



Face Masks and Respirator Project Checklist per FDA Guidance During COVID-19 Public Health Emergency

Type of mask	BFE (%)	Delta P mmH ₂ O/cm ²	PFE (%)	Blood 160 mm Hg	Flamm	Biocomp	NaCl (%)	In/Ex mmH ₂ O	Valve mL/min
Face Masks NOT Intended for a Medical purpose	≥95	<5.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
*Respirators NOT Intended for a Medical purpose	N/A	N/A	N/A	N/A	N/A	N/A	≥95	≤35 for In ≤25 for Ex	≤30
Medical Face Masks NOT Liquid Barrier Protection	≥95 or ≥98	<5.0 or <6.0	≥95 or ≥98	N/A	Pass	Pass See Page X	N/A	N/A	N/A
Surgical Face Masks that Provide Liquid Barrier Protection	≥98	<6.0	≥98	Pass	Pass	Pass See Page X	N/A	N/A	N/A
*Surgical Respirators that Provide Liquid Barrier Protection	N/A	N/A	N/A	Pass	Pass	N/A	≥95	≤35 for In ≤25 for Ex	≤30
*Filtering FacePiece Respirator that can be Reprocessed before and after reprocessing	N/A	N/A	N/A	N/A	N/A	N/A	≥95	≤35 for In ≤25 for Ex	≤30
Current Face Mask/Respirator Manufacturers of Non FDA or NIOSH Cleared	Contact FDA at CDRH-COVID19-SurgicalMasks@fda.hhs.gov . Refer to the guidance document for information to provide. You will also be required to provide description of testing performed, standards met, such as filtration efficiency, breathability, liquid barrier protection, flammability and biocompatibility.								
Non Face Mask/Respirator Manufacturers Interested in Manufacturing these Masks	Contact FDA at CDRH-COVID19-SurgicalMasks@fda.hhs.gov and describe proposed approach								



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Test/Standards Key: Filtration Efficiency: Bacterial Filtration Efficiency (BFE) ASTM F2101, Latex Particle Challenge (PFE) ASTM F2299, Filtration Efficiency (NaCl) NIOSH TEB-APR-STP-0059(N95) and 0058(N99) Breathability: Differential Pressure (Delta P) EN 14683, Inhalation/Exhalation (In/Ex) NIOSH TEB-APR-STP-007 and STP-003 Liquid Barrier Protection: Synthetic Blood Penetration ASTM F1862 and Leakage (for exhalation valves only): Valve leakage (Valve) NIOSH TEB-APR-STP-0004 Safety: Flammability (Flamm) 16 CFR Part 1610, Biocompatibility (Biocomp) ISO10993 *contact NIOSH for certification which may require verification of fit capability for non-typical filtering respirator face pieces. Fit test data is required for post reprocessing.									
Test Details	BFE	Delta P	PFE	Blood	Flamm	Biocomp	NaCl	In/Ex	Valve
Test Code	BFE101	DPT110	PFE115	SBP210	FTS101	See Page 3	NRC110 for full 20 samples NIOSH pre-certification SCL110 for reduced sampling	NRC120	NRC125
Number of Samples	32 x 3 non-consecutive lots = 96 total	32 x 3 non-consecutive lots = 96 total	32 x 3 non-consecutive lots = 96 total	32 x 3 non-consecutive lots = 96 total	14 x 3 non-consecutive lots = 42 total	See Page 3	20 samples for NRC full NIOSH 3-5 samples for SCL reduced sampling	3	3
How to Submit Samples Sample Submission form can be found here: https://www.nelsonlabs.com/submitt-a-sample/	Ship Samples to: Attn: Sample Login Nelson Labs 6280 S. Redwood Rd. Salt Lake City, UT 84123				-Ensure the sample ID from the Sample Submission Form is clearly visible on the box or bag that masks are sent in -Provide a printed, signed and dated copy of the completed Sample Submission Form (to prevent any delays). -Ensure a copy of the Purchase Order is included				