Understanding and Applying ASTM F3502 for Face Coverings for Different Population Needs

Round Table on Standardization of Community Masks for the Current Pandemic

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Relevant Experience and Qualifications

- 37 years of experience in PPE
  - 5 years in U.S. Coast Guard: fire and hazardous materials protection
  - 5 years Texas Research Institute: PPE research, testing & certification
  - 27 years International Personnel Protection: full range of PPE services
    - R&D projects related to PPE materials, design, development, testing
    - Positioning of products against specific standards and regulatory requirements
- Involvement in PPE standards development
  - Original author for ASTM F1862 fluid resistance test; F2100 specification on medical face masks; ASTM F1671 viral penetration resistance test
  - Technical lead for ASTM F3502 standard for “barrier face coverings”
  - Former lead U.S. Delegate to ISO TC94/SC13 on Protective Clothing

New Specification on Barrier Face Coverings

Origin and Key Attributes of ASTM F3502

- Intended to define acceptable “mask” products
- Collaboration group of over 80 individuals
  - Broad interests represented (small & large companies)
  - Many non-US participants
- Approved through full ASTM consensus process in 7 months
- Significant debates over intended use
  - Targeted end users of product
  - Appropriate level of design criteria
  - Minimum types of testing and product qualification
  - Application of conformity assessment

This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: F3502 – 21

Standard Specification for Barrier Face Coverings[1]

This standard is issued under the fixed designation F3502; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

This is the first ASTM standard to address this type of product. The standard was primarily established in response to the global COVID-19 pandemic beginning in 2019 to address a product that is neither a medical face mask per ASTM Specification F2100 for providing source control, nor a respirator for providing inhalation protection as defined by regulatory requirements specified in the United States under 42 CFR Part 84.

This specification is intended to establish a national standard baseline for a source control device. This standard brings value by specifying minimum design, performance, and testing requirements and allowing comparison of products by end users where current guidelines have been limited. Evolving literature suggests that barrier face coverings could reduce the potential for disease transmission, as well as offering a reduction of inhalation particulate matter by the wearer. The focus of this specification is to identify how the device should perform in terms of source control/protection, comfort, and re-use potential. The level of source control/protection depends on how well particles are blocked from going through the barrier face covering and minimizing the amount of leakage that may occur around the perimeter of the barrier face covering. The specific performance property for filtration efficiency provides a greater challenge than most other particulate filtration tests, including BFE, based on the use of smaller particles and more rigorous test conditions. Barrier face coverings must be comfortable enough for individuals to be willing to wear them for long periods of time. Requirements for breathing resistance were incorporated into the specification. The final performance criterion was the potential for re-use of the barrier face covering, so the possibility of re-use was identified in the specification.

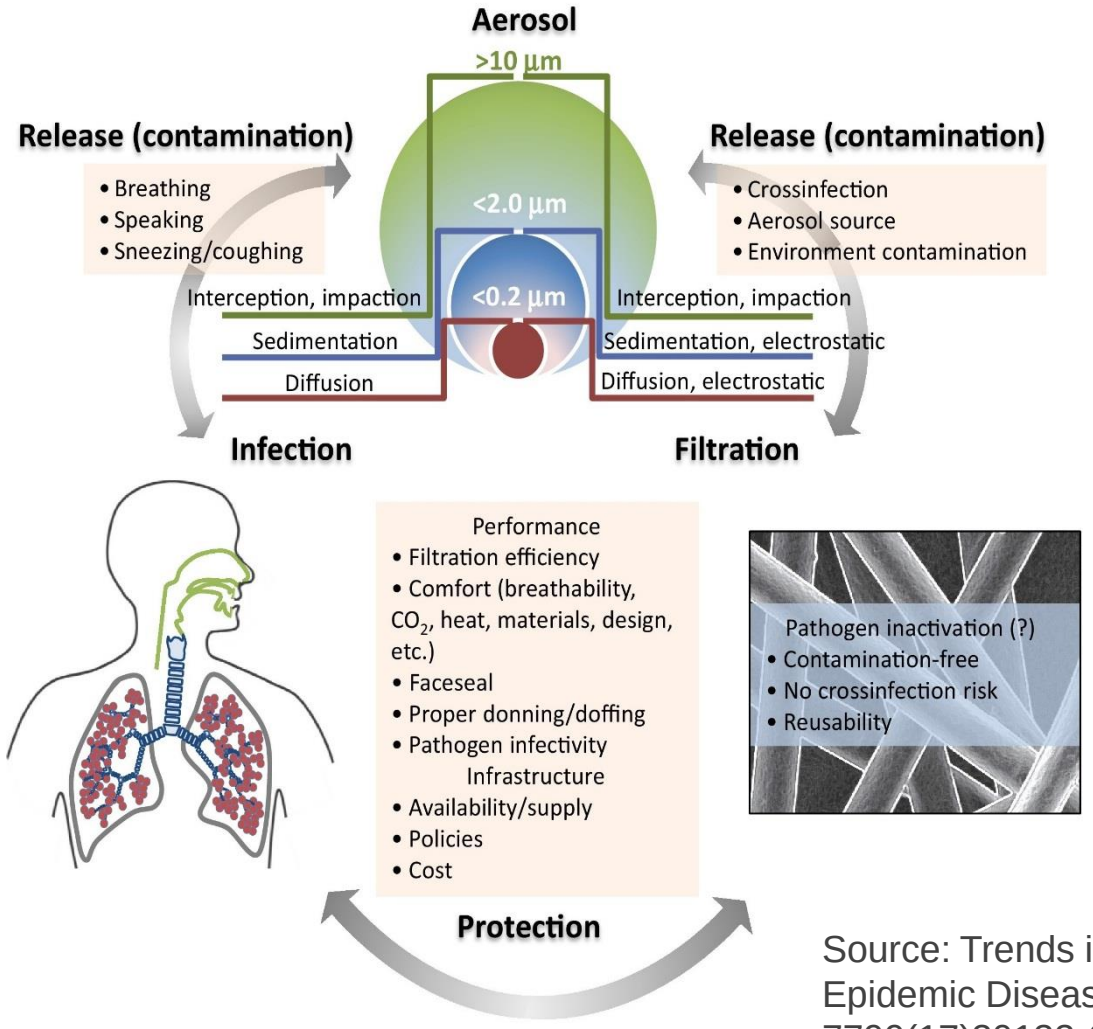
Users of this standard are directed to Section 1 (Scope) and Section 4 (Significance and Use) to understand the specific areas addressed by this standard and its limitations, along with the reasons for choice of specific requirements. Users of this standard are further directed to the specific caveats for this standard that are included in 1.3 – 1.11. The subcommittee responsible for this standard intends to further evolve this specification for addressing new knowledge about disease transmission reduction and barrier face covering design, performance, labeling, conformity assessment, and other aspects of these products’ safety, health, and environmental impact as this information becomes available.

Preventing Transmission by Source Control

- Source control refers to use of well-fitting cloth masks, facemasks, or respirators to cover a person's mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing
  - For face-worn products, product filtration and leakage are key factors

Source: CDC (2021); https://www.cdc.gov/coronavirus/2019-ncov/your-health/effective-masks.html

Preventing Transmission by Protection



- Product prevents exposure to wearer by keeping infectious droplets or aerosols from being inhaled
- Factors affecting effectiveness:
  - Droplet/aerosol size
  - Filtration media capture rates
  - Product seal or leakage on individual
  - Wear comfort and function

Source: Trends in Biotechnology: Respiratory Protection against Pandemic and Epidemic Diseases; https://www.cell.com/trends/biotechnology/fulltext/S0167-7799(17)30133-6

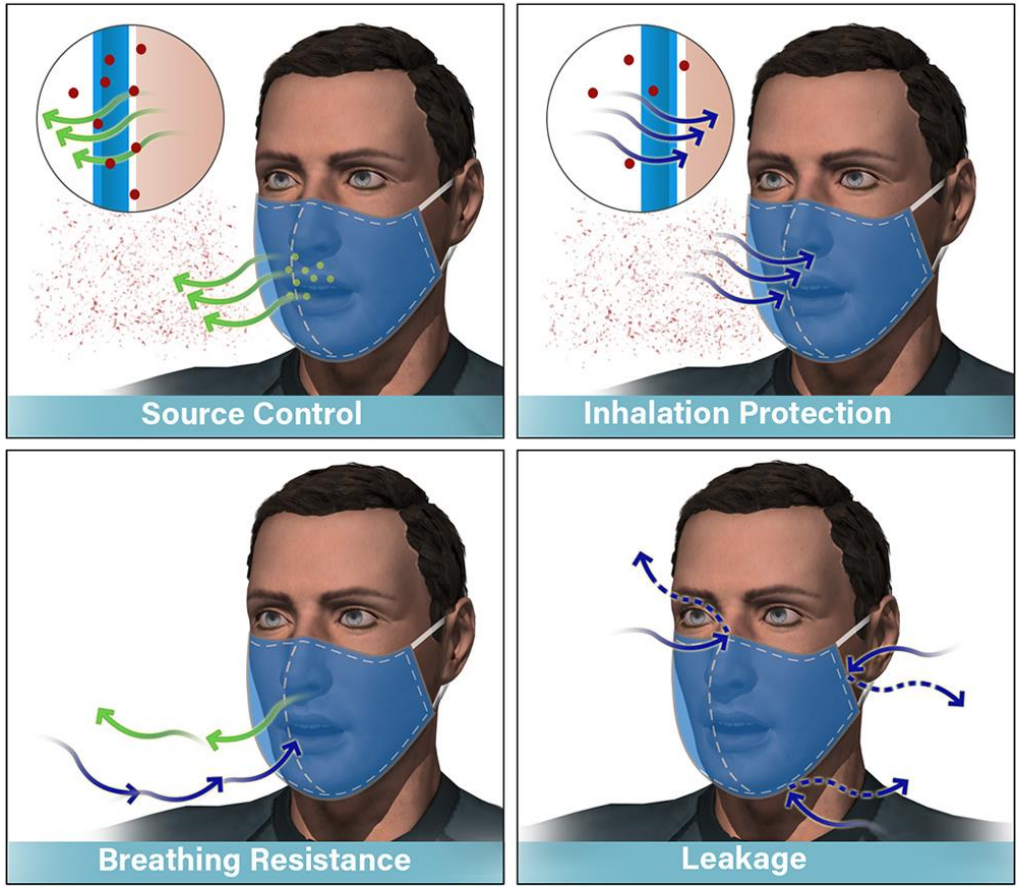
Performance Requirements

Key attributes are assessed

Sub-micron particulate filtration efficiency
- Establishes % particles blocked by product
- Higher values are better

Airflow resistance (inhalation)
- Measures resistance to air passing through product
- Lower values are better

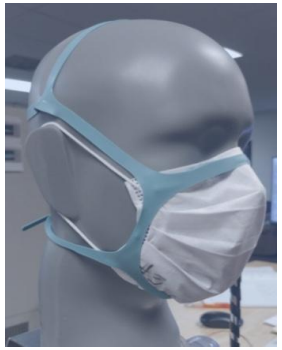
Applies to single use and reusable products
- Reusable products are evaluated before and after maximum number of cycles for manufacturer specified laundering/cleaning procedures



Design Requirements

Standard avoids being design-restrictive

- Kept to a minimum to permit product type flexibility
  - Not be made of irritating or toxic materials
  - Not pose a flammability hazard
  - Cover at least nose and mouth
  - Fit snugly against the wearers face
  - Have a means of head retention
  - Not employ exhaust valves or open vents
  - Be permitted to be available in a universal or multiple sizes (including pediatric sizing)

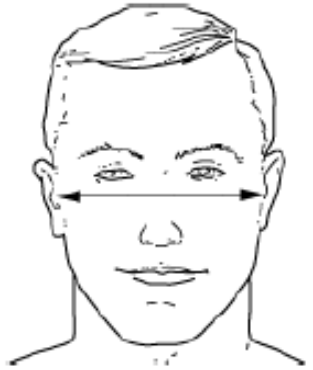


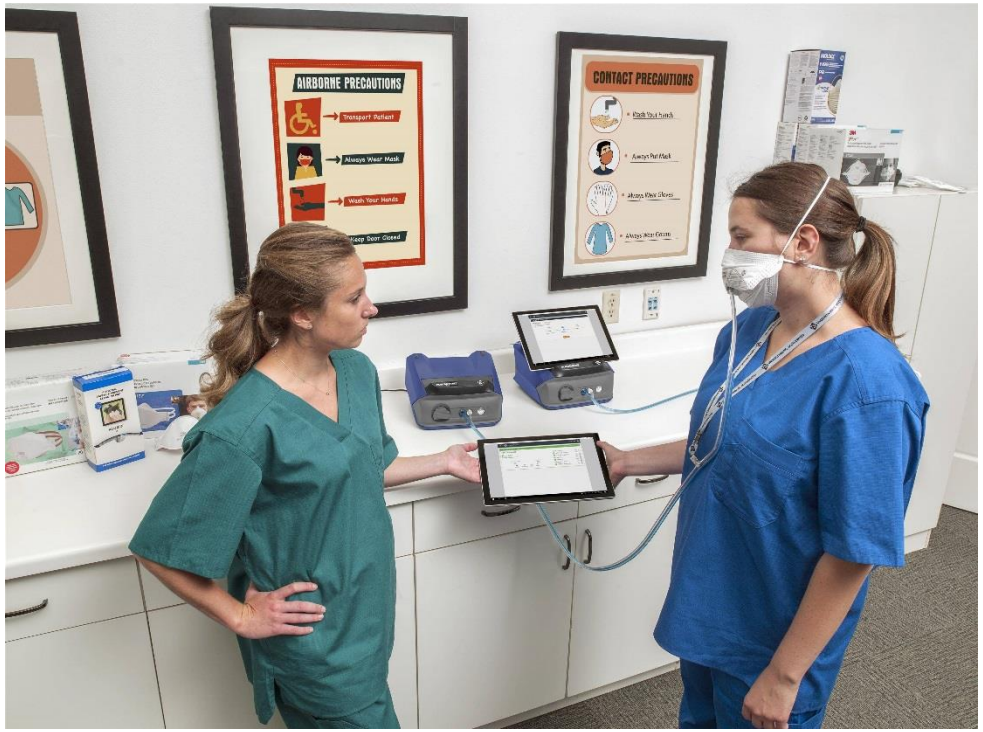
- Manufacturer required to conduct a “design analysis” to assess leakage around edges of BFCs on intended user population

Optional Quantitative Leakage Test

Quantifies key characteristic of performance

- Allows measuring BFC leakage
  - Around edges and through material
- Can be performed to support or supplement design analysis
- References ASTM F3407 with changes:
  - Smaller test subject panel
  - Representation of different facial dimensions
  - No specific passing criteria

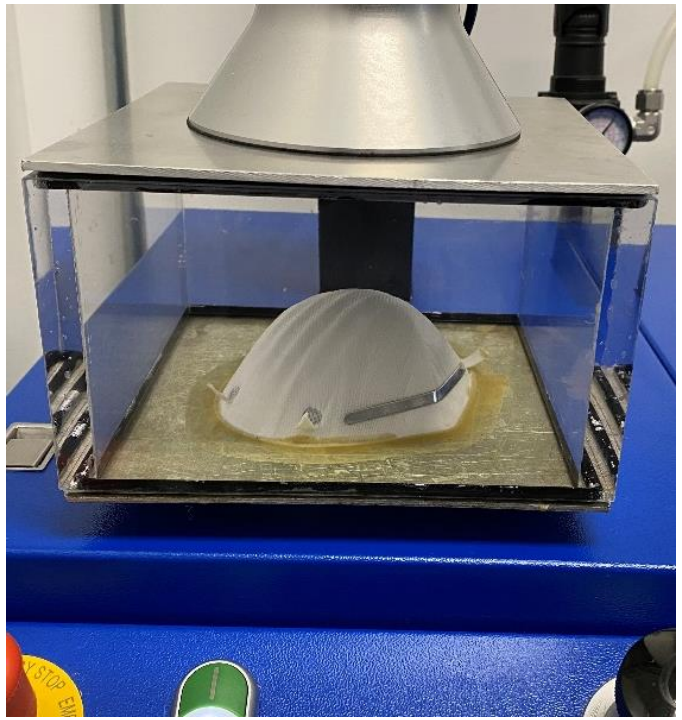




Test Methods

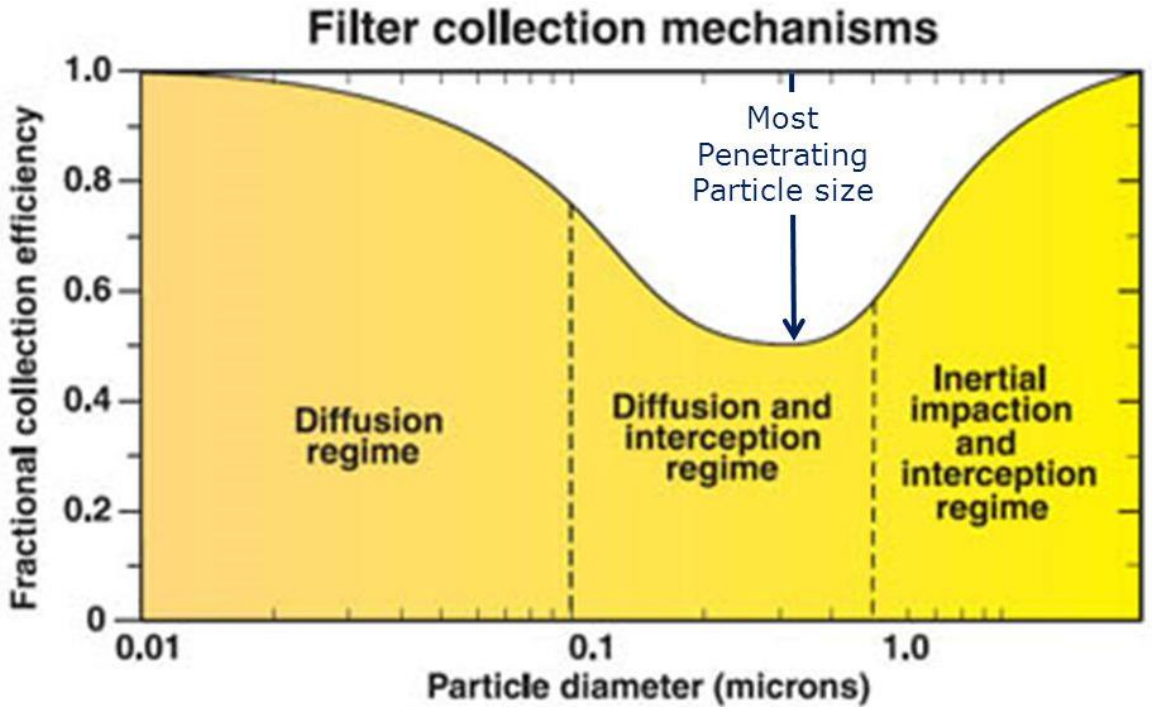
Analogous methodology as applied to respirators

- Test method based on NIOSH procedures
  - Uses NaCl particles aerosol with diameter of 75 nm (aerodynamic diameter of 0.3 μm)
  - Airflow rate of 85 Liters/min adjusted to face velocity of 10 cm/s
- Evaluates full product (not just material)
- Utilizes holder to position face covering test sample on test apparatus
- Provides greater challenge than other filtration tests (much better at discriminating filtration performance)
- Allows for concurrent measurement of airflow resistance



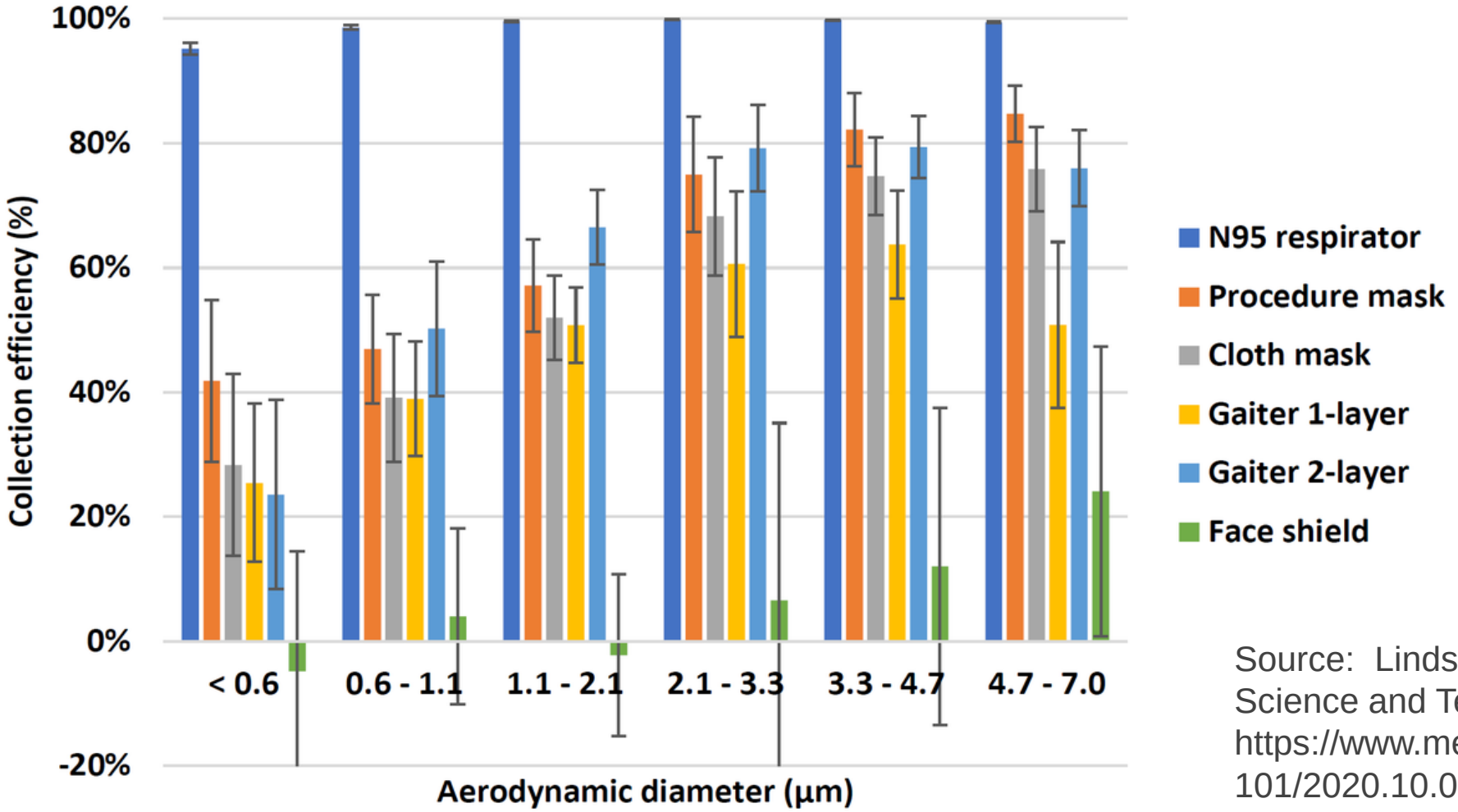
Common test platform, globally available

NIOSH Filtration Testing



- Test method based on 42 CFR Part 84
  - Uses poly-disperse sodium chloride particles
  - Count medium diameter of 75 nm diameter
  - Mass median aerodynamic diameter of 0.3 µm
  - Airflow rate of 85 Liters/min
- Evaluates full product (not just material)
- Provides greater challenge than other filtration tests (much better at discriminating filtration performance)

Filtration Efficiency Differences



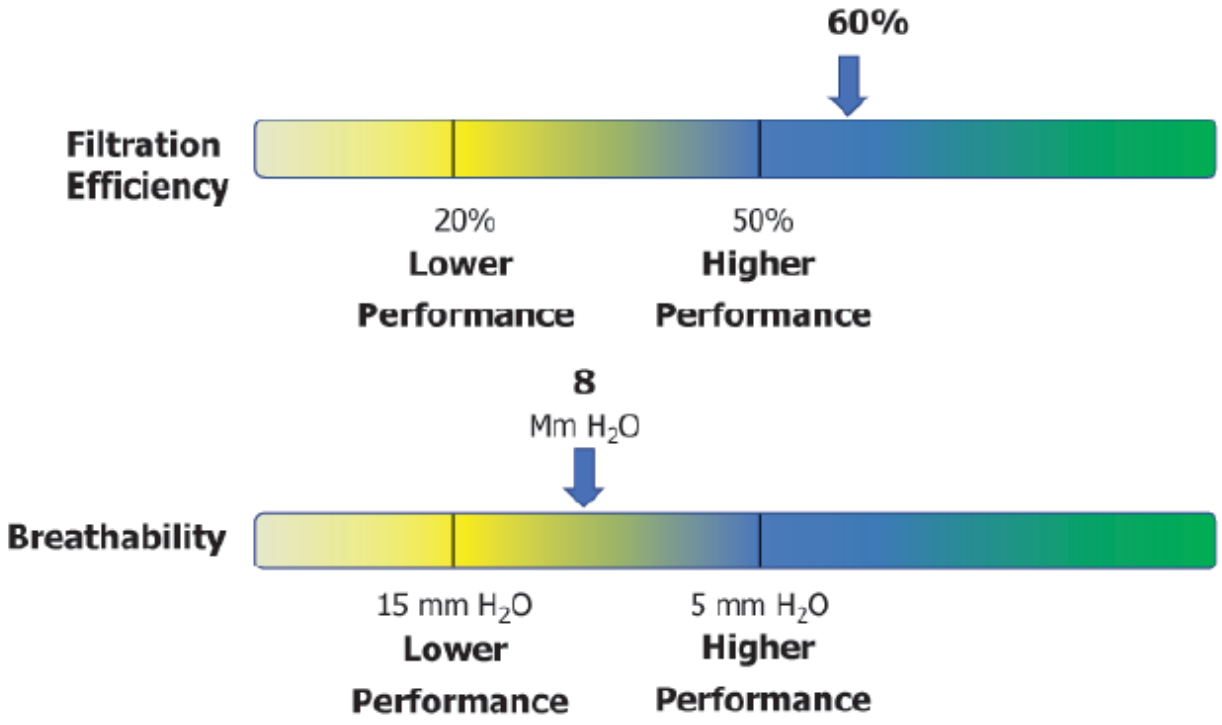
Source: Lindsley et al., Aerosol Science and Technology; https://www.medrxiv.org/content/10.1101/2020.10.05.20207241v1

Performance Classification

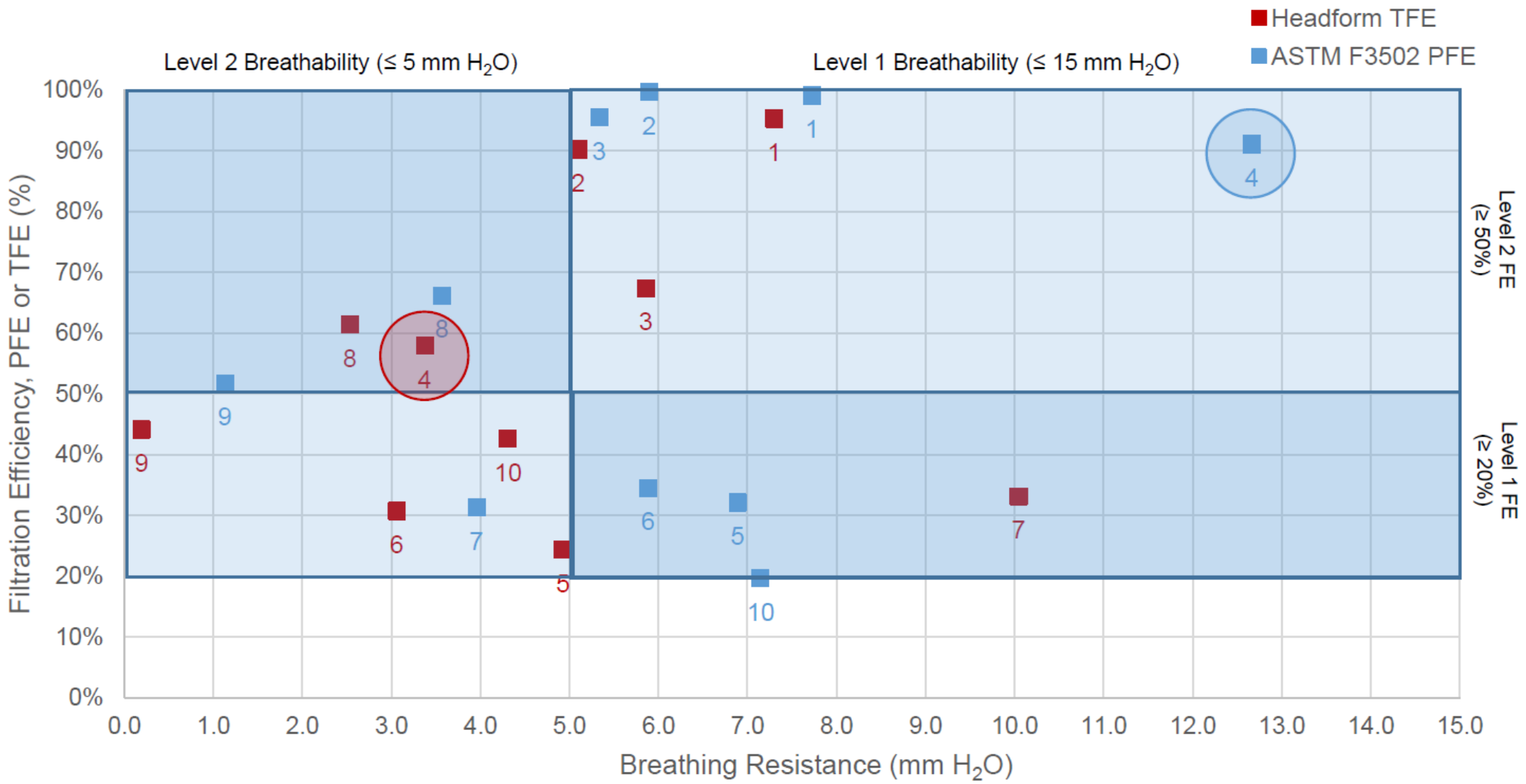
Multiple Levels Allowing Tradeoffs

Property	Level 1	Level 2
Filtration efficiency	≥ 20%	≥ 50%
Airflow resistance	≤ 15 mm H_2O	≤ 5 mm H_2O

Each property is classified separately



Analysis of Total Leakage through Masks



Application of Leakage Information

	Inward Leakage of Face Covering on Uninfected Receiver				
Outward Leakage of Face Covering From Infected Source	No Face Covering (100% Leakage)	80%	60%	40%	20%
No Face Covering (100% Leakage)	15 min	19 min	25 min	38 min	75 min
80%	19 min	23 min	31 min	47 min	94 min
60%	25 min	31 min	42 min	1 hr	2 hr
40%	38 min	47 min	1 hr	1.5 hr	3 hr
20%	75 min	94 min	2 hr	3 hr	6.25 hr

*Assumes that, for a dose with a high probability of infection, the time to infectious dose = 15 min (CDC contact tracing time). Also assumes perfect mixing of the aerosol in the space

Labeling and User Information

Identifies and documents compliant products

- Product label
  - Manufacturer name
  - Product name or model
  - “MEETS ASTM F3502”
- Package label (smallest unit/package)
  - Product performance property classes
  - Materials of constructions
  - Month/year of manufacture
  - Lot or trace number (if applicable)
  - Indication of single use or reusable
  - Expiration date (if applicable)

REPORT OF TESTING AND OTHER INFORMATION REQUIRED BY ASTM F3502-21 SPECIFICATION ON BARRIER FACE COVERINGS											
Manufacturer Name											
Product Name or Model number											
Laboratory Name/Address											
Laboratory Accreditation Credentials											
Sub-micron Particulate Filtration Efficiency (Section 8.1)						Date of Testing					
Test Values (%) by Specimen											
Condition	1	2	3	4	5	6	7	8	9	10	Report Value†
Pristine*											
After Wash**											
Air Flow Resistance (Section 8.2)						Date of Testing					
Test Values (mm H_2O) by Specimen											
Condition	1	2	3	4	5	6	7	8	9	10	Report Value†
Pristine*											
After Wash**											
* Description of Condition if Other than Pristine (identify where performed)											
** Description of Laundering or Cleaning Conditions Applied (identify where performed)											
Description of Approach Applied as Part of Product Design Analysis (provide supporting documentation, as needed)											
Results of quantitative leakage assessment with leakage ratio (if applicable – document full findings in separate report)											
PERFORMANCE CLASSIFICATION***				Sub-micron Particulate Filtration Efficiency				Air Flow Resistance			

Conformity Assessment / Regulatory Oversight

ASTM F3502 has been applied in U.S. and other countries

- Specification requires ISO 17025-based testing
- FDA “recognized” standard 2 weeks following adoption
  - Considers products “medical devices” (currently unclassified)
  - Part of enforcement guidance
- CDC developed additional specifications for workers
  - Developed Workplace Protection/Workplace Protection Plus
- Referenced in OSHA Emergency Temporary Standard
  - Likely to be proposed in infectious disease regulations
- Cited by World Health Organization
- Being adopted by other countries

Workplace Protection	Workplace Protection Plus
Filtration efficiency ≥ 50%	Filtration efficiency ≥ 80%
Leakage ratio ≥ 5	Leakage ratio ≥ 10

Supplemental CDC Guidance

Current CDC/NIOSH Website F3502 Postings

https://wwwn.cdc.gov/PPEInfo/RG/FaceCoverings

Manufacturer	Product Name or Model	Single Use/ Reusable	Particulate Filtration Efficiency(%)	Breathability (mm H2O)	Leakage Ratio[1]	Workplace Performance/ Workplace Performance Plus Rating[2]
3M Contact: Linda Eichinger	Advanced Filtering Face Mask AFFM	Single	99% - Level 2	13 mm – Level 1	73	Workplace Performance Plus
Aries Contact: Jane Foreman	Aries Barrier Face Covering	Single	83% - Level 2	5 mm – Level 2	n/a	n/a
Impulse Fashion, Inc. Contact: Donald Roberts	Hope Mask	Reusable	22% – Level 1	12 mm – Level 1	n/a	n/a
Buckeye Mask Company Contact: Carla Macklin	PFM-153081	Reusable	24% - Level 1	5 mm – Level 2	n/a	n/a

24 products have been listed through early 2022 (the first four listings are shown)

Proposed Revisions to ASTM F3502

- Changes to introduction
- Use of the term aerosol to refer to particles and droplets
- Clarification of product performance for both source control and inhalation protection
- Restriction of claims for anti-viral or anti-microbial performance
- Better definition for using of non-toxic or irritating materials
- Procedures to address logos and embellishments
- Updates to conformity assessment requirements
- Provision of sample declaration form