Validation of 3D-Printed Swabs
(Class 1 Medical Device)

Nelson Labs®
A Sotera Health company

There are a number of aspects to consider when addressing the appropriateness of a 3D-printed swab for use in the context of COVID-19 testing. Depending on the manufacturer, some of the parts mentioned below might not be necessary. However, according to our experience you should address everything listed in some form.

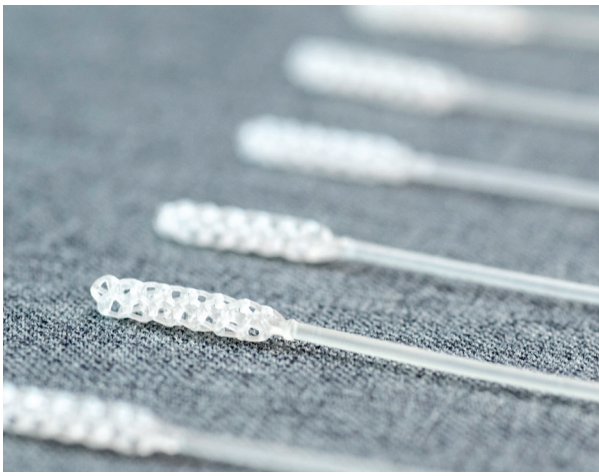

Photo Courtesy of Stratasys & Origin

Necessary Information
- Material(s) of construction
- Processing agents used in manufacturing
- Cleaning/disinfecting agents used after manufacturing

Biocompatibility of Swab to Patient
- Cytotoxicity test
- Toxicological evaluation for sensitization and irritation based on a knowledge of the materials and process chemicals
  - Not necessary to perform extractable and leachable testing

Suitability of Swab for Virus Sample Recovery
- Perform comparison tests for the 3D-printed swab along with approved predicate device swabs which are currently on the market. These tests may include testing patients known to be positive for COVID-19 or possibly using a bench top test designed to simulate the capture of a nasopharyneal sample using a surrogate virus.
- Using the results of the comparison tests, demonstrate adequate detection and capture of sample for the COVID-19 virus or a comparable simulated virus. Also verify the absence of interference from the 3D-printed swab.

Microbiological Quality
- Risk assessment to determine necessary level of microbiological quality
  - Sterility
    General guidelines seem to recommend sterile:
    https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
  - Microbiologically controlled
- If sterility is indicated, determine sterilization process
  - Might be acceptable to initially use abbreviated sterilization process validation
    Under emergency use approval (EUA) approach

Functionality
- Establish specifications – for example:
  - Angle of flexibility without failure
  - Tensile strength
  - Ability to break the applicator stick at appropriate location
  - Consider using predicate swab
  - Consider simulated use test
- If sterile swabs, verify functionality after sterilization process

For more information email
AdvisoryServces@NelsonLabs.com
or call 801-290-7552
to request your free quote today.

Packaging
- Bulk or individually packaged - General guidelines seem to recommend individually packaged:
  https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
- Validate packaging - Might be acceptable to initially use abbreviatedpackaging validation
  Under EUA approach
- Determine shelflife