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

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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
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
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

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<th>Total</th>
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<td>inc</td>
<td>0</td>
<td>2</td>
<td>2</td>
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<tr>
<td>Total</td>
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<td>207</td>
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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.
A 3D-printed nasopharyngeal swab for COVID-19 diagnostic testing

Jonathan Ford,1 Todd Goldstein,2 Sean Trahan,3 Allison Neuwirth,2 Kyle Tatoris,1 and Summer Decker1

Abstract

The nasopharyngeal swab is a critical component of the COVID-19 testing kit. Supply chain impacts greatly from the pandemic. Teams from USF Health Radiology and Northwell Health System developed a 3D-printed testing system. 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
COVID-19 Heroes of Tampa Bay Award
3D Printed NP Swab Team

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