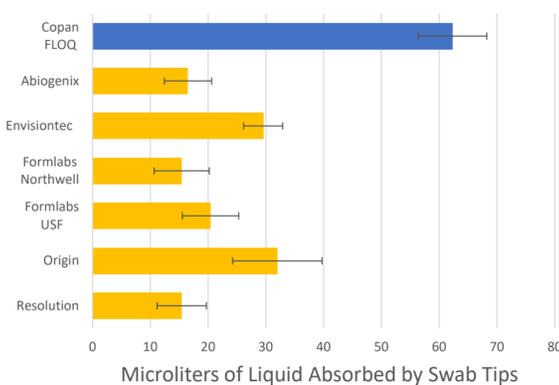
Swab Type	Cepheid Vial (SWAB/M-100)	BD Vial (220531)
BD	N/A*	1.00
Copan FLOQ	1.00	1.00
Abiogenix	1.83	2.00
Envisiontec	1.00	1.00
FormLabs Northwell	1.83	1.67
FormLabs USF	1.00	1.00
Origin	1.00	1.00
Resolution	1.00	2.33

N = 6 swabs per brand, per vial type (e.g., Cepheid and BD); Swabs were tested by 3 different users. Each user broke a total of 4 swabs of each brand- 2 in the vial that came with the Cepheid kit (80 mm length, 11.6 mm internal diameter) and 2 in the vial that came with the BD kit (101 mm length, 14.2 mm internal diameter). The number of attempts at breaking off the swab was recorded, and averages are presented here. *The breakpoint of the BD swab is 100mm, and thus is too long to fit in the 80mm vial that accompanies the Cepheid kit.

LABORATORY TEST COMPATIBILITY

Absorption Protocol:

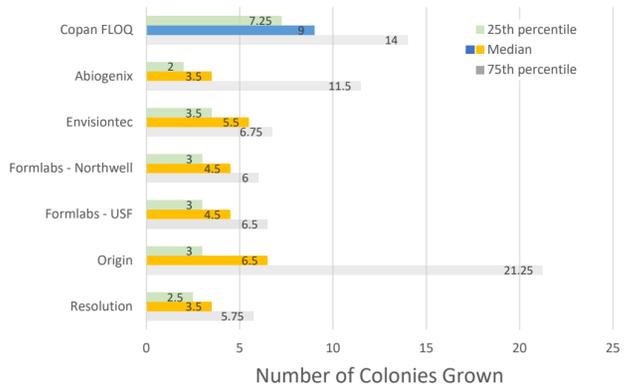
Purpose: Assesses the ability of the swab tip to absorb liquid containing microorganisms (in this case, the bacteria Staph aureus)



N=20 swabs per swab brand. The data is expressed as mean ± Standard deviation.

Elution Protocol:

Purpose: Assess the ability of a swab to absorb and elute a microorganism (in this case the bacteria Staph aureus)



N=20 swabs per swab brand. The data is expressed as the Median, with 25th and 75th percentile also plotted. The data is shown as median rather than mean given the data had a rightward distribution.

PATIENT SAFETY TESTING

rtPCR Compatibility Protocol:

Purpose: Assesses the ability of the swab to absorb and elute a virus sample (positive Covid-19 sample/ control) from a test tube into rtPCR reagents and yield an accurate rtPCR test result. This test also assesses whether the swab material interferes with the rtPCR assay.

TESTING IN PROGRESS

Abrasion Protocol:

Purpose: Assesses the abrasive qualities of the swab tip, as a surrogate for the risk of epistaxis (nosebleed).

TESTING IN PROGRESS

Indentation Protocol:

Purpose: Assesses the penetration of the distal tip of a swab into compliant material, as a surrogate for potential puncture risk.

TESTING IN PROGRESS