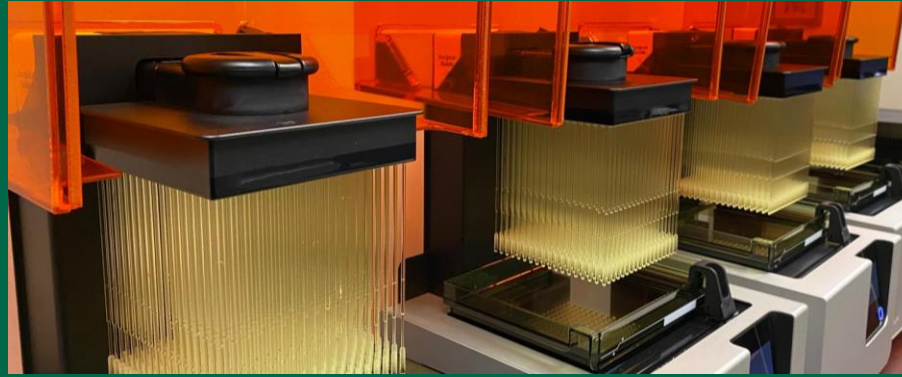


# 3D Printed Alternative to the Standard Synthetic Nasopharyngeal Swabs Used For COVID-19 Testing



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Department of Radiology

University of South Florida Morsani College of Medicine



November 5, 2020

# COVID-19 Testing Kit & Crisis

- Three key parts
  - Test Tube
  - Viral Transport Media
  - Nasopharyngeal Swab (Main producers are Italy and China)
- Synthetic flocked swabs standard as organic (cotton) swabs interfere with viral testing

*Global supply chain has been disrupted directly impacting the ability to test in the US*



# 3D Printed Swabs

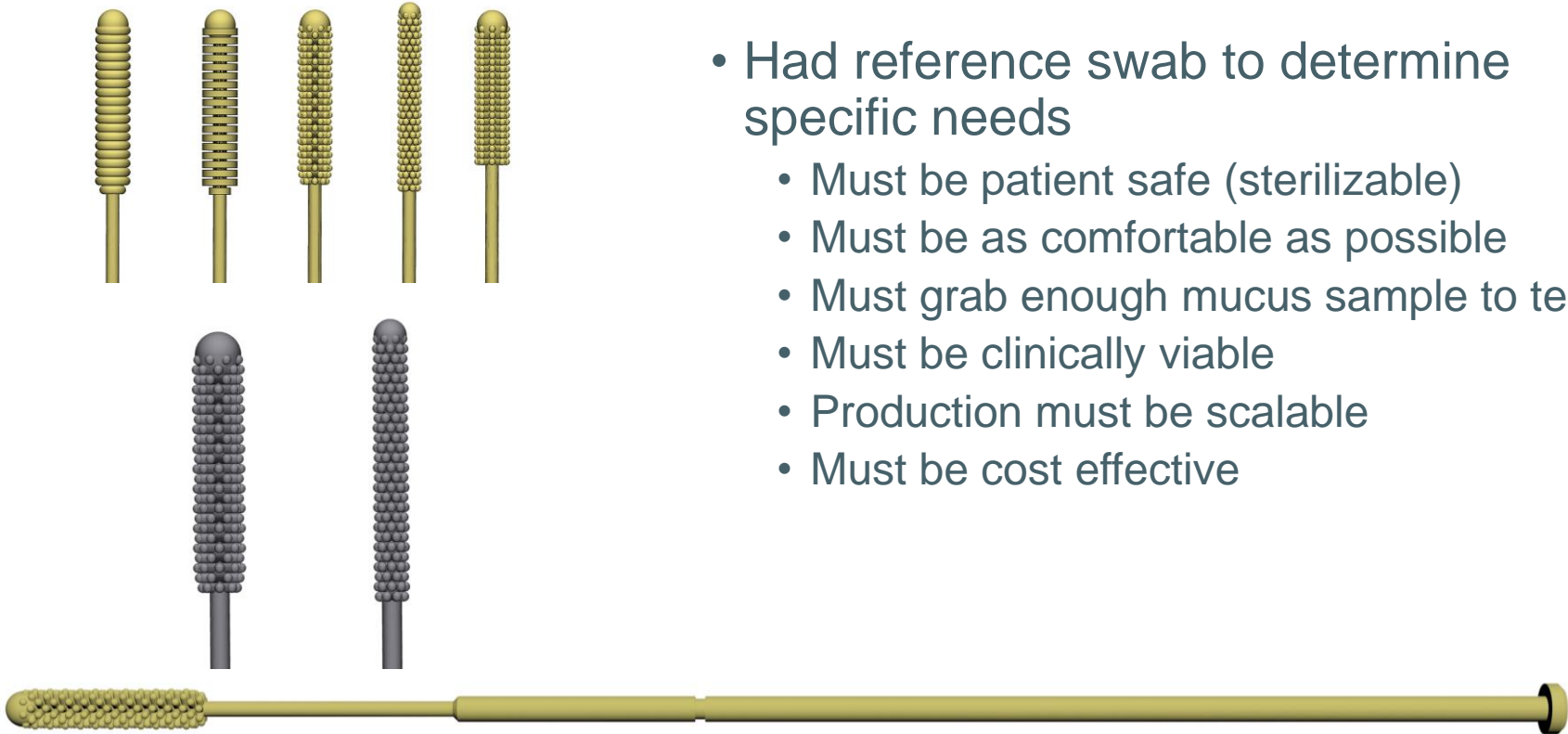
- USF Radiology Division of 3D Clinical Applications
  - Point-of-Care 3D Printing lab at Tampa General Hospital
- Northwell Health's Division of 3D Design and Innovation- New York City



USF Health

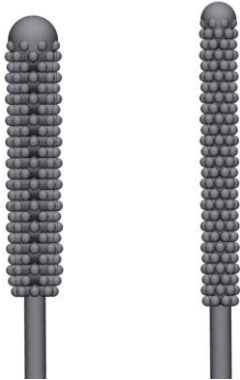


# Design



- Had reference swab to determine specific needs
  - Must be patient safe (sterilizable)
  - Must be as comfortable as possible
  - Must grab enough mucus sample to test
  - Must be clinically viable
  - Production must be scalable
  - Must be cost effective

# Design



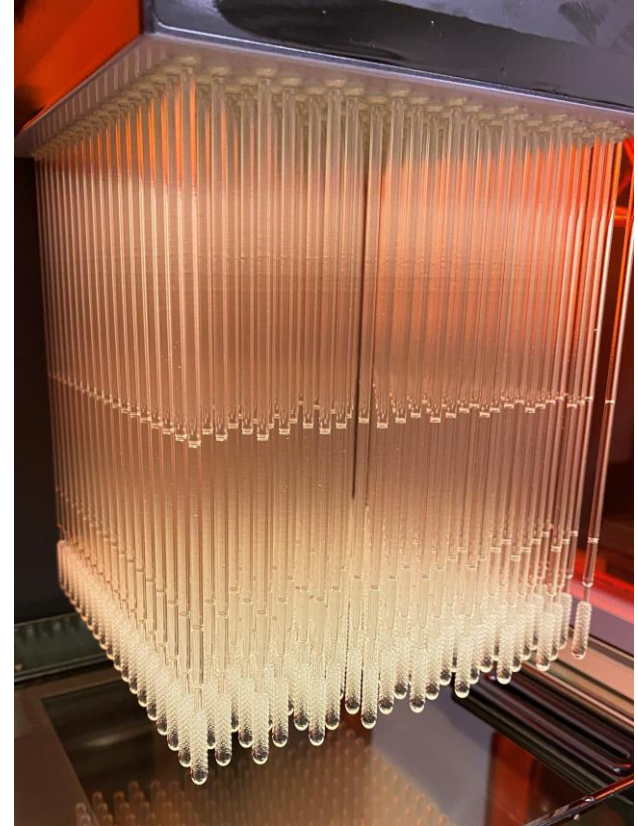
- Designed several tip and stem iterations
- Received feedback from clinicians
- Tested on volunteers for ergonomic comfort
- Finalized design before bench lab testing
- Bench Lab testing successful



# Printer and Material Selection

## 3D Printer Type and Material

- Formlabs Form 2 and Form 3B
- Surgical Guide Resin - Already cleared by FDA for clinical and dental use
- Sterilizable via autoclave
- Existing widespread use in Clinical and Dental 3D Printing so already in many hospitals and clinics





- USF Health/Tampa General Hospital
- Northwell Health
- Thomas Jefferson University
- Direct head-to-head comparison on same patient in alternative nostrils
  - Synthetic swab in one nostril
  - 3DP swab in alternate nostril
- Results of 291 patients
  - 156 Females, 135 Males
- Significance
  - 3 different assay machines

		3DP	3DP	3DP	Total
		+	-	inc	
FLNP	+	<b>74</b>	2	3	79
FLNP	-	4	<b>203</b>	1	208
FLNP	inc	0	2	<b>2</b>	4
Total		78	207	6	<b>291</b>

**Conclusion:** Cycle threshold was statistically the same so the 3DP swab as good as the synthetic standard, in some cases better.

Hospital review boards accepted 3DP swab as alternative swab.

## Clinical Trial Testing: Comparison of C(t) for Viral Targets

# Costs

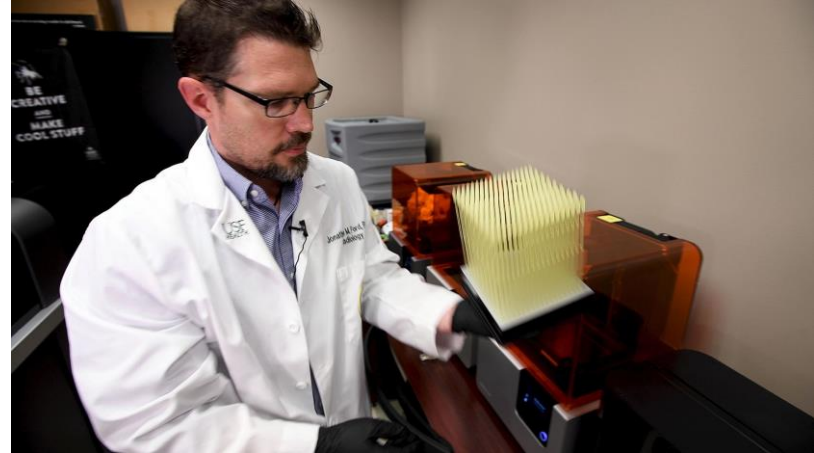
- Swabs are produced 324-380 a batch
  - Print time is 11-16 hours
  - Monthly output is 9,720 swabs per printer.
    - USF Radiology can produce ~58,000 per month
  - Standard Swab costs approximately \$1/swab
    - 3DP Swabs production cost is \$0.25 a swab
- Printers are affordable and are already deployed across the state and country





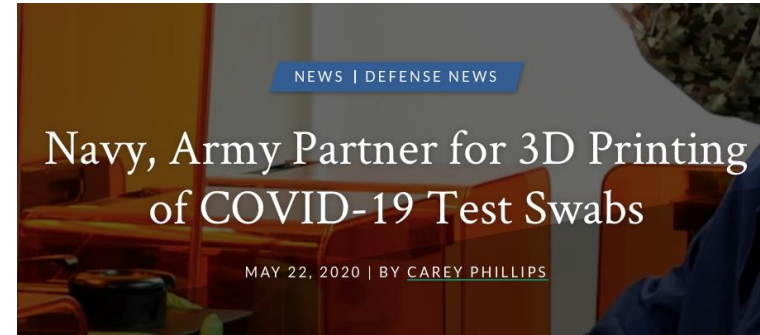
# Completing the Kit

- Swabs are delivered to USF Health Dept of Infectious Disease labs for sterilization
- Each swab is individually wrapped before autoclaving
- Bundled with the other testing kit components
- Distributed to affiliate hospitals
- USF Radiology Team printed over 100,000 swabs for test kits for local hospitals



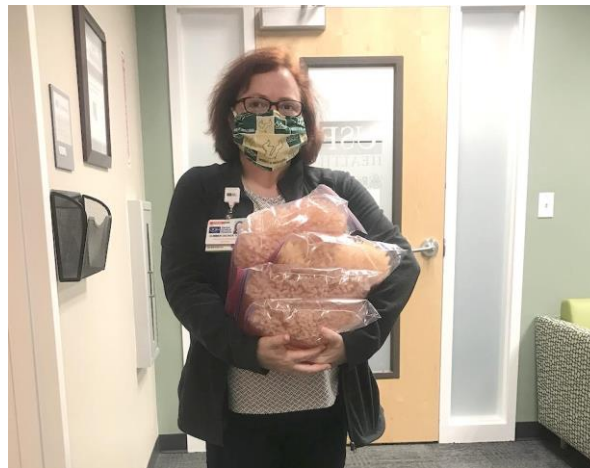
# National / International Distribution

- Provisional Patent
  - Granted March 20, 2020
- Posted files in Box to share with any hospital or medical center who needed help for free
- Work weekly with the FDA
- Partnered with FormLabs to distribute swabs to hospitals and clinics beyond our legal bounds at cost
- Partnered with US Military



# Florida Impact

- USF Health Clinics
- Tampa General Hospital
- Moffitt Cancer Center
- James A Haley VA Hospital
- Bay Pines VA Hospital
- BayCare Hospitals
- Nemours Hospital
- UF Shands and UF Shands Jax
- FIU
- More



# Global Impact

- US VA system- 25% of the 170 hospitals are using the USF Health swab
  - Majority are printing their own; some are being supplied by affiliates like USF MCOM
  - Doubled the 3D printing in VA facilities across the US
- Numerous states using the USF Health swab including New York, Massachusetts, Kansas, Oklahoma, and Ohio
  - Ohio has over 1 million alone
- Over 60 hospitals and hospital systems including the Mayo Clinic, Brigham and Women's, LSU Medical Center, etc.
- Used in 25+ countries

*In total, there are over **40 million** USF Health designed swabs in the world which have directly impacted the national response to COVID.*

# Publications

Ford et al. *3D Printing in Medicine* (2020) 6:21  
<https://doi.org/10.1186/s41205-020-00076-3>

## 3D Printing in Medicine

### TECHNICAL NOTE

### Open Access

## A 3D-printed nasopharyngeal swab for COVID-19 diagnostic testing

Jonathan Ford<sup>1\*</sup>, Todd Goldstein<sup>2</sup>, Sean Trahan<sup>2</sup>, Allison Neuwirth<sup>2</sup>, Kyle Tatoris<sup>1</sup> and Summer Decker<sup>1</sup>



### Abstract

The nasopharyngeal swab is a critical component of the COVID-19 testing kit. Supply chain remains greatly impacted by the pandemic. Teams from USF Health Radiology and Northwell Health System developed a 3D-printed stopgap alternative. This descriptive study details the workflow and provides guidance for hospital-based 3D printing labs to leverage the design to make a positive impact on the pandemic. Swab use is also outlined, and the early information regarding clinical use is described, including an ongoing multicenter trial methodology.

**Keywords:** Nasopharyngeal swab, COVID-19, 3D-printing, Point-of-care, Supply chain

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## 3D Printing in Medicine: COVID-19 Testing with 3D Printed Nasopharyngeal Swabs

Frank J Rybicki, MD, PhD

*Clinical Infectious Diseases*, ciaa1437, <https://doi.org/10.1093/cid/ciaa1437>

**Published:** 19 September 2020 **Article history ▼**

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**Keywords:** COVID-19, coronavirus, 3D printing, nasopharyngeal swab, testing

**Issue Section:** Editorial Commentary

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ACCEPTED MANUSCRIPT

## 3D Printed Alternative to the Standard Synthetic Flocked Nasopharyngeal Swabs Used for COVID-19 testing

Summer J Decker, Ph.D, Todd A Goldstein, Ph.D, Jonathan M Ford, Ph.D, Michael N Teng, Ph.D, Robert S Pugliese, Pharm.D, BCPS, Gregory J Berry, Ph.D, Matthew Pettengill, Ph.D, Suzane Silbert, Ph.D, Todd R Hazelton, M.D., M.S, Jason W Wilson, M.D., M.A, Kristy Shine, M.D., Ph.D, Zi-Xuan Wang, Ph.D., MBA, Morgan Hutchinson, M.D, Joseph Castagnaro, M.S, Ona E Bloom, Ph.D, Dwayne A Breining, M.D, Barbara M Goldsmith, Ph.D, John T Sinnott, M.D, Donna Gentile O'Donnell, Ph.D, James M Crawford, MD, Ph.D, Charles J Lockwood, M.D., M.H.C.M, Kami Kim, M.D

*Clinical Infectious Diseases*, ciaa1366, <https://doi.org/10.1093/cid/ciaa1366>

**Published:** 10 September 2020 **Article history ▼**



# COVID-19 Heroes of Tampa Bay Award

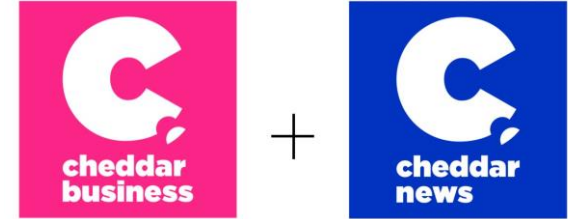




# National and International News



Forbes



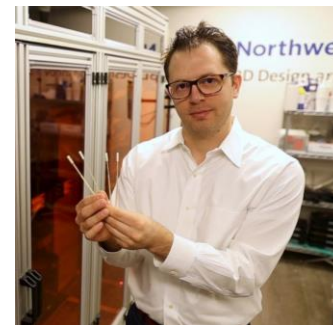
# 3D Printed NP Swab Team

## • USF Health

- Dr. Summer Decker\*
- Dr. Jonathan Ford\*
- Dr. Todd Hazelton
- Dr. Michael Teng
- Dr. Kami Kim
- Dr. Jason Wilson
- Dr. John Sinnott
- Dr. Suzane Silbert
- Dr. Charles Lockwood

## • Northwell Health

- Dr. Todd Goldstein\*
- Dr. Greg Berry
- Dr. Ona Bloom
- Dr. James Crawford
- Dr. Dwayne Breining
- Mr. James Castagnaro



## • Thomas Jefferson University

- Dr. Robert Pugliese
- Dr. Matthew Pettengill
- Dr. Kristy Shine
- Dr. Zi-Xuan Wang
- Dr. Morgan Hutchinson
- Dr. Barbara Goldsmith
- Dr. Donna Gentile O'Donnell

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