TPA Network
Research Consortium

UPDATED

How to Avoid Buying Your Family and Employees

Counterfeit and Substandard Reusable Face Coverings

Whether an individual, corporate or government buyer, ***don't fall victim to a dishonest manufacturer.***

U.S. Customs and Border Protection | 10,080 Counterfeit Surgical Masks Seized in Cincinnati

THE WALL STREET JOURNAL.
Low-Quality Masks Infiltrate U.S. Coronavirus Supply

INDEPENDENT
"Total disregard for people's lives":
Hundreds of thousands of fake masks flooding markets as coronavirus depletes world supplies

The New York Times
FEMA Sends Faulty Protective Gear to Nursing Homes Battling Virus

U.S. Immigration and Customs Enforcement
DHS prevents millions of counterfeit N95 masks from reaching hospital workers, first responders

USA TODAY
Up to 70% of KN95 masks imported from China don't meet filtration standards, study says

FORTUNE
'It's just unprecedented': Counterfeit face masks are reaching frontline health care workers in U.S.

VICE NEWS
European Countries Are Throwing Out 'Rubbish' Chinese - Made Masks and Coronavirus Tests

TRANSNATIONAL ALLIANCE TO COMBAT ILLICIT TRADE
TRACIT.ORG

COVID-19: PRODUCT FRAUD ALERT
WARNING: FAKE, FALSIFIED AND SUBSTANDARD MEDICAL PRODUCTS AND MEDICINES

sky news
Coronavirus: Millions of sub-standard face masks seized at Heathrow since outbreak

INTERPOL
Global operation sees a rise in fake medical products related to COVID-19

FOX NEWS channel
Washington hospitals pulling fake N95 masks off shelves: " We're horrified "

CONSTRUCTION MANAGER
HSE issues warning over substandard face masks

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
Counterfeit Respirators: Misrepresentation of NIOSH-Approval

The advent of the new national general-purpose face covering standard in February 2021 gave rise to three unintended consequences: substandard and counterfeit face coverings…and lax and dishonest manufacturers willing to make them. Ergo, the need for you, as a face covering consumer, to be aware of, concerned with and equipped to identify and avoid them. This ten-minute read will provide you with everything you need to know to feel confident in your future purchase decisions.

The Importance of Trustworthy Face Covering Labels

Face coverings are critical to our ridding the world of CoVid-19: if they are effective at both *curbing viral spread* and *protecting the wearer* and, if they are *breathable* and *comfortable* enough to wear all day. Face coverings must also be *safe*, *non-toxic*, *environmentally friendly* and *affordable*. The good news is that the just-released national standard for (barrier) face coverings contains minimum performance thresholds, fit and construction requirements that will surely improve the overall quality of face coverings, enhance end-user awareness and provide consumers with the means by which to assess and compare them.

MEETS ASTM F3502, SPECIFICATION FOR BARRIER FACE COVERINGS. THIS PRODUCT IS PRIMARILY INTENDED AS A MEANS OF SOURCE CONTROL FOR MINIMIZING THE PROJECTION OF EXPELLED MATERIALS FROM THE WEARER'S NOSE AND MOUTH.

Consumers rely upon product labels to be authentic as they are a key source of transparent, expert-certified product-specific information that can be relied upon to be accurate, complete and credible. The veracity of a face covering's label and the information it contains is a prerequisite; as labels that are untrustworthy can induce a consumer to purchase substandard or counterfeit face coverings that may expose them to risk, injury or illness by fostering a false sense of wearer and workplace security. Laws protect consumers against false claims and misrepresentations whether viewing a TV commercial or reading a product label. This includes face covering manufacturers that misrepresent certification or compliance with all relevant statutes, regulations and standards, including the new rigorous and complex *ASTM F3502-21 Standard Specification for Barrier Face Coverings*.

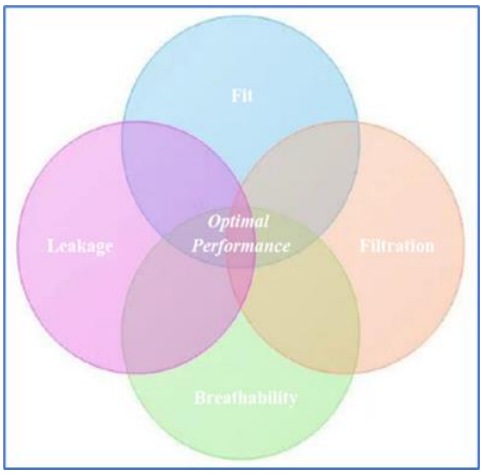
Counterfeit vs. Substandard Face Coverings

A substandard face covering is one that fails to satisfy the standard's minimum requirements. A manufacturer (distributor or retailer) may or may not be aware of this. It occurs when the manufacturer is unaware of the standard or its requirements, or if it mistakenly believes that its product satisfies it. When exposed, these companies will use the "ignorance of the law" excuse.

A counterfeit face covering is one that is untruthfully claimed to comply with the new standard's requirements, when it is not. The claim is typically the result of a promoter's blatant disregard for regulatory compliance or willingness to take the risk of being exposed if challenged. These manufacturers believe that "it is easier to get forgiveness, than to seek permission".

Identifying Noncompliant Face Coverings: Label Veracity

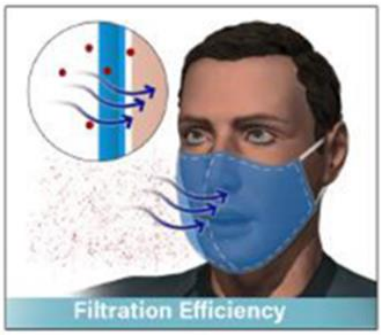
The standard's performance, labeling, reporting and compliance substantiation requirements are unambiguous. To evidence compliance, manufacturers must make a *Manufacturer Declaration of Conformity (MDOC)* available – having the raw results and calculations of each of the design, fit, performance, bio-compatibility and leakage tests. See the specimen *MDOC* faceplate on page 6.



To evaluate ongoing performance capability after prolonged use over its service life, the fit, filtration and breathability test must be performed with new samples and ones that have endured the manufacturer's claimed number of maximum laundering cycles, per its instructions. The lower performance result is noted on the product label. *Consumers (individual, bulk, reseller and retailer) are advised to request a copy of the MDOC to verify each product claim.*

The *Manufacturer Declaration of Conformity* focuses primarily on the measures that most influence optimal performance (fit, leakage, filtration and breathability) while addressing the standard's bio-compatibility and textile requirements. What follows are the five major things that consumers need to do in order to substantiate the veracity of the claims made of compliance with the new face covering standard, and to identify products that may potentially be substandard or counterfeit.

1. *(Sub-Micron Particle) Filtration Efficiency*



This test measures the degree to which infected particles flow through the face covering to possibly be inhaled by the wearer. Manufacturers must display the lab name, accreditation credentials, test date, individual test values and calculations.

Filtration performance is measured on a scale from 1% to 99.7%. A result of ≥ 20% is needed to achieve the standard's minimum *Lower Performance* or *Level 1* rating whereas BFC's with results ≥ 50% are rated as *Higher Performance* or *Level 2*.

Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)	"My Mask"
Filtration Efficiency	≥ 20% F1	≥ 50% F2	F2

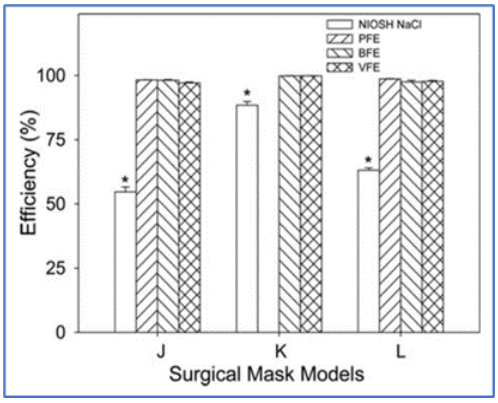
Manufacturers must clearly display their BFC's ratings on the product labeling. Manufacturers may use various visual rating schemes like these to convey its BFC performance classification / rating.

Why are the standard's 20% / 50% filtration levels so much lower than the 97% PFE claims of many mask makers?

Note: The particle filtration efficiency tests required to be passed to demonstrate compliance with ASTM F3502-21 are very different, and far more challenging, than the traditional, familiar FDA PFE tests that generate much higher results.

This standard created a new product class: barrier face covering. To facilitate meaningful consumer evaluations and comparisons of face coverings for source control and wearer protection, this standard's performance tests were purposely selected and modified to generate filtration performance results that are as comparable as possible to those of other face covering options (e.g. surgical/procedural masks, K/N95-type respirators, etc.). Ergo the move to the NIOSH-based scale.

Filtration testing is done by measuring the percentage of projected particles that penetrate a face covering. To visualize the difference in test methods, envision an underhand softball pitch versus a major league baseball pitch. The PFE test methods that are most commonly used by face covering manufacturers are employed by the FDA; whereas the test method used in the new standard is a modified version of the NIOSH-based test used on N95s. The differences start with the particle: common PFE tests use latex spheres; the NIOSH test uses NaCl aerosol particles. Other variables include particle size, distribution variance and polarity (neutralized, unnaturalized, blend); the projection velocity; the distance traveled; whether the textile or actual BFC itself is tested; the test article's conditioning; the number of samples tested; and the calculation formula.



NIOSH PFE testing is rigorous and produces relatively low results. The exhibit* at right compares the results of FDA-type PFE testing with NIOSH-based testing (using surgical masks as they perform similar to most BFCs). Note the great variance in results: those tested at ≥ 90% with the traditional PFE test method scored < 60% when tested using the NIOSH method. *More recent studies that measured the PFE of several popular BFCs using the F3502-21 test method produced results as low as 5% to no more than 50% !*

Bacterial filtration efficiency (BFE) and viral filtration efficiency (VFE) are other filtration measures that evaluate larger aerosols under less severe test conditions. As such, although they may be optionally presented by the manufacturer to supplement the required NIOSH-based tests, they too will generate results that are much higher, but not comparable.

The PFE test must be performed by an ISO/IEC 17025 lab accredited to perform it, on ten new samples and ten samples that have endured the manufacturer's claimed number of maximum launderings. *No other PFE test may be substituted*.

* Exhibit from: "A Comparison of Facemask and Respirator Filtration Test Methods", a study conducted by scientists from the NIOSH National Personal Protective Technology Laboratory (that oversaw the development of ASTM F3502-21) and Nelson Laboratories. Published in 2017 in the Journal of Occupational and Environmental Hygiene and Laboratories. www.ncbi.nlm.nih.gov/pmc/articles/PMC7157953/pdf/UOEH_14_1225157.pdf

2. Breathability / Airflow Resistance

This test assesses breathability by measuring the air flow pulled through the face covering. It has the same test results reporting requirement as the PFE test.

Airflow resistance is measured in millimeters of water gauge pressure (mm H2O), where lower values indicate easier breathing. A result of ≤ 15 mm H2O is needed to achieve the standard's minimum *Lower Performance* or *Level 1* rating whereas BFCs with results of ≤ 5 mm H2O are rated as *Higher Performance* or *Level 2*.

Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)	"My Mask"
Breathability	≤ 15 mm H_2O B1	≤ 5 mm H_2O B2	B1

This rating must be clearly displayed on the product's label. Here again, visual rating schemes like these can be used to convey this BFC rating:

Unlike the PFE test that can be easily gamed by an unscrupulous manufacturer, this test is unlikely to be tampered with as it is performed on the same apparatus as the PFE test, and it is subject to less variation. Like the PFE test, this test must be performed by an ISO/IEC 17025 lab accredited to perform it, on ten new samples and ten samples that have endured the manufacturer's claimed number of maximum laundering cycles. *No other air-flow test may be substituted.*

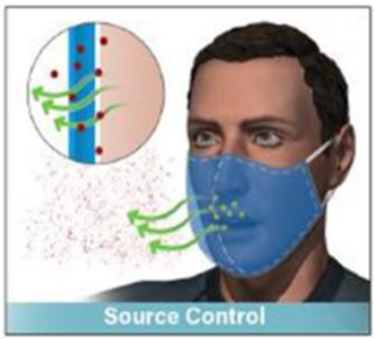
The Filtration vs. Breathability Tradeoff

The two-tier rating system is intended to draw attention to the *potential trade-off between higher levels of filtration efficiency and breathability.* Face coverings with a high filtration efficiency rating may, however, offer less breathability…or vice versa.

Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)
Filtration Efficiency	F1	F2
Breathability	B1	B2

3. Leakage Tests and Fit Assessments for Source Control

How to best evaluate the overall performance of a community face covering (whether worn for source control or wearer protection) has eluded many PhDs; in part, because coverage and fit greatly impact air leakage and filtration efficiency.



Source control tests measure the extent that infected particles flow from the wearer through the face covering into the air. While there is no proven test to accurately measure this flow, a face covering's design may be evaluated for its ability to focus exhaled air to go through the covering's fabric rather than leak into the atmosphere.

PFE and air flow testing must be complimented by an assessment of the sealing ability and leakage through and around the mask. *A Design Analysis is required to assess fit, potential gaps and leakage pathways* that can include a qualitative assessment or a Quantitative Leakage Assessment. This test must be performed pre- and post-laundering. A 10-person NIOSH Bivariate Panel is required to ensure the accuracy of the fit/leakage assessment, performed on each product size.

There is no easy way for consumer to evaluate the results of fit, design and leakage assessments, and the standard does not identify pass/fail criteria. Nonetheless, one BFC's results may be compared to another, and, the mere fact that the manufacturer had the assessments performed and included in its *Manufacturer Declaration of Conformity* evidences its understanding of the standard's requirements and its willingness to be transparent. That said, when a BFC demonstrably fails an assessment, it will likely be obvious.

4. Biocompatibility

Biocompatibility is the property of a material being compatible with living tissue; a key factor as it relates to products that are intended to be in direct contact with the wearer's skin for extended periods. Cytotoxicity, dermal irritation and skin sensitization testing are biocompatibility measures that assess the toxicity, irritation, allergic reaction and hyper-sensitivity potential of the materials and chemicals used on the face covering, especially after repeated, prolonged use.

ASTM F3502-21 requires compliant face coverings to pass the ISO/ANSI/AAMI 10993-5/10 group of biocompatibility tests or provide results from other independent reliable sources that evidence that its skin-touching materials (treated with the same chemicals used in their creation or subsequently added) passed tests equivalent to ISO/ANSI/AAMI 10993-5/10. These test results must be included in the *Manufacturer Declaration of Conformity*. They are easily understood.

Despite its measures to ensure that compliant face coverings meet certain minimum biocompatibility requirements, in the author's opinion, the standard falls short by failing to alert consumers to the many other potential health, safety and environmental concerns that are attendant to wearing, and breathing through, a face covering for an extended period. Indeed, it states that it "does not address the use of antimicrobial or antiviral materials, finishes, or mechanisms" and "does not purport to address all of the safety concerns, if any, associated with its use". It further states that "it is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use". Lastly, it notes that "the use of antimicrobial materials, finishes, or mechanisms is generally subject to regulatory oversight by government agencies…[e.g., the EPA and FDA]...which applies additional safety and efficacy requirements to these products." While this is all well and good, in the author's opinion, the standard leaves it up to the consumer to fend for him/herself as it relates to these critical concerns.

Efficacy, cost-effectiveness and value are certainly important aspects of general-use face coverings; however being safe, healthy, and ecofriendly is of equal concern to many. This standard, though comprehensive in many ways, fails to identify several potential safety, health and environmental risks/hazards that may be the rightful concern of a face covering users.

These risks relate to the use of:

1) antimicrobial agents; 2) activated charcoal filters; 3) nanoparticles; 4) toxic fabrics; and, 5) the impact of viral bioburden build-up on the face coverings surfaces. Each of these topics are discussed in detail in the Appendix.

While it is true that the new standard is focused on other more fundamental aspects of general-purpose face covering construction, by allowing labelling that does not address these issues, it fails to meet one of the standard's stated objectives which is to lessen "consumer confusion" with regard to face covering purchasing. Further, an argument can be made that a national face covering standard that is silent in this area not only fails to fully fulfill its intended purpose but is remiss by not warning the public about potential risks and failing to extinguish pre-existing misconceptions. Given this, at this juncture, that author believes it is important that face covering end users become familiar with each of the specific special manufacturer claims made about their face coverings by demanding information and data to verify each.

Note: The author has lobbied standards organizations/consumer groups across the globe to get them to adopt consumer advisory product labels and warnings along these lines:

> " *There are several aspects that relate to the material composition and design of barrier face coverings that are not addressed in this standard but warrant attention relative to the safety, health, and environmental impact of these products including, but not limited to potentially toxic finishes, inhalable substances from materials, and bioburden inhibitors. Therefore, it is important that end users familiarize themselves with the specific special claims being made for products and ask for information to verify such claims. "*

5. Textile

Manufacturers must evidence that their face coverings pass the Flammability test (per 16 CFR 1610). They must also identify the composition of the face covering's materials by performing a Fiber Composition test (per 16 CFR Part 303). These test results must be included in the *Manufacturer Declaration of Conformity*. They are easily understood.

Face Covering Manufacturer Responsibility and Liability

Manufacturers have an obligation to properly provide details of their product and warn of any safety hazards they might pose.

Untruthful, deceptive, misleading, inaccurate, incomplete or ambiguous advertising or labeling harms consumers by inducing them to purchase products that may expose them to risk, injury or illness. Misrepresentation can include falsely portraying a product as superior to a competitor; and misrepresenting standards certification or compliance. Further, any party involved in the promotion of a misrepresented product can be held liable for false claims *(e.g., marketing and advertising agencies, producers, distributors, resellers, product endorsers and retailers in certain circumstances).*

As it relates to general-purpose face coverings, this could easily manifest itself in the real world if, by example, a company were to purchase substandard or counterfeit general-purpose face coverings for its workforce only to find that they are less effective, at source control and wearer protection, and likely the cause of an avoidable viral workplace outbreak that occurred by giving wearers a false sense of security about their face covering's ability to curb the spread and provide wearer protection.

Reasons for Noncompliance

Noncompliance with the new face covering standard can occur "accidentally" or deliberately: neither is excusable, however.

Many BFC makers have jumped the gun and are *deliberately* making untruthful claims about their products' being compliant. The fact is that ASTM F3502-21 is very new, and few labs are prepared or accredited to perform the specific design, fit and performance tests needed to be compliant. Conversely, *many BFC manufacturers are simply unaware of the standard, while others don't understand it or mistakenly believe that past performance testing results are adequate to satisfy this standard.* Either way, these claims are made by counterfeiters solely to gain competitive advantage... or lax manufacturers that have no concern for putting the public at risk with substandard face coverings. Ergo, even if you are prone to trusting, *verify anyway*.

Regulatory Enforcement

ASTM F3502-:21 was created and written with the intent that government regulatory agencies would adopt and enforce it. As of April 1, 2021, this is the status of the adoption and enforcement situation:

- The FDA adopted the standard as of March 1, 2021;
- OSHA will soon likely update its *COVID-19 Emergency Temporary Standard* to incorporate it;

These regulators have expressed a keen interest, and the capability and history of, policing, investigating and prosecuting the variety of violations that are attendant to manufacturing, promoting and selling substandard and counterfeit BFCs:

- Federal Trade Commission (Bureau of Consumer Protection and Bureau of Competition);
- Department of Justice (Health Care Fraud Unit); and the
- Consumer Protection Divisions of various state Attorneys General offices

Indeed, these regulators represent the only means by which both consumer and competitor interests can be fairly addressed.

To file a complaint or request for an investigation:

FDA: www.fda.gov/consumers/consumer-updates/how-report-product-problems-and-complaints-fda

OSHA: www.osha.gov/workers/file-complaint

FTC Bureau of Consumer Protection: www.ftc.gov/about-ftc/bureaus-offices/bureau-consumer-protection

FTC Bureau of Competition: www.ftc.gov/about-ftc/bureaus-offices/bureau-competition

DOJ Health Care Fraud Unit: https://www.justice.gov/criminal-fraud/health-care-fraud-unit

Conformity Assessment

Consumers and end-users expect the products they purchase to perform in conformance with the standards they claim to meet. *"Conformity assessment" is the process by which a manufacturer demonstrates that its barrier face covering fulfills all of this standard's specified requirements.* A *Manufacturer Declaration of Conformity* is a written declarative statement that clearly states that the BFC has met ALL of this standard's requirements and intended to instill confidence in the purchaser and end-user that the product that they are relying upon conforms to the standard's requirements.

Conformity assessments take a variety of forms appropriate to the nature and level of the subject risk/ hazard…and whether the regulation pursuant to it will be mandatory or voluntary. By example, the requirement to establish "proof" for (or the veracity of) a conformance claim should be more stringent for critically important N95 respirator devices than face coverings designed largely to curb community spread. Within the process of establishing a standard's conformity assessment requirements, there is recognition of the delicate tradeoff between the difficulty and cost of demonstrating conformity and the risk at hand.

ASTM F3502-21 Manufacturer Declaration of Conformity

ASTM F3502-21 requires following Model A, Annex A of ASTM F3050: Standard Guide for Conformity Assessment of PPC&E which permits the manufacturer to self-declare compliance; with the single caveat being that it contains a variance that *requires the use of only accredited laboratories for the sub-micron particle efficiency and air flow tests* (the two mandatory performance requirements). The only role of the accredited laboratory is to perform these two tests. This *MDOC* extends to all design, performance, reporting, labeling, user information, and conformity assessment requirements. The manufacturer must also meet all of the Model A requirements for other aspects of conformity assessment that address testing/inspection facilities, a quality management system, records retention, ongoing conformity recalls and safety alerts, and marking.

Note: In that any facepiece's performance is a function of various filtration efficiency, breathability and fit (leakage) factors, that must be considered in their totality, there is no provision for any form of provisional, limited or partial conformance. No claim to conformity with a portion, segment or subset of requirements may be made. Only MDOC's that state that the barrier face covering conforms to the complete specification are permitted.

Note: ASTM F3502-21 ensures that BFCs meet its requirements throughout their service life. As such its *fit, filtration and breathability tests must be performed on new/pristine samples and again with samples that have endured the manufacturer's claimed number of maximum laundering cycles, per its instructions.* The average of ten test samples of each (pre- and post-) test round is calculated and the lower of the two test results is used for the product label.

Guide F3050 requires the manufacturer shall maintain (or cause to be maintained by subcontractors) all design, performance, inspection, and test data used for the MDOC and shall such upon request to the purchaser or any authority having jurisdiction. This shall include test methods, test data and related documentation pursuant to

- Design Analysis (qualitative) in the form of a dimensional analysis, computer modelling, head or head-torso forms analysis or a quantitative analysis per ASTM Test Method F3407
- Particle Filtration Efficiency testing in accordance with the ASTM F3502-21's unique specs,
- Breathing /Airflow Resistance testing in accordance with the ASTM F3502-21's unique specs,
- Fiber Composition testing per 16 CFR Part 303,
- Dermal Irritation testing per ISO/ANSI/AAMI 10993-5 and -10,
- Flammability testing per 16 CFR 1610,

*Consumers (individual, bulk, reseller and retailer) should request a vendor's **Manufacturer Declaration of Conformity** to verify all product claims. Any reputable seller will have its **MDOC** immediately available or proudly displayed on its website.*

ASTM F3502-21 contains the *Manufacturer Declaration of Conformity* face plate below. The BFC' s design, fit, leakage and bio-compatibility test results are also required to be included in the *MDOC* to evidence full compliance with the standard.

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**			

† Report the lowest value of filtration efficiencies measured

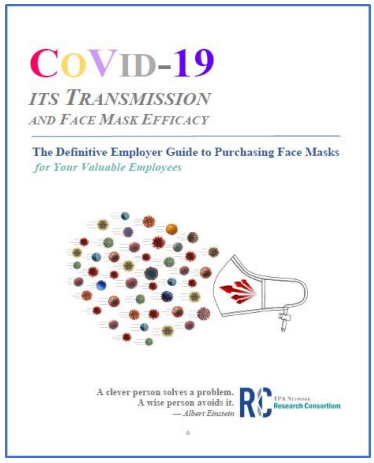
† Report the highest value of air flow resistances measured

*** Base performance classification on lowest sub-micron particulate filtration efficiency value for all conditions evaluated (≥ 20% = Lower performance; ≥ 50% = higher performance). Base performance classification on highest air flow resistance for all conditions evaluated (≤ 15 mm H_20 = Lower performance; ≤ 5 mm H_20 = Higher performance).

The raw test value for all tests, measures and assessments must be furnished in the MDOC; not just calculated results. By example, the raw test values of both the Sub-Micron Particle Filtration Efficiency test and the Air-Flow Resistance test, performed on each of the ten pre- and post-wash samples, is reported, as well as the calculated average. This is key data for consumers as the "average" figure alone is inadequate; here's why. The average of 3+3+3+5+11 is 5 and the average of 4+5+5+5+6 is also 5. The variance in values in the first case portends a likely lab testing issue or manufacturer quality control problem; this is not indicated in the second example. Consumers need this data; ergo its inclusion in the *MDOC*.

About the Author and the Research Consortium

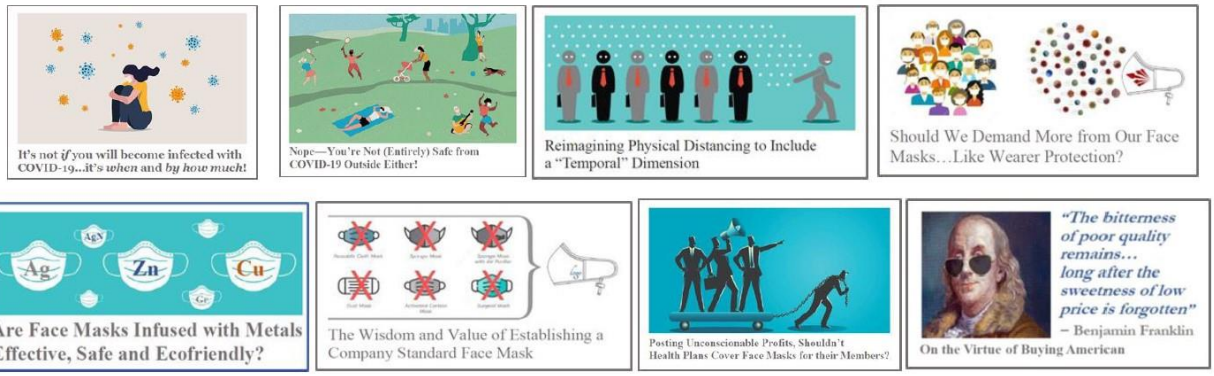
A seasoned industry veteran having four decades of management-level experience in the self-funded, managed care and outsourcing sectors, Richard Nicholas has owned and held executive positions with national TPAs, BPOs and MCOs; represented 200+ health plan administrators before the U.S. House of Representative and has been trusted to facilitate more health plan administrator mergers and acquisitions than anyone. An innovator, author and newly-minted "social entrepreneur", Mr. Nicholas created the *Research Consortium* to undertake much needed payor-focused translational research on new and emerging medical technologies / health innovations and to facilitate more, smarter, and less costly medical research. Richard earned a BA with distinction from Boston College and an MBA from Duke University's Fuqua Graduate School of Business.



Richard is the author of the study: COVID-19: ITS TRANSMISSION, AND FACE MASK EFFICACY, The Definitive Employer Guide to Purchasing Face Masks *for Your Valuable Employees* At 70 pages, and with 176 cited references, it was written to help employers understand viral transmission, select the best general-purpose face covering and manage the risks, liabilities and regulatory challenges attendant to providing face coverings to employees. Click the study's cover to read or download.

He is a member of the committee that created the first community face mask specification: AATCC M14-2020 *Guidance and Considerations for General Purpose Textile Face Coverings* and the workgroup established under CDC / NIOSH oversight to develop and maintain ASTM F3502-12: *Standard Specification for Barrier Face Coverings*, the new national standard. Richard has studied the face covering specifications of the British Standards Institute, European Committee for Standardization and more than two dozen countries.

Richard has written several articles on topics related to COVID-19, its transmission and face mask efficacy. They may be read or downloaded by clicking on the image below.



To learn more about the ASTM F3502-21 face covering standard, and how it will impact employers, click the image at right to view our webinar.

This 75-minute webinar covers topics of interest to employers and their professional advisors including: viral transmission and bioburden risk, killing vs. blocking COVID-19, face covering efficacy, exposing false claims / dispelling myths, comparing face coverings, new performance measures, consumer advisory labelling deficiencies and how the new standard impacts employer exposure, liability and compliance.

The **TPA NETWORK *Research Consortium*** is an emerging industry-wide research initiative created to help health plan sponsors evaluate new medical technologies and emerging health innovations…by conducting much needed payor-focused translational research and facilitating more, smarter and less costly clinical trials.

For full disclosure, the *RC*'s own patent-pending face covering will be launched ***as soon as we evidence full compliance.***

Appendix: Support Discussion

1. Antimicrobial Agents

Face coverings that feature an anti -bacterial, -microbial or -viral (collectively "antimicrobial") material, finish or mechanism have become increasingly popular. In part, this is likely because of the commonsense belief by the public that coverings treated with an antimicrobial offer an added degree of wearer protection.

Enjoying decades of success on textiles, even in healthcare settings, this belief is not unfounded. A face covering having an antimicrobial treatment should theoretically offer an added level of wearer protection versus one that does not if the antimicrobial is effective at fending off and inhibiting the growth and spread of pathogenic microbes on the covering's surface over time. Indeed, there is considerable evidence that (enveloped, gram-negative) coronaviruses are among the easiest pathogens for antimicrobials to inactivate.

Notwithstanding that a barrier face covering can be effective at blocking a certain percentage of undesirable particulates, a portion of those blocked infected viral can survive for a considerable period on the covering's surface and propagate. Fabric face coverings create an environment that is conducive to microbial growth given their extended close contact with the wearer's skin (and optimal nutrient, temperature and moisture conditions). And, while viruses are not living things, they do hijack healthy cells by attaching to and penetrating hosts; injecting them with noxious genetic material; building new viral proteins and finding new hosts to infect. Employing a variety of methods, antimicrobials are intended to ensure that pathogenic microbes do not attach to a fabric's surface and, if they do, to kill. Some are highly effective at doing so.

Face covering buyers are wise to research and scrutinize the often-exaggerated claims made by manufacturers and marketers as to the efficacy of the antimicrobial substances they employ. Metal-based antimicrobials are only marginally effective as they must come in direct contact with the virus to be effective. To do this, the metal would have to be incorporated into every fabric fiber to live up to its potential. Antimicrobials that rely upon toxic poisoning have limited useful lives as their reservoir of toxins is finite and eventually runs out. Lastly, an antimicrobial's ability to remain fixed to fabric is a key determinant of its safe useful life. Most metal-based antimicrobials are added to fabric post-manufacture that wears off with each machine wash cycle and eventually degrades to an unreliable level over time.

In addition to effectiveness claims it is important to note that many antimicrobials pose potential health, safety and environmental risks. Heavy metals are used as antimicrobials due to their biocidal/poisonous qualities. The most common metal-based antimicrobials used on face covering fabrics are zinc, silver and copper. These antimicrobials work because of the metal's inherently toxic characteristics: these toxins are transferred to the infected host cell to chemically poison it. When metal-infused fabrics are used in face coverings this noxious "chemistry experiment" occurs a few centimeters from the wearer's mouth and nose.

While each of these metals has some inherent medicinal quality that makes it beneficial to human health when used in a certain way, these same properties cause heavy metal poisoning and other toxicity issues.

- *The Mayo Clinic advises against zinc nasal sprays, as many people suffer a loss of smell afterward.*
- *While not a carcinogenic, mutagenic or reproductive toxicant in low doses, copper can cause serious health problems if it accumulates at high levels in the liver and other organs. Breathing high levels of copper can cause nose/throat irritation; exposure to copper fumes can cause chronic copper poisoning.*
- *Silver has many toxicity issues. Though normal silver concentrations in human tissues are low, with overexposure it can accumulate in the skin, liver, kidneys, eyes, etc. with serious health consequences. It poses a risk of neurotoxicity; it may interact with skin flora to weaken the skin's defense barrier; and more. Inhaling silver compounds/dust/fumes can cause/contribute to respiratory tract irritation, bronchitis, emphysema and lower pulmonary volume. Some silver nanoparticle strains are very toxic.*

The EPA and FDA are charged with regulating antimicrobial agents based on their intended application. In general, agents used on inanimate objects are regulated by the EPA as antimicrobial pesticides under FIFRA; and agents used in or on living animals or humans are regulated by the FDA under FFDCA.

The EPA has strict rules regarding marketing claims made about the capabilities of antimicrobials. Among them are prohibitions against making claims beyond that of the "treated article" itself. Without specific EPA approval, claims cannot be made about an antimicrobial's protection against or prevention from specific organisms infectious to humans (e.g., COVID-19) or that of the treated fabric. These prohibitions cover the product's packaging, advertising and communications.

As it relates to face coverings, unless authorized by the EPA, any claim as to an antimicrobial's ability must be limited to the face covering itself; be specific and not unqualified; refrain from referencing health-related microbes and from denoting personal (e.g., "for skin, wound, or respiratory") protection. Graphic representations of the covering's antimicrobial protections cannot include or imply protection of public health significance or take prominence above other normal product claims.

Although claims are in fact made by manufacturers about an antimicrobial's perceived ability to kill the COVID-19 virus, no entity can justly make such a claim as, to date, there has been no approval, or any form of government-sanctioned testing performed to prove the effectiveness of any antimicrobial agent against COVID-19. Despite this, many face covering manufacturers disregard these prohibitions or maintain that the intended purpose of their antimicrobial is for odor control, a default position that appears to work.

2. Activated Charcoal Filters

Many face coverings feature built-in or removable and replaceable filtration mechanisms that include non-woven melt-blown layers, activated carbon/charcoal filters and HEPA filters. The popularity of these types of face coverings is growing and products with integrated / removable filters account for a large share of the US fabric face covering market. The recently released TIME Magazine List of 100 Best Inventions of 2020 features three face coverings, each with a changeable filter, some boasting of filtration rates of up to "99.6%... of airborne particles, down to 0.1 micron". These claims are based on the less-challenging FDA-type test method.. Putting filtration claims aside, there are potential; health, safety and environmental issues related to the use of activated charcoal filters in face coverings.*

The activated charcoal filtration process is not entirely efficient, effective or safe. It is formed from powder-sized carbon particles that have been treated to be extremely absorbent through "activation", which refers to the injection of hot air, CO2 or steam into the carbon. This process, enhanced by chemicals, create a mesh of tiny pores to increase overall surface area and filtration. Highly absorbent, activated charcoal media is effective at attracting and removing organic compounds, chemicals and gasses from the air. Contaminated air passes through the filter and is adsorbed (bonded to the carbon surface) to prevent their inhalation. Often, the carbon media is given a positive charge to attract negatively charged microbes.

Activated charcoal filters are not effective against most pathogenic bacteria or viruses and not good at removing chemicals that are not attracted to carbon (e.g., sodium, nitrates, heavy metals, fluoride). As such, activated charcoal filters are often paired with other filters (e.g., HEPA) to address an extended range of contaminants however they should not be promoted as a way to filter pathogenic viruses.

Note that activated charcoal filters adsorb rather than absorb contaminants: nothing is brought inside anything; instead, pathogenic microbes that are attracted to carbon stick or bond to the outside of the carbon structure (and adsorbed). This adsorption of the contaminated microbes creates a" bioburden build-up" over time, eventually saturating the filter to the point where it will lose its ability to trap and retain contaminants. Ultimately, these contaminants are released back into the environment, defeating the purpose of the filter.

Beyond effectiveness and efficiency, activated carbon filters can also present significant health risks. While activated charcoal has been reported to be an inert substance, mounting evidence suggests that inhaling charcoal is associated with acute respiratory distress syndrome and pulmonary compromise. Many epidemiologists suspect that breathing in charcoal fragments, particles and dust is not good for your lungs; may cause mild irritation to the upper respiratory tract and infection; and can produce skin, nose and eye irritation. Impurities found in carbons (e.g., iodine) can be toxic. Persons with impaired respiratory function, airway diseases, emphysema or chronic bronchitis are likely to be more severely impacted by inhaling such particulates. All of this is important as it is very possible that carbon particles (and other related toxins and harmful impurities) may be inhaled from a face covering having an activated charcoal filter. Lastly, when wet, activated carbon removes oxygen from the air: not a good face covering feature.

3. Nanoparticles

Nanoparticles are pieces of matter between 1 and 100 nanometers (nm) in diameter. Nanotechnology is essentially the push toward microminiaturization and the expansion of science into the nanoscale. The characteristics that make nanoparticles attractive for applications in industry, medicine and technology are not just their miniature size but also the way that their surfaces are assembled or modified with chemical treatments to increase their stability and the ease with which they can interact with biological systems.

Nanotechnology is used to make materials stronger, lighter, cleaner, water- and residue-repellent, anti-reflective, self-cleaning, resistant to UVA and IR, scratch-resistant, more reactive, more sieve-like, better electrical conductors, etc. It has helped revolutionize many products, processes, industry sectors and technologies as nanoscale materials are used in hundreds of household products (from paint to sunscreens to eyeglasses), enable smart fabrics with nanoscale sensors, and facilitate the delivery of drugs, heat, light, genes, etc. to specific types of cells. Some antimicrobial agents now feature (metallic) nanoparticles.

Despite the many benefits that nanotechnology affords, great concern exists that the use of nanomaterials may be harmful and even unsafe in certain applications. Indeed, the dangers associated with contact with nanoparticles is not just speculation as more research is conducted, concern increases. It is now believed that the very properties that make nanoparticles appealing (size and chemical surface modification for biologic purposes) are the same properties that pose potential danger for humans and the environment.

- *Nanosized particulates can be deposited throughout the human respiratory tract when inhaled, with a consequential number reaching the lungs. They move easily and depending upon exposure time, material amounts can travel from the lungs to the liver, spleen, brain and possibly even a fetus.*
- *Nanoparticles can also be brought into the body through the olfactory nerve (that conveys smell) through the nose's mucous membrane. It is the shortest route from the nasal passage to the brain.*
- *Exposure via skin contact can result in nanoparticles entering the body. Further, they may adsorb onto the surface of larger molecules they encounter as they enter the tissues and fluids of the body.*
- *Studies have also demonstrated the passage of inhaled nanoparticles into the bloodstream.*
- *In general, the most prominent effects of inhaled nanoparticles are lung inflammation and heart problems. However, another reason why the use of nanoparticles in certain applications is suspect is that the properties of certain nanoparticles often differ markedly from those of larger particles of the same substance. As such, materials which by themselves are not very harmful can be toxic if they are inhaled in nanoparticle form.*

The rapid and more widespread use of nanomaterials has caused concern among many as the long-term effects of chronic exposure to them on humans are not well known. It raises legitimate health concerns related to the wisdom of using nanoscale materials (e.g., nano-silver) as an antimicrobial agent base for treatments used on face coverings specifically intended to be worn for extended periods of time.

Nanosilver is an example of how nanoparticles can be unsafe, unhealthy and environmentally unfriendly.

The medicinal benefits of silver are well documented and large doses of silver can be safely tolerated. What is of concern to physicians, scientists and environmental watchdogs is the manipulation of nanoparticles and their use for applications where silver has never been used. Consumer products companies have been adding nanosilver particles for antibacterial purposes to an ever-expanding array of items as diverse as cutting boards, underwear, yoga mats, running shirts, gloves, socks, toothbrushes. With the emergence of the pandemic, many popular face coverings now feature nanosilver as an antimicrobial. Worse yet, in addition to its inherent toxicity, nanosilver is often added to face covering fabric at the finishing stage. This can inhibit its bonding to the fabric, allowing it to be easily removed by normal use / laundering over time.

Environmentalists and public health officials fear the negative impact the disposal of various silver treated medical and consumer products has when they end up in sewage treatment systems and, ultimately, in the environment. This is because there are presently no effective ways to filter silver nanoparticles. Many scientists believe that the large-scale contact with, or release of nanosilver particles into the atmosphere, may lead to not only disturbances of the microbiological ecosystem but also our bacterial resistance to silver. Researchers at the U. S. Geological Survey warn against the overuse of silver and have expressed their fear of the explosion of its use on products where we do not know it to be effective; noting that it is important to evaluate the risk of using silver before putting it into the environment. Recognizing that there may be adverse long-term effects from the consumption of, or exposure to, silver many believe that the use of nanosilver products should be avoided unless justified (e.g., for needed medical interventions).

Graphene, a nanoparticle, also poses potential risks. Still in its infancy as it relates to real world applications, graphene is a nanomaterial comprised of sheets of carbon atoms in a honeycomb pattern. It is essentially graphite oxide (GO) in one layer. Graphene is the world's first two-dimensional material and the thinnest and lightest object ever made: it is 300 times stronger than steel. Flexible, transparent and a better conductor than copper many scientists believe that graphene could one day enhance, or replace, metals and plastics in our daily lives as a one-atom-thick sheet of it can be applied to many materials in many ways

Given this, it is not surprising that engineers and scientist began to explore the use of graphene and GO for use in the fight against COVID-19. Some are focused on the potential to create a graphene (oxide)-based antibacterial as graphene is reported to exhibit strong anti-bacterial activity. This, it is hoped, could help make face coverings repel bacteria (and, presumably, viruses). By applying a graphene coating to the covering's outer layer, private researchers claim to have created a bacteria-resistant graphene coated surface that repels, reduces or otherwise inactivates ≥ 90% of various bacteria, even after multiple washings.

For some, graphene may not be ready-for-primetime as it relates to it use on face coverings. In large part, this is because of the many issues inherent to the material and its limited use in textiles. It is still a reasonably high-cost material fraught with uniformity, transport and handling challenges and it is not subject to the standards that are customary in most industries. Further, like other nanoparticles, it poses potential health, safety and environmental problems: the (June 2018) American Society for Microbiology's Journal of Antimicrobial Agents and Chemotherapy publish that "…their possible ecological effect must be properly evaluated before their widespread use". Studies of graphene have indicated that it could be toxic to the liver, kidneys and lungs like other nanoparticles. Given the other proven alternative ways to safely imbue fabrics used in face coverings with antimicrobial properties, prudence dictates that the use of graphene should be delayed until further evidence of its effectiveness and safety are better understood.

4. Bioburden Build-Up

Even when used properly, ordinary paper surgical masks and fabric face coverings create large populations of viable microorganisms that scientists call a "bioburden". Bioburden build-up develops as a result of

- *the wearer breathing and coughing germs and viruses into the face covering,*
- *the face covering collecting pathogenic particles that have been transmitted by others, and*
- *the face covering's surface being allowed to host microbial build-up over time from not washing it enough.*

COVID-19 is a deadly virus making bioburden build-up of this virus a particularly dangerous. This makes putting on, taking off, storing and laundering face coverings critical tasks that must be mastered to ensure that both the self-contamination and transmission risk is not needlessly amplified.

Today, we know to what extent microbes like COVID-19 can survive on various surfaces. A study in the Journal of Clinical Microbiology (February 2000) on the transfer and survivability of micro-organisms concluded that bacteria survive longer on polyester vs. cotton and can become a vector for the spread of microorganisms, creating serious infection control implications. A study in The Lancet (April 2020) noted that "a detectable level of infectious virus could still be present on the outer layer of a surgical mask on day seven" of a study. Infectious disease researchers and doctors at Johns Hopkins University/Health System found that COVID-19 survives better on less porous artificial fibers like polyester (and spandex) vs. cotton. Understanding this, with respect to the dangerous bioburden build-up of COVID-19 microbes, the evidence is clear that polyester is not a wise fabric choice for face coverings. This is because one of the intended purposes of face coverings is to act as barrier against virus-infected droplets and aerosols understanding that some of those particles will remain on the face covering and accumulate over time. Knowing this, the fabric used on face coverings should inhibit the possibility of bioburden build-up, not enhance it.

Certain antimicrobials and electrostatic air filters provide proven, safe means by which to inhibit and defeat bioburden build-up. Both approaches rely upon continuously inactivating/killing viral microbes rather than just blocking them and allowing them to build-up into a bioburden that can infect the face covering wearer and be transported to infect others. Unlike simple barrier filtration, antimicrobial and electrostatic methods address all sized particles. Because they kill infected microbes, a face covering's fit is not quite as critical a matter for it to be effective in use; there is less risk of face hand-to-face bioburden transmission when removed; and, relative to ordinary face coverings, it is safer to transport and store (as it is not covered with active microbes). This is important as each time the wearer touches, adjusts or discards a covering, the potential to infect the wearer, and others, increases the impact of bioburden build-up.

5. Toxic Fabrics

Barrier face coverings are typically made of cotton, a man-made/synthetic fiber (e.g., polyester), or a blend. Synthetic fibers often carry with them health, safety and environmental concerns that may not be known to face covering consumers who may not purchase clothing articles regularly. In fact, it is unlikely that most face covering consumers are familiar with the toxicity and environmental characteristics of various fabrics.

Fibers like polyester are fraught with issues that make them noxious materials that many people believe are inappropriate for use in face coverings. A type of plastic, polyester is a synthetic material that contains embedded toxic chemicals and is made with antimony, a known carcinogen, and other noxious chemicals (e.g., thermoplastic) that outgas toxic plastic molecules when heated in the clothes dryer. Prolonged contact with polyester can cause chronic and severe respiratory infection and excessive wearing of it can cause skin problems and lung, heart and other cancers. Polyester is neither sustainable nor bio-degradable, is dangerous to the environment and causes eco-friendly consumers to frown on its use. Its production disposes toxins into the water and emits lots of air pollutants. It is hard to recycle and, when it is, it uses more energy than producing cotton from scratch. Indeed, it takes two to ten times more energy to produce polyester vs. cotton.