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| **Sponsor Name:** | **Sponsor Email:** | | | **Sponsor Address:** |
| **FACE MASKS** | | | | |
| **Are Consulting Services Needed?** | | | | |
| Consultation regarding designing a Face Mask | | Sterilization or reprocessing of Face Mask | | |
| **Do you have a Face Mask ready for testing?** | | | | |
| Yes | | No | | |
| **Where are you looking to market?** | | | | |
| U.S. FDA (ASTM F2100-9), *specify level below:*  Level 1  Level 2  Level 3 | | Europe (EN 14683), *specify type below:*  Type I  Type II  Type IIR | | |
| **Who is the targeted end user of these Face Masks?** | | | | |
| Click here to enter text. | | | | |
| **Type of Testing** | | **Not sure what I need** | | |
| **ASTM 2100** *(Select all that apply) – the below sample size recommendations are for FDA submission* | | | | |
| Bacterial Filtration Efficiency (BFE), ASTM  F2101  Differential Pressure EN 14683 | | 96 samples (BFE101) *(32 separate samples from 3 non-consecutive lots for BFE; each sample must be 4 x 4 inches minimum or full face mask)*  96 samples (DPT110) *32 separate samples from 3 non-consecutive lots for Delta P required; each sample must be 4 x 4 inches minimum or full face mask)* | | |
| Latex Particle Challenge (PFE), ASTM F2299  0.1 ASTM F2100  0.3 micron  0.5 micron  1.0 micron | | 96 samples (PFE115) *32 separate samples from 3 non-consecutive lots (each sample must be 5 x 5 inches (12 x 12 cm) min. or full face mask)* | | |
| Synthetic Blood Penetration, ASTM F1862  80 mmHg (Level 1)  120 mmHg (Level 2)  160 mmHg (Level 3) | | 3 sets (SBP210), *(32 masks are required from 3 non-consecutive lots for each pressure , 1 extra for setup)* | | |
| Flammability, 16 CFR Part 1610 | | 3 sets (FTS101), *(14 complete masks from 3 non-consecutive lots = 3 sets)* | | |
| **EN 14683** *(Select all that apply)* | | | | |
| Bacterial Filtration Efficiency (BFE), ASTM  F2101  Differential Pressure EN 14683 | | 5 samples (BFE101) *(5 separate samples for BFE; each sample must be 4 x 4 inches minimum or full face mask)*  5 samples (DPT110) *5 for Delta P required; each sample must be 4 x 4 inches minimum or full face mask)* | | |
| Synthetic Blood Penetration, ASTM F1862    120 mmHg/16.0 kPa | | Type IIR only, 1 set (SBP210), *(32 masks are required, 1 extra for setup)* | | |
| Microbial Cleanliness, ISO 11737-1 | | 1 set (MCM100), *(set of 5 samples required)* | | |
| **Other** *(Select all that apply)* | |  | | |
| Viral Filtration Efficiency  Click here to enter text. | | 5 samples (VFE110), (minimum 5 samples recommended; each sample must be 4 x 4 inches (10 x 10 cm) minimum) | | |
| **Service Offerings** | | **Additional Notes and Comments** | | |
| STAT  GLP | | Click here to enter text. | | |
| **RESPIRATORS** | | | | |
| **Where are you looking to market?** | | | | |
| U.S. FDA (42 CFR 84)  N95 (95% filtration pass criteria)  N99 (99% filtration pass criteria)  N100 (99.97% filtration pass criteria) | | | Europe (EN 149)  FFP1 (80% filtration)  FFP2 (94% filtration)  FFP3 (99% filtration) | |
| *\*N95 ratings are good for general use, however if marketing to an area with a known viral/bacterial outbreak N100 is the most beneficial* | | | | |
| **NIOSH for Respirators** | | | | |
| Sodum Chloride (NaCl) (NRC) | | | *20 samples* | |
| Dioctyl Phthalate (DOP) | | | *20 samples* | |
| Inhalation and Exhalation (NRC) | | | *3 samples* | |
| Valve Leak Test (NRC) | | | *3 samples* | |
| Sodium Chloride (NaCl) | | | *5-7 samples* | |

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| **GOWNS** | |
| **ANSI/AAMI PB70** *(Barrier Level Claim (1-4))* | |
| Gown Type | |
| Isolation Gown *(4 critical areas: chest, sleeve seam, tie attachment (if applicable) & back)*  Surgical Gown *(3 critical areas: chest, sleeve seam, tie attachment (if applicable))*  Coverall *(4 critical areas: chest, sleeve seam, other seams in critical front area & zipper (if applicable))* | |
| Level 1: Minimal risk | |
| Spray Impact Test (SIT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
| Level 2: Low risk | |
| Spray Impact Test (SIT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
| Hydrostatic Pressure Test (HPT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
| Level 3: Moderate risk | |
| Spray Impact Test (SIT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
| Hydrostatic Pressure Test (HPT) | 96 samples per critical area; (*AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 requires minimum 32 samples from 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
| Level 4: High risk | |
| Viral Penetration, ASTM F1671 (VPT) | 96 samples per critical area; *(ASTM F1671 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1671 requires minimum of 32 specimens from 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum)* |

***\*\*\*If not needing to compliance with ANSI/AAMI PB70 see below\*\*\****

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| **Do not need compliance with ANSI/AAMI PB70** *(nor Barrier Level Claim)* | |
| Isolation Gown *(4 critical areas: chest, sleeve seam, tie attachment (if applicable) & back) x 3 non-consecutive lots* | |
| Synthetic Blood Penetration, ASTM F1670  (SBP)  **OR**  Viral Penetration, ASTM F1671(VPT) | *(ASTM F1670 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1670 requires minimum of 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)*  *(ASTM F1671 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1671 requires minimum of 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)* |
| Hydrostatic Pressure Test (HPT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 requires 32 specimens x 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
| Spray Impact Test (SIT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires 32 specimens x 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
| Surgical Gown *(3 critical areas: chest, sleeve seam, tie attachment (if applicable)) x 3 non-consecutive lots* | |
| Synthetic Blood Penetration, ASTM F1670  (SBP)  **OR**  Viral Penetration, ASTM F1671(VPT) | *(ASTM F1670 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1670 requires 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)*  *(ASTM F1671 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1671 requires 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)* |
| Hydrostatic Pressure Test (HPT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 32 specimens x 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
| Spray Impact Test (SIT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 requires 32 specimens x 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |
| Coverall *(4 critical areas: chest, sleeve seam, other seams in critical front area & zipper (if applicable))* | |
| Synthetic Blood Penetration, ASTM F1670  (SBP)  **OR**  Viral Penetration, ASTM F1671(VPT) | *(ASTM F1670 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1670 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)*  *(ASTM F1671 AQL 4%/RQL 20% sampling plan required for FDA Submission (ASTM F1671 32 specimens x 3 non-consecutive lots); each specimen must be 3 x 3 inches (75 mm x 75 mm) minimum. Include 4 extra samples for setup.)* |
| Hydrostatic Pressure Test (HPT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC127 32 specimens x 3 non-consecutive lots); each specimen must be 8 x 8 inches (203 x 203 mm) minimum)* |
| Spray Impact Test (SIT) | *(AQL 4%/RQL 20% sampling plan required for FDA Submission (AATCC42 32 specimens x 3 non-consecutive lots); each specimen must be 7 x 13 inches (178 x 330 mm) minimum)* |