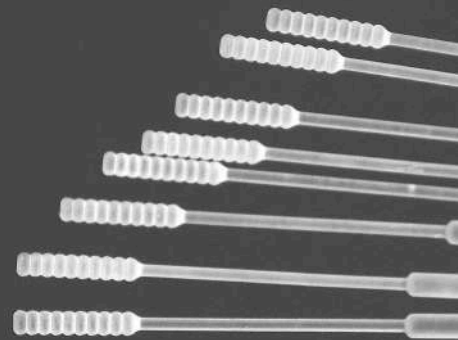


EnvisionTEC COVID-19 Efforts Working Together to Combat COVID-19



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Links and Publications

EnvisionTEC Press Release:
<https://envisiontec.com/envisiontec-to-3d-print-mass-quantities-of-naso-pharyngeal-swabs-for-covid-19-testing-based-on-successful-clinical-trial/>

BIDMC Press Release:
https://www.newswise.com/coronavirus/bidmc-led-clinical-trial-identifies-four-novel-3d-printed-swabs-for-use-in-covid-19-testing/?article_id=730220

Preprint of BIDMC manuscript:
<https://www.medrxiv.org/content/10.1101/2020.04.14.20065094v1>

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3D Printed NP Swabs

Description

EnvisionTEC engineers have designed a 3D printed collection tip for a flexible nasal swab that has completed testing in an IRB-approved clinical trial for use in this unprecedented time. In order to be given this approval, a rigorous, multi-phase testing procedure was required. This testing of both the design and the material included several rigorous mechanical and chemical tests. This was done to ensure that the swabs pick up viral RNA particles and do not interfere with PCR/reagents, that they are chemically safe, that they would bend 180 degrees without breaking, and that the design would be able to safely collect enough viral particles from the nasal passage to effectively test.

One of the major advantages of the EnvisionTEC NP swab is that it continued to perform the same after being sterilized by steam at 270°F at 27 Pa in an autoclave. According to Dr. Ramy Arnaout, MD, DPhil, Associate Director of the Clinical Microbiology Laboratories at Beth Israel Deaconess Medical Center (BIDMC) of Boston's Biomedical Laboratory, "Analytical results were positive, with a high level of concordance with the reference swab and with subjective results showing that [EnvisionTEC's] swab performed neutrally or better than other test swabs." The EnvisionTEC swabs received positive comments from study staff for comfort, flexibility, and ease of insertion.

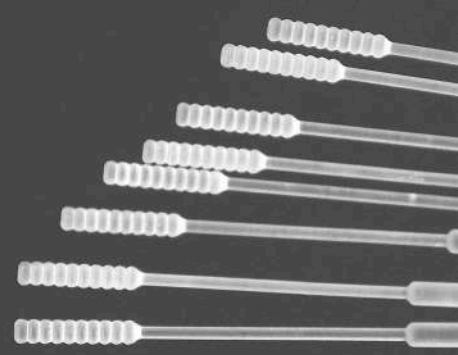
EnvisionTEC is now taking orders and producing sterilized and unsterilized swabs for hospitals, healthcare providers, government agencies, and the armed forces.

EnvisionTEC is the only 3D printed swab manufacturer that makes the equipment AND the materials, offering a completely stable supply chain.



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FAQ

Are the swabs packaged and sterilized?

Test swab samples are available in sterilized or unsterilized options, based on customer needs.

What is the manufacturers capacity?

Up to 1 Million per day through its network of Envision One users.

Are the swabs FDA approved?

The swabs are Class 1 and do not require FDA approval but are registered on the FDA website and an IRB-approved clinical trial has been completed

Applicator, Absorbent Tipped, Sterile, Product Code KXG: [Link](#)

Applicator, Absorbent Tipped, Non-Sterile, Product Code KXF: [Link](#)

Do the swabs cause any interference with PCR or molecular test platforms?

As part of the rigorous testing performed by BIDMC, a spiked sample was used to test performance of the 3D printed swab against a polyester control swab. The results between the two swabs did not vary.



Dimensions

Total Length: 148mm

Handle Diameter: 2.5mm

Neck Diameter: 1mm

Neck Length: 39mm

Head Diameter: 3mm

Head Length: 17mm

Head Feature Thickness:
0.4mm

Handle Breakpoint Diameter:
1.5mm

Material

E-Guide Soft C-29C resin

Non-cytotoxic, not a sensitizer, non irritating

Of the four swab manufacturers approved by the BIDMC Harvard IRB, EnvisionTEC has the most established supply chain, having over 18 years experience in the 3D printing business, and over 17 years of that providing 3D printed medical device solutions globally.

