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Advanced Manufacturing Crisis Production Response (AMCPR)

3D Printed Swab Design and Testing Considerations

3D printed swabs utilized for COVID-19 testing must adhere to standard regulations and should exhibit equivalent performance compared to the standard of care (SOC). Various protocols exist to evaluate the performance, efficacy, and safety of 3D printed swab designs compared to the SOC. Several important swab design requirements and associated risks and testing protocols are outline in the table below. These protocols have been applied to several commercially available 3D printed designs.

Test results from multiple 3D printable swabs can be downloaded here **Updated: August 17, 2020.**

Diagnostic (Dx) Test Compatibility: Nasal swabs are meant to be used as part of a testing kit. 3D printed nasal swabs need to be compatible with the transport tubes, viral transport media and real-time PCR testing protocol to ensure an accurate result.

Mechanical Testing: Nasal swabs need to be strong enough to not break in use, flexible enough to reach the sample site, but not so flexible that they will buckle when inserted into the nasal passage. Mechanical tests are designed to address these design requirements. See custom devices for nasal swab testing.

Patient Safety: Swabs need to be safe for patient use. This covers potential injuries such as nose bleeding (epistaxis), potential foreign body (from a broken swab during use), as well as more global injuries that can occur from an incorrect COVID-19 diagnosis (positive or negative).

Swab Requirements	Dx Test Compatibility	Mechanical Failure	Patient Injury	Potential Risks	Testing Protocol
Must be sterilizable	●	○	●	Unsterile swabs may introduce infection to the patient and may invalidate the test result	3rd Party Report of Sterilization Validation
Must be able to fit through the nasal cavity and reach the sampling location (e.g. nasopharynx, mid-turbinate region)	●	○	○	Inability to complete test; lost patient and staff time	Go/ No-Go Gauge Dimensional Analysis
Sterilized swab should not substantially increase the risk of epistaxis (nose bleeds) as compared to the SOC*	○	○	●	Usually self-limited; in some cases, can lead to excessive blood loss and need for medical intervention	Abrasion Protocol Indentation Protocol
Sterilized swabs should not break while in the nasal cavity	○	●	●	Swab material retained in patient and/or mucosal injury, necessitating additional diagnostic testing and/ or procedures	Go/ No-Go Gauge Fatigue Bending Protocol
Sterilized swab must collect and release a sufficient amount of SARS-CoV-2 sample to render a valid test result (benchmarked to standard of care)	●	○	●	Inaccurate test result, improper patient care delivered as a result	Absorption Protocol Elution Protocol
Sterilized swab must be compatible with (e.g., fit within) the transportation tube	●	●	○	Additional burden on testing staff (e.g., needing to cut a swab that is too long)	Dimensional Analysis Report Breakpoint Function Test
Sterilized swab material must not interfere with the PCR test results	●	○	○	False negative test result, improper patient care delivered as a result	PCR Interference Protocol
Sterilized swab material must be proven safe for mucus membrane contact	○	○	●	Mucus membrane irritation, adverse tissue reaction, patient illness	Material Biocompatibility Analysis report (ISO 10993)

DEFINITIONS: *SOC = Standard of Care; SARS-CoV-2 = the virus that causes COVID-19; PCR = Polymerase Chain Reaction, a step in the diagnostic test for COVID-19 that amplifies the viral genomic material of SARS-CoV-2, to indicate if the virus is present in the patient.*

● **Risk is relevant to the requirement** ○ **Risk area is not primarily applicable**

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