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EnvisionTEC to 3D Print Mass Quantities of Nasopharyngeal Swabs for COVID-19 Testing Based on Successful Clinical Trial

Dearborn, Michigan, April 15, 2020 — EnvisionTEC, a leading global manufacturer of desktop and full-production 3D printers and materials, is proud to announce they have successfully completed a clinical trial to use the EnvisionTEC 3D printed Nasopharyngeal (NP) Swabs for COVID-19 testing. EnvisionTEC, as well as a growing number of their Envision One cDLM customers who have also registered with the FDA to take part in this endeavor, have the mass production capabilities to produce up to a million of the desperately needed swabs per day.

One of the biggest immediate needs in the fight against the global pandemic known as COVID-19 is simply identifying those who have been infected as early as possible. Globally, the testing kit availability has been vastly inadequate for the large-scale testing needed in order to identify and isolate known cases of the virus and get ahead of its spread within each community both in the United States and across the globe. The traditional manufacturing method for the swabs is tedious and limited, with the final testing swab needing to exhibit unique properties of softness and flexibility that are difficult to produce. EnvisionTEC worked with Beth Israel Deaconess Medical Center (BIDMC) to develop a swab design and material to be printed on their best-selling Envision One cDLM 3D printer.

The Envision One, launched in early 2019, has been EnvisionTEC's best-selling 3D printer to date, with over a thousand units currently in use among dental labs, orthodontic practices, universities, medical device manufacturers and more. Many of the owners of these units are accustomed to producing medical-grade products, making them the ideal production partners for this enterprise. The Envision One is capable of producing up to 2400 swabs in 24 hours. This leads to a production capacity of EnvisionTEC and its Envision One user network of up to a million swabs per day.

EnvisionTEC engineers have designed a 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 testing procedure was required to be

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passed. 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 PCA/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 virus particles from the nasal passage to effectively test.

One of the major advantaged of the EnvisionTEC NP swab is that it continued to perform mechanically the same after being sterilized by steam at 270°F at 27 Pa in an autoclave. Other 3D printed swabs have shown deterioration following autoclave procedures. According to Dr. Ramy Arnaout, MD, DPhil, Associate Director of the Clinical Microbiology Laboratories at Beth Israel Deaconess Medical Center, "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".

During the clinical trials performed by BIDMC, the EnvisionTEC swabs received positive comments from study staff for comfort, flexibility, and ease of insertion, which we attribute to the use of EnvisionTEC's E-Guide Soft material.

E-Guide Soft, a biomedically safe 3D printing material from EnvisionTEC, and EnvisionTEC's swab design have both passed all of the required tests. EnvisionTEC has been working with Beth Israel Deaconess Medical Center (BIDMC), which ran the trial, whose results were finalized this week.

EnvisionTEC has long been committed to providing solutions to their customers and is now preparing to take on the call to action of helping to equip medical professionals with the tools needed to help combat this global pandemic. With a vast network of thousands of customers eager to help, EnvisionTEC is already taking orders and producing sterilized and unsterilized NP swabs for hospitals, healthcare providers, government agencies, and armed forces.

To place an order, interested parties can email covid19@envisiontec.com.

More information about this initiative and others by EnvisionTEC can be found at: https://envisiontec.com/envisiontec-covid-19-efforts/



About EnvisionTEC

EnvisionTEC is a leading global provider of professional-grade 3D printing solutions. Founded in 2002 with its pioneering commercial DLP printing technology, EnvisionTEC now sells a variety of printer configurations based on six distinct technologies that build objects from digital design files. The company's premium 3D printers serve a variety of medical, professional and industrial markets, and are valued for precision, surface quality, functionality and speed. EnvisionTEC's intellectual property includes more than 140 pending and granted patents. Learn more at EnvisionTEC.com.

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