

## **Fabrication Process of nasopharyngeal (NP) swabs at Hospital Virtual Valdecilla:**

### **Nasopharyngeal Swabs 3D Printing Workflow**

This section records the manufacturing process of NP swabs that is used at Hospital Virtual Valdecilla in Cantabria, Spain. Our hope is that the parties interested in manufacturing the NP swab will be able to learn from this and what we are doing at HvV and determine for themselves whether and how to adopt the process.

This is the process that is working for HvV, but we do not guarantee that it can work for every facility every time.

The following workflow has been developed using a **Form 2 stereolithography 3D printer** and **Surgical Guide Resin** by Formlabs.

#### **Important considerations prior to beginning to 3D print NP swabs:**

- Cartridges should be separated from other materials.
- A dedicated build platform should be used for Surgical Guide Resin. Proceed to disinfecting it prior to use: with 99% IPA or higher and disposable paper towel.
- A dedicated Resin Tank LT should be used for the Surgical Guide Resin.
- Use a dedicated pair of gloves and face mask to manage the protocol.
- Sterilized tools should be used to handle the 3D printed NP swabs at every stage of the process.

#### **1. Production records and lot number:**

- a. Identify each batch that will be printed with the following:
  - i. Batch number
  - ii. Date of manufacturing
  - iii. Date of packaging
- b. For each 'Quality Control' step the information is registered in the IT system. Reevaluate the manufacturing process every 5 printed batches.

#### **2. Printing/manufacturing instructions:**

- a. A Form 2 stereolithography 3D printer has been used.
- b. Use the latest file provided at HvV website.
- c. Upload the PreForm file to the printer. This PreForm file allows 324 swabs per print.
- d. Place in the printer the dedicated Resin Tank LT for Surgical Guide Resin.

- e. Select a cartridge of Surgical Guide Resin for printing. Place the cartridge in the printer and open the ventilation valve.
- f. Insert the previously disinfected Build Platform designated for swab production on the printer.
- g. Print the parts.
- h. Take the build platform directly to the post-processing station.

### **3. First Quality Control:**

- a. Inspect the printed parts and check for swabs that have not printed properly (**Annex 1**).
- b. Parts that do not fulfill the criteria to pass are counted and registered so they can be analyzed.

### **3. Washing instructions:**

- a. Refer to washing instructions on HvV website for the latest recommendation.
- b. A separate pair of gloves should be used for handling the swabs.
- c. Wash the parts in the build platform in a dedicated Form Wash for Surgical Guide Resin using clean 99% IPA for 20 minutes.
- d. After cleaning, allow parts to dry for 30 minutes.
- e. Control the saturation of IPA using the hydrometer everyday (after 2 batches were washed).
- f. In order to control the saturation of IPA, follow the instructions from the Washing machine by Formlabs.
- g. We change the IPA every 10 batches

### **4. Second Quality Control:**

- c. Inspect the printed parts again and check that the swabs that didn't print correctly are properly registered.
- d. Parts that do not fulfill the criteria are registered, set apart from the rest and will be analyzed.

### **5. Curing instructions**

- a. Use the latest information on HvV website to follow the curing process.
- b. A dedicated pair of gloves must be used to handle the swabs.
- c. Use a sterilized forceps to remove the parts from the build platform and place them in a support structure (**Annex 2**).
- d. Swabs are cured in a vertical orientation in the support structure. Check that no parts are overlapping.
- e. Place the support structure with the swabs in the Form Cure to post cure with the following parameters: 60°C for 30 minutes.
- f. Remove the parts from the Form Cure using special sterilized tools and proceed to third quality control.

### **5. Third Quality Control:**

- e. Inspect the printed parts. If cracks or distortions are detected, discard the printed part.
- f. Parts that do not fulfill the criteria are registered and removed from the rest and will be analyzed.
- g. Three swabs are randomly selected from each batch and are submitted to quality check.

### **6. Packaging and Labeling Instructions:**

- a. Swabs are placed in an autoclavable pouch in groups of 10 using sterilized forceps and the package is then sealed.
- b. Check that the swabs are not overlapping.
- c. Personnel manipulating the swabs need to wear a dedicated pair of gloves.
- d. Store the swabs in a place away from direct sunlight.

### **7. Sterilization:**

- a. Packages with the swabs are sterilized at the hospital facilities following parameters established in the Surgical Guide Resin application guide by Formlabs:
  - i. Pre-vacuum steam sterilizer: 132 °C / 270 °F 4 minutes
  - ii. Gravity displacement: 121 °C / 250 °F 30 minutes

### **Annex 1**

This picture shows what type of defects can be detected when doing the quality control and identifying 'failed prints'.

These include: incomplete prints, cracking, deformation, warping.

Check for defects in all the swab observing integrity of the tip and body.



**Annex 2**



Rack made out of ABS in order to withstand the curing temperatures.