13—
Assessment of the Protective Properties of Textiles against Microorganisms

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1—
Scope

A—
Types of Textiles

There are many different types of textiles used today in an attempt to either limit or prevent the transmission of hazardous microorganisms. These materials range from solitary layers of nonwoven single-use products to composites of woven and knitted multiple-use products that include film reinforcements. There is a multitude of various different fiber types, ways in which fiber assemblies and textile and film structures can be bonded together, and different chemical finishing applications and additives that can be used in textile constructions to impart varying degrees of protection against microorganisms. Often, there are entirely different performance objectives for textiles, depending on the nature of their intended application, which can dictate which types of textile structures are appropriate for use as microbial barriers.

Some structures must allow for the transfer of fluids, such as air or liquid, while limiting or preventing the transfer of potentially pathogenic microbes being transported within them. (The fluids transporting microorganisms are often referred to as vehicles.) These materials are generally characterized as being porous, where the pores would allow the transfer of the vehicles and the surrounding structures would act to impede the penetration of the microorganisms to varying degrees. The resistance of the materials to the penetration of both the fluids and the microbes will depend on a whole host of very important factors, many of which are discussed later in this chapter.

Other structures are made in an attempt to limit or prevent the transfer of the vehicles and thereby indirectly prevent the transfer of the microbes.
Materials

protecting against airborne biohazards in this way would generally be characterized as being nonporous. Textiles used for this purpose can be augmented by film reinforcements, which will not allow the bulk flow of air through the material and thereby prevent the transfer of microorganisms. In the case of protecting against liquid-borne biohazards in this manner, both porous and nonporous structures can be utilized; however, the objective for both structures would be to prevent the bulk flow of liquid through the materials and thereby prevent the transfer of microorganisms. Depending on the nature of the liquid-borne biohazard, various textile or textile and film structures can be used.

These two basic performance objectives, allowing fluid flow and not allowing fluid flow, are fundamentally different and require utilizing different experimental approaches to the analysis of the barter properties of the respective materials to microorganisms.

B—
Types of Applications

Applications requiring fluid flow while limiting or excluding microbiological penetration would include such things as high-efficiency particulate air (HEPA) filtration for sensitive environments (operating and clean rooms), microfiltration of heat-labile pharmaceuticals (disk and cartridge filter media), sterile packaging for the steam sterilization of medical devices (vents for pouches and container systems, wrappers for surgical instrument trays and linen packs), and respiratory protection for health-care workers (surgical masks and respirators). Alternatively, applications that do not require fluid flow while limiting or excluding microbiological penetration include such things as providing certain types of personal protection (garments, headwear, gloves, and footwear), providing or maintaining an aseptic environment for infection control purposes (medical device and pharmaceutical clean-room apparel and surgical gowns, patient drapes, table covers, and equipment covers), and caring for wounds (occlusive wound dressings).

This chapter focuses mainly on strategies for the laboratory analysis and decision logic related to textile structures used in clothing systems for personal protection and textile structures used to provide or maintain an aseptic environment for infection control purposes. This chapter does not cover all of the potential applications for textiles as barriers to microorganisms or the associated strategies for the laboratory analysis and decision logic related to each one. However, similar strategies for laboratory analyses may be applied to textile structures used in many other applications where microbial barrier properties are important.

C—
Types of Hazards

There are many different types of microorganisms that are important when discussing textile structures used in clothing systems for personal protection and providing and maintaining aseptic environments for infection control. These microbes

fall into three major categories; viruses, bacteria, and fungi. Obviously, whole intact organisms in each of these categories can cause problems; however, there are also some subcellular components and by-products of metabolism that can cause problems as well. The strategy of experimentation used to evaluate the barrier properties of textile structures against these agents has typically been specific for each agent, although in some circumstances it may be possible to develop a model that has broad application and predictive capabilities.

There are many important factors in determining the nature of the biohazards: the type of vehicle by which the microbe is being transported, the physical and chemical characteristics of any carders associated with the microbe (particles, cells, tissue fragments, hair, etc.), the concentration of the microbe in the vehicle, the state of the vehicle (dynamic or static), the forces or pressures associated with the vehicle, the physical and chemical characteristics of the microbe, the stability of the microbe (the viability of the microorganism under various environmental conditions), the virulence of the microbe and the dose necessary to cause infection, the susceptibility of the potential host, and the resistance of the microbe to disinfection, sterilization, and antimicrobial therapy. Modes of transport for microbes, other than common vehicles, must also be considered. It is possible for microbes to alSO be transported via direct contact with contaminated animate (bites, scratches, etc.) and inanimate objects (needle sticks, cuts, etc.).

The route of transmission plays a significant roll in the biohazard exposure assessment. Relative to the prevention of infection, each pathway—oral, respiratory, mucous membrane, percutaneous (surgery, needle sticks, cuts, nonintact skin, etc.)—that would allow a susceptible host to become infected should be recognized and dealt with in the assessment of each respective textile barrier. In many cases, textile barriers are not the first line of defense against biohazards and must be used in conjunction with other means of mitigating biohazard risks, such as engineering controls (laminar-flow biohazard exhaust hoods, clean or steam inPlace bioreactor designs, self-sheathing needles, etc.), work-practice controls (double gloving, use of eye or face shields, Use of sharps containers, removal of overtly contaminated protective clothing, etc.), and immunization (against diphtheria/tetanus, rubella, rubeola, varicella, mumps, measles, polio, influenza, and hepatitis B).

D—
Significance of Laboratory Test Data

Textile structures that are used to limit or prevent the transmission of microorganisms play an ever-increasing role of importance in our society today. The strategies that are employed in the laboratory analysis of these materials and the resulting understanding of their performance expectations are of paramount importance when deciding which materials are fit for what application. These strategies should be relative to the perceived risk associated with the transmission of

each microbe or class of related microbes. Even though it may be virtually impossible to duplicate the myriad of physical, chemical, and thermal stresses placed on textile materials in the real world, the goal of laboratory testing should be to provide information that would allow a realistic estimation of the performance of barrier textiles during actual use. Risk reduction decisions are likely to be made based on the laboratory data, and the conclusions that are drawn from the laboratory data should in fact provide a reduction in risk during actual use.

II—
General Characterization of Textiles

A—
End-Use Requirements

The overall performance requirements of textiles in each personal protection and infection control end-use application can be quite different. Understanding the performance requirements for each end-use application is the key to developing a successful strategy of experimentation and defining a risk reduction decision logic. In each end-use application all of the technical attributes that are required for the textile to perform adequately should be identified. Two different end uses may require the same protection against the penetration of microorganisms; however, there may be completely different requirements for physical, chemical, and thermal properties. In some cases, one attribute may have to be sacrificed in order to obtain the goal for another attribute. As an example, strength objectives might dictate that the weight of the textile has to be increased; however, increasing the weight can negatively impact the hand (stiffness) of the textile. When considering the performance objectives for textiles in just a few end uses, such as firefighter turnout clothing, emergency medical response clothing, and surgical apparel, it becomes obvious that the biobarrier demands for the textiles used in these applications will have to be integrated and balanced with a multitude of other technical attributes. Other significant influences, which are not technical performance attributes but can have a direct impact on deciding which textile to use, are cost and environmental impact.

It is beyond the scope of this chapter to address all of the end-use requirements for textile structures used in personal protective clothing and infection control applications. Outlined next is a discussion of a few physical, chemical, and thermal properties that should be considered when evaluating textile materials as barriers to microorganisms.

B—
Physical Properties

Four of the easiest and most objective analyses for textiles are weight, thickness, bulk density, and microscopy. Together, these tools can serve to benchmark different textiles for comparison and help to predict other important microbial bartier and physical attributes.

1— Weight

The weight of textiles is often determined in order to be used with thickness measurements to obtain a bulk density. Weight measurements for similar textile structures can also be related to other physical attributes, such as strength, abrasion resistance, and stiffness. The international units of measurement for weight are grams per square meter (Fig. 1).

2— Thickness

As stated earlier, thickness determinations can be used with weight measurements to calculate bulk density, which can be used for a variety of purposes. Thickness measurements for similar textile structures can also be related to other physical attributes, such as strength, abrasion resistance, and stiffness. The compressibility

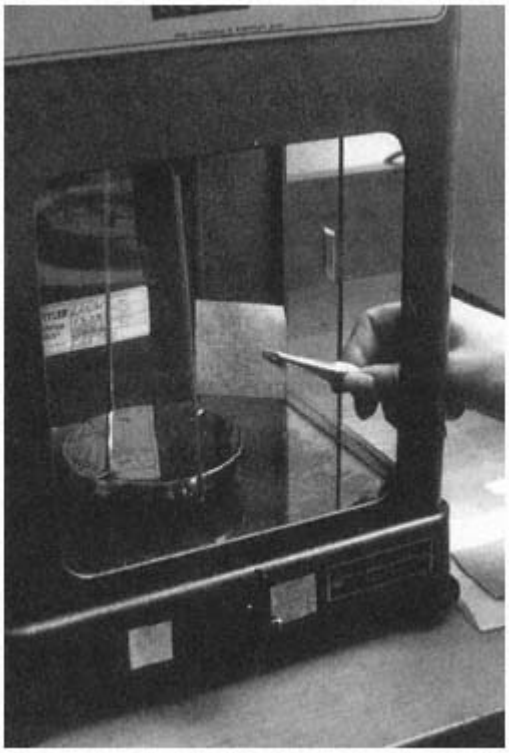

Figure 1
The weight of textiles can be determined using ASTM D 3776-85 [Standard Test Methods for Mass Per Unit Area (Weight) of Woven Fabric: Option C—Small Swatch of Fabric].
(Photo courtesy of the Institute for Environmental Research, Kansas State University, Manhattan, KS.)

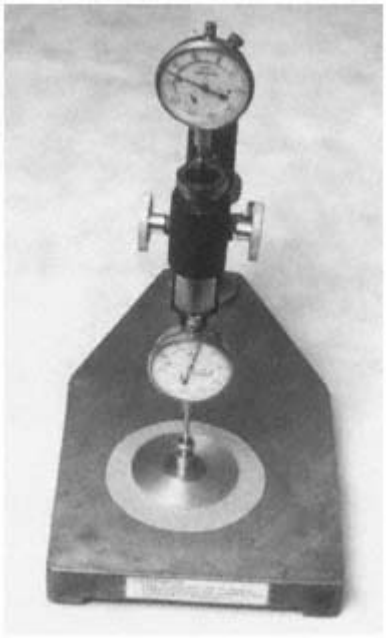

Figure 2
The thickness of textiles can be determined using ASTM D 1777-64 (Reapproved 1975) (Standard Test Method for Measuring Thickness of Textile Materials).
(Photo courtesy of the Institute for Environmental Research, Kansas State University, Manhattan, KS.)

of various textile structures may be different and need to be taken into account when making this measurement for comparative purposes. The international units of measurement for thickness are millimeters (Fig. 2).

3— Bulk Density

Bulk density calculations for textiles can be related to the insulative properties and may also be useful in helping to understand the liquid, air, moisture vapor, and microbial penetration resistance characteristics. Generally speaking, for textiles with similar physical and chemical structures, as the bulk density increases the penetration resistance increases. The international units of measurement for density are kilograms per cubic meter [1].

$$\text{Bulk density (kilograms/cubic meter)} = \frac{\text{mass (grams)/area (square meters)}}{\text{thickness (millimeters)}} \quad (1)$$

When textiles include a film reinforcement, the characteristics of the film will be the overriding factor in determining the penetration resistance properties. Film reinforcements may have little impact on the overall bulk density calculations while significantly changing the penetration resistance properties.

4—
Microscopy

Visually observing the magnified images of textiles is perhaps the most interesting and informative analysis that can be made in order to better understand the physical structures. Virtually all of the physical elements can be investigated, including the type of structure (type of weave, knit, or nonwoven), additional features of the structure (calendered, texturized, entangled, point bonded) the complexity of the structure (multiple layers, fiber blends, film reinforcements), the porosity of the structure (define pathways, approximate the size of yarn and fiber interstices, approximate the pore size of some films), yarn characteristics (filaments/yarn), fiber characteristics (diameter, cross-sectional shape, classification of some types), film bonding techniques (adhesive laminated, direct coated/extruded, point bonded), and film types (monolithic, bicomponent, microporous). Many of these features can be determined using either a stereomicroscope or a mono-objective compound microscope; however, scanning electron microscopy (SEM) has the flexibility to determine all of them and more.

In order to illustrate the diversity of some of the structures, products that represent the most common types of textile structures currently being used in personal protective clothing and infection control applications were chosen and SEM was employed to view their outside surface and cross-section. Refer to Figures 3-10. (Please note that different magnifications would be necessary to make some of the determinations listed in the preceding paragraph.) (Figures 34 and 35 denote the physical and microscopic characterization of two of the most common types of film-reinforced textile structures.)

C—
Antimicrobial Properties

Incorporating antimicrobial compounds into textile fibers and finishes has beenpracticed for many years. Desirable features for an antimicrobial textile include durability of activity (including laundering and sterilization or dry cleaning if necessary), selective activity against undesirable microorganisms, acceptable moisture transport properties (important for agents that rely on a controlled release mechanism), compatibility with other finishing agents, absence of any toxic effects to the wearer or user, and commercial availability [4].

Textiles that include antimicrobial additives require special consideration when assessing the microbiological barrier properties. These textiles may confound normal microbial challenge testing by eliminating the challenging organisms. Most of the standard microbial challenge tests evaluate the ability of a textile

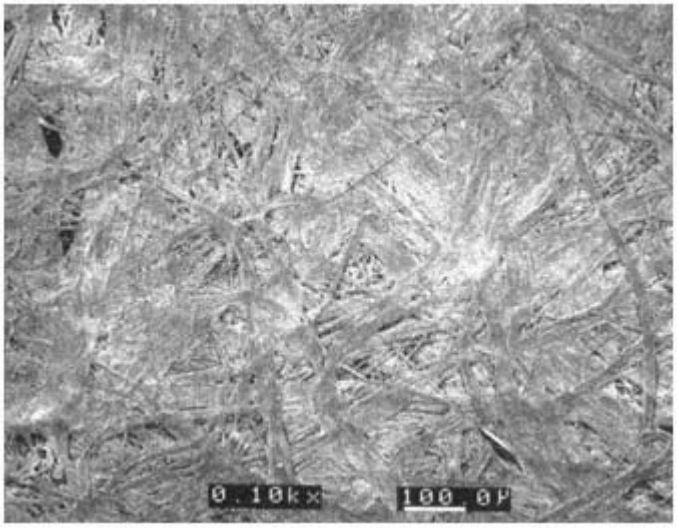

Figure 3
Scanning electron micrograph: surface at 100× magnification, Tyvek, supplied by E. I. du Pont de Nemours & Co., described as spun-bonded plexifilamentary linear high-density polyethylene.

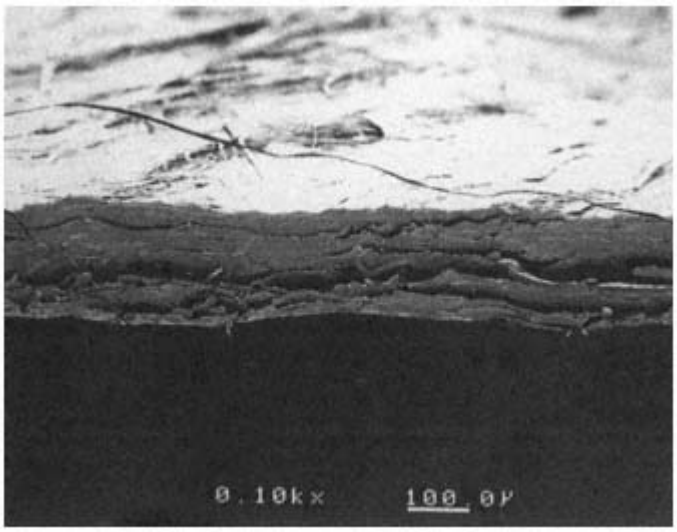

Figure 4
Scanning electron micrograph: cross section at 100× magnification, Tyvek, supplied by E. I. du Pont de Nemours & Co., with weight 41.32 g/m^2, thickness 0.24 mm, and bulk density 172.17 g/m^3.

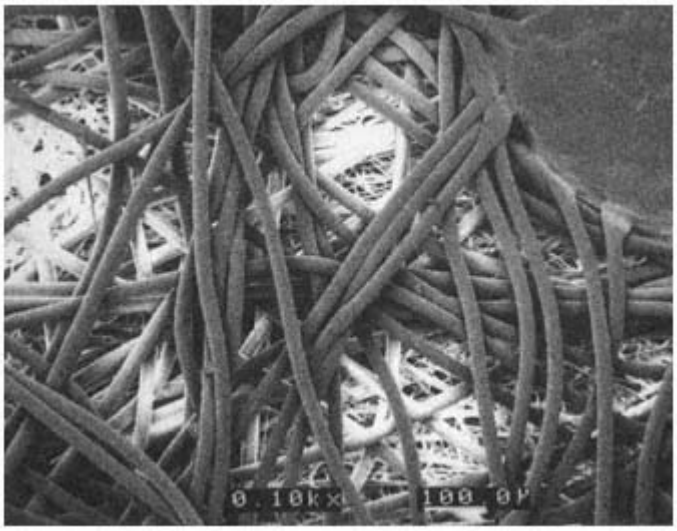

Figure 5
Scanning electron micrograph: surface at 100× magnification, Evolution, supplied by Kimberly-Clark Corp., described as spunbond/meltblown/spunbond (SMS) polypropylene (point bonded).

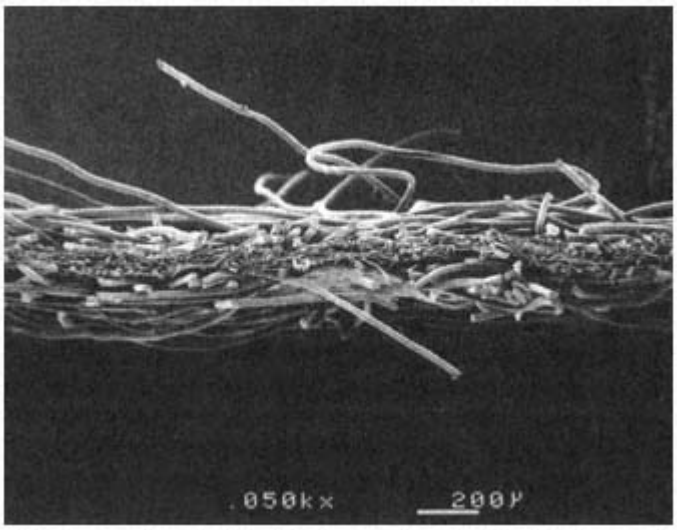

Figure 6
Scanning electron micrograph: cross section at 100× magnification, Evolution, supplied by Kimberly-Clark Corp., with weight 92.95 g/m^2, thickness 0.67 mm, bulk density 138.73 g/m^3.

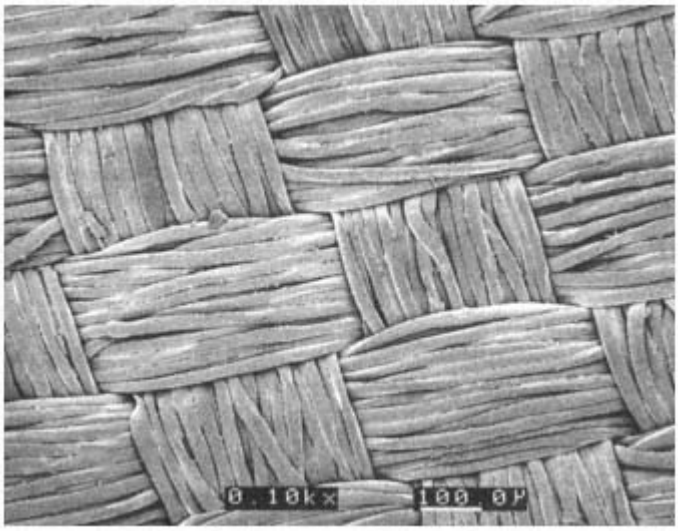

Figure 7
Scanning electron micrograph: surface at l00× magnification, Compel, supplied by Standard Textile Co., described as woven continuous fiament polyester microfiber (calendered).

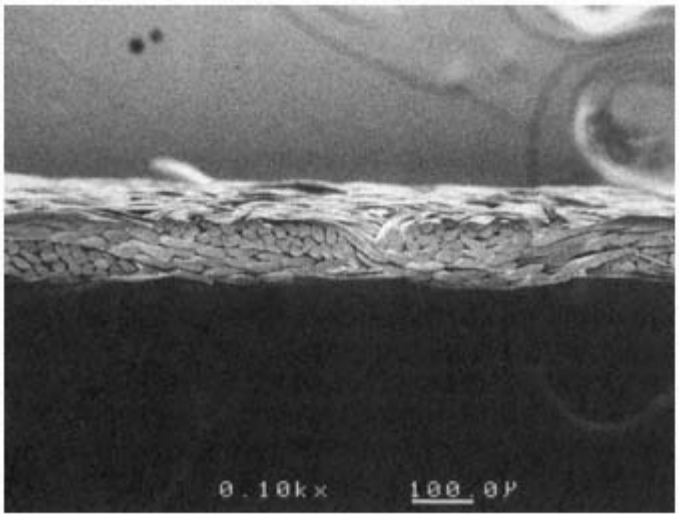

Figure 8
Scanning electron micrograph: cross section at 100× magnification, Compel, supplied by Standard Textile Co., with weight 117.90 g/m^2, thickness 0.20 mm, bulk density 589.50 g/m^3.

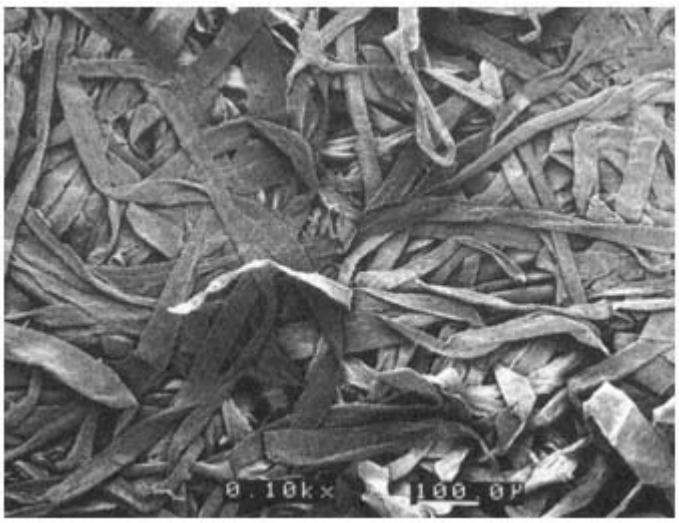

Figure 9
Scanning electron micrograph: surface at 100× magnification, Optima, supplied by Baxter Healthcare Corp., described as spunlace woodpulp/polyester nonwoven (entangled).

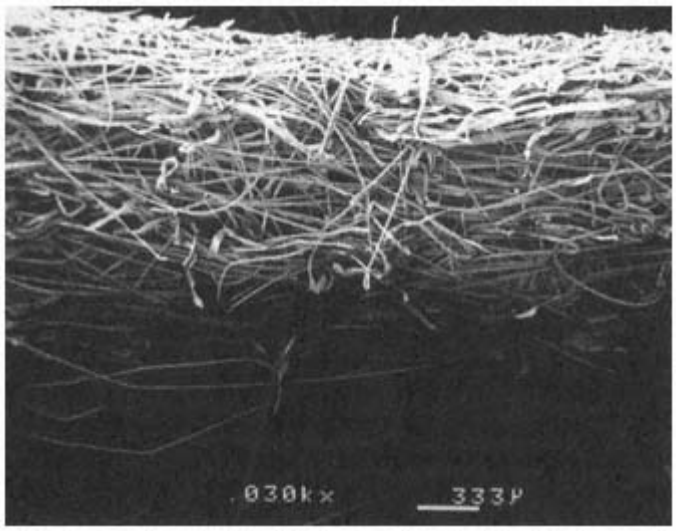

Figure 10
Scanning electron micrograph: cross section at 30× magnification. Optima, supplied by Baxter Healthcare Corp., with weight 69.85 g/m^2, thickness 0.34 mm, bulk density 205.44 g/m^3.

to prevent penetration and assume that the challenging organism remains viable throughout the process. If the mechanism by which the textile acts to protect against the penetration of microorganisms is to inactivate the microorganisms, then this fact should be fully understood and appropriate means to evaluate the protective properties of that textile should be utilized in the laboratory. Textiles incorporating antimicrobial agents might not prevent the penetration of or direct contact with viable pathogenic microbes during use, as the effectiveness of antimicrobial agents requires direct contact with the microbe for a specified period of time under defined conditions. The antimicrobial agent can be ineffective if penetration of the microbe through the textile occurs quickly or if the activity of the antimicrobial agent is diluted or inactivated by the vehicles carrying the microbe (such as with blood or body fluids).

Certain specific textile end uses may not require microbial penetration resistance, but may rely on antimicrobial treatments to reduce the overall bioburden in the work environment or to reduce the likelihood of cross contamination. This chapter does not address test methods for assessing the antimicrobial activity of textiles. It is assumed, and required by some microbial challenge tests, that the textile materials will be compatible with the challenging microorganisms.

D—
Chemical Resistance Properties

In virtually every end-use application for textiles being used as microbiological barriers there exists the potential for exposure to various types of chemical agents. A complete list of all chemical agents that are likely to come into contact with textiles in each personal protection and infection control end-use application should be made. Some of these agents will be hazardous and require that the textile also act as a barrier to them. This list could include many different chemical types, such as disinfectants, acids, bases, solvents, fuels, and lubricants. If dual protection to both microorganisms and chemicals is required, then both types of laboratory analyses for textiles in these applications will need to be performed. Depending on the type of chemical that the textile is exposed to and the chemical resistance properties of the textile, the chemical may seriously compromise the ability of the textile to effectively limit or prevent microbial penetration. Whether the chemical is hazardous or nonhazardous, some types of textiles and film reinforcements, particularly those that are porous in nature, can be made to allow microbial penetration to occur after contact with chemical prewetting and contaminating agents. If dual exposure situations can be clearly defined, then preconditioning textile samples with the chemical agents of concern prior to microbial challenge testing would be appropriate. For more information on assessing the chemical barrier properties of textiles, refer to Chapter 12.

E—
Thermal Properties

Most of the personal protection and infection control end-use applications have standards and regulations governing flammability requirements for textile-based products. These requirements should be recognized and appropriate flammability testing should be performed. In each end-use application, situations involving possible exposure to heat and ignition sources should be recognized and appropriate strategies should be developed in an effort to avoid overexposure. The thermal stability of textiles, including flame resistance, dimensional stability, insulative properties, etc., should be well characterized for those end-use applications requiring thermal protection. The microbiological barrier properties of some textile materials may degrade with repeated or prolonged exposure to hot environments. For those applications requiring both thermal protection and microbiological barrier properties, preconditioning textile samples with thermal exposures prior to assessing the microbial barrier properties should be considered. For further references see the Appendix.

III—
Theoretical Basis for Preventing Penetration of Microbes

A—
Modelling the Real World

Perhaps one of the most important concepts in determining how to evaluate the barrier properties of textiles against microorganisms, in the laboratory, is that the evaluation should relate to the real-world application of the product in such a way as to allow a meaningful judgment to be made regarding the risk of transmission. This assessment requires a very thorough understanding of the end use of each product, including all of the various factors that could stress the barrier integrity and negatively impact performance, Certainly, the more risk associated with the transmission of any given microbe, the more rigorous the laboratory analysis required.

There are two fundamentally different approaches that can be taken with regard to evaluating the microbial barrier properties of textiles in the laboratory. The first approach would be to define test conditions whereby the barrier properties are evaluated on a continuous scale of measurement to allow a relative comparison to be made between the breakthrough points for all products. This approach is often employed when the use conditions for products are not well defined or not controlled enough to determine predictive performance limits and when absolute barrier properties cannot be achieved because of the need to balance them against other technical requirements (such as low air penetration resistance). The second approach would be to define laboratory test conditions based on a thorough examination of the application for each product, whereby the barrier properties are evaluated and determined to be adequate (passing the test) or inadequate (failing

the test). Depending on the limitations of the test device and procedure used, the failure point may or may not be identified in the laboratory with either approach. However, acceptance and rejection judgments should be made based on sound logic related to an understanding of the actual use conditions for each textile application.

Recognizing the complexities of the different end-use environments for microbial barrier textiles and the various stresses that can be imposed on their barrier integrity is the first step in developing a logic related to product evaluation in the laboratory. Most likely there will be no perfect strategy; however, the means with which to characterize the physical, chemical, and thermal properties of textiles appear to be very abundant. Therefore, it would seem feasible that a hierarchy or decision tree could be built based on combinations of various tests, some of which may need to be used as preconditioning steps prior to barrier testing, with the ultimate goal of reducing the risk of product failure during actual use.

The degree of hazard associated with exposure to the microbe(s) will dictate how carefully the end use application for the textile will need to be studied, how conservative the modeling and experimental approach should be in the laboratory, and the definitions for adequate versus inadequate microbial barrier performance. Many of the key variables that should be identified in situations where engineering controls, work practices, immunization, and antimicrobial therapy cannot reduce the risk associated with the transmission of hazardous microorganisms to an acceptable level are discussed in Section III. J.

B—
Behavior of Liquids

In considering the various performance requirements for textiles intended to be used in personal protective clothing products and products used to provide or maintain an aseptic environment, it is important to understand the behavior of liquids as potential vehicles for microbial transport. Depending on the application, there could be a variety of different liquids that could challenge the integrity of textile barriers. Liquid challenge sources can vary from single insults with contaminated pure liquids to multiple insults with contaminated mixtures. Textile barriers can be confronted by liquids in many forms: splashing, spraying, pooling, and soaking. There may be cases where the sequence of liquid challenges can allow wetting of otherwise nonwetting liquids to occur, and there may be circumstances where the exact composition of the challenging liquids is not known or cannot be predicted. The severity of liquid challenges can also be greatly influenced by the pressure and time of the exposures. Once the general behavior characteristics of liquids are understood and possible exposure scenarios have been clearly thought through, worst-case modeling in the laboratory is appropriate. In most situations, due to the fact that the microbes of concern are so small in comparison to the interstices between the yarns/fibers of the textile or the pores in porous film rein-

forcements, the goal will be to prevent the wetting and subsequent penetration of the microbiohazardous liquids through the materials.

There are a number of important factors that can impact the resistance of textiles to liquid wetting and penetration. The literature is replete with references to demonstrate the importance of variables such as the surface tension, viscosity, and density of the challenging liquids, the contact angle of the liquids against the textiles, the porosity of the textiles, and the pressure and time of the liquid exposures.

1—
Surface Tension of Liquids

Surface tension of liquids is a property that results from unbalanced intermolecular cohesive forces, such as electromagnetic interactions (γ_{LW}), whether due to oscillating temporary dipoles (London), or permanent dipoles (Keesom), or induced dipoles (Debye), and acid—base interaction, including hydrogen bonding (γ_{AB}), at or near the surface, that causes the surface to contract. This theory of surface tension was pioneered by Fowkes and is expressed by Good [5] as:

$$\text{Surface tension } (\gamma) = \gamma_{LW} + \gamma_{AB} \quad \text{(newtons/meter)} \qquad (2)$$

One means of measurement of the surface tension of liquids is the du Nouy ring method. This test is illustrated in Figure 11.

The surface tensions for a variety of liquids, including human body liquids and liquids that could commonly be found in the laboratory and clinical settings, are listed in Table 1. This list is far from complete, but serves to illustrate the range of some of the liquid surface tension values that can be found in the environments requiring personal protective clothing and aseptic barriers. As mentioned previously, it would not be difficult to imagine situations where textile barriers could be exposed to a complex array of liquids such as these, in diverse forms with different pressure and time factors. Some of the lower surface tension liquids, such as 70% isopropyl alcohol, can prewet certain textiles and create a pathway for other higher surface tension liquids to follow. Other liquids may leave behind contaminating residues and surface active agents that can compromise the liquid resistance properties of certain textiles at a later time.

2—
Contact Angle: Hydrophilicity vs. Hydrophobicity of Textiles

The behavior of liquids on solid surfaces can be illustrated by Young's [12] stated equation:

$$\gamma_{SL} = \gamma_{SV} - \gamma_{LV} \cos \theta \qquad (3)$$

This equation contains components for deriving surface tension. These components include the surface free energy of the solid—liquid interface (γ_{SL}), of the solid—vapor interface (γ_{SV}), of the liquid—vapor interface (γ_{LV}), and the projection of the vector for γ_{LV} ($\cos \theta$) on the plane of the surface [13]. Young's equation assumes an ideal solid—chemically homogeneous, rigid, and flat—on an atomic

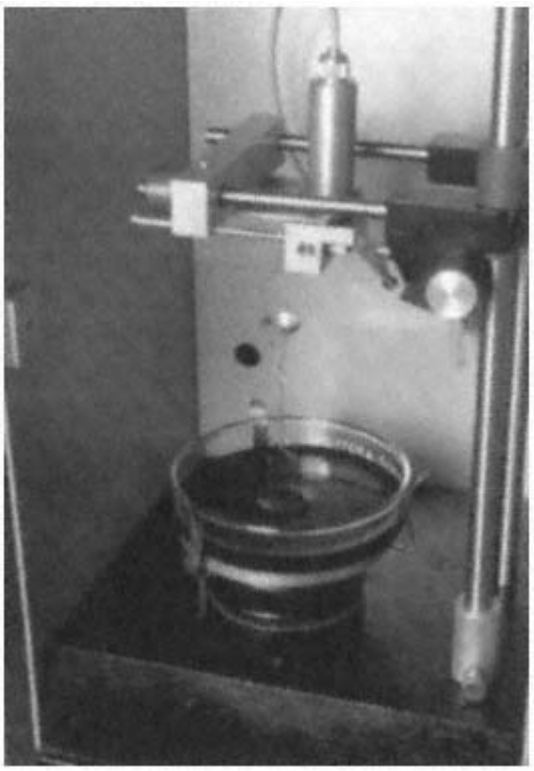

Figure 11
The surface tension of challenging liquids can be determined using ASTM D 1331-89 (Standard Test Methods for Surface and Interfacial Tension of Solutions of Surface-Active Agents). Here the test liquid has been placed in a glass petri dish on an elevator platform. The strain required to pull an immersed 6.0-cm platinum iridium ring, which is suspended from a balance beam that is connected to a pressure transducer, out of the liquid is recorded. The direct reading (apparent surface tension) can be converted to obtain the absolute (corrected) surface tension of the liquid. The temperature of test liquids must be controlled; 25°C is prefered. The correction factor must be adjusted to compensate for temperature changes, as lower temperatures will raise the apparent surface tension and higher temperatures will lower the apparent surface tension of the test liquids.

scale. Contact angle hysteresis, as evident by comparing the difference between advancing and receding contact angle measurements of liquid drops on tilted textile surfaces, theoretically occurs because textile surfaces are not ideal solids and because some liquids and solids may chemically interact.

In order to determine the relative hydrophilicity or hydrophobicity of textiles, contact-angle measurements can be made for sessile drops of pure water placed on

Table 1 Surface Tension Measurements for a Variety of Liquids

Liquids	Surface tension; γ(N/m)
Human body liquids	
Sweat (37–38°C)	0.069–0.070
Urine (temperature not specified)	0.064–0.069
Cerebrospinal fluid (20°C)	0.060–0.063
Semen (15°C)	0.052–0.060
Tears (30°C)	0.040–0.050
Whole blood, fasting (20°C)	0.056
Blood serum (25°C)	0.047
Bile, hepatic and gallbladder (37°C)	0.040–0.044
Saliva (temperature not specified)	0.015–0.026
Laboratory-grade reagents and media	
Saline, 0.6–2.8% (20°C)	0.073–0.074
Water (20°C)	0.073
Trypticase soy broth (temperature not specified)	0.059
AOAC letheen broth (temperature not specified)	0.045
Phi-X174 nutrient broth, with 0.1% Polysorbate 80 (23°C)	0.042
Mineral oil (23°C)	0.031
Isopropyl alcohol, 70% (23°C)	0.024
Isopropyl alcohol, 100% (23°C)	0.021
Clinical liquids	
5% Dextrose + 0.45% NaCl inj., USP (23°C)	0.046
Sterile water for irrigation, USP (23°C)	0.046
5% Hypochloride (23°C)	0.044
Lactated Ringer's inj., USP (23°C)	0.044
5% Dextrose inj., USP (23°C)	0.043
5% Dextrose in lactated Ringer's inj. (23°C)	0.042
0.9% NaCl inj., USP (23°C)	0.041
Amphyl (23°C)	0.035
Metaquat (23°C)	0.033
2% Gluteraldehyde (23°C)	0.033
0.75% Iodine scrub (23°C)	0.032
1% Topical iodine paint (23°C)	0.031
3% Lysol (23°C)	0.031

Ultradex, PCMX (23°C)	0.030
Iodofore (23°C)	0.029
4% Chlorohexidine gluconate (23°C)	0.028

Source: Refs. 6–11, 23.

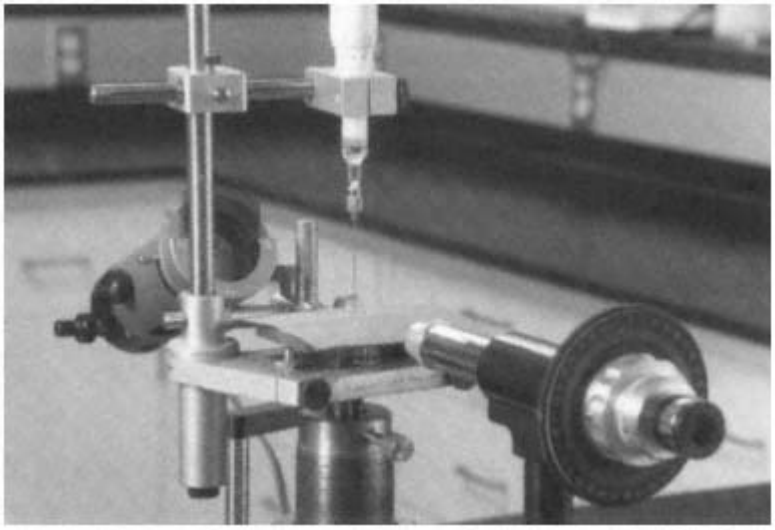

Figure 12
The contact angle of a sessile drop of liquid on the surface of a textile can be determined using TAPPI T 458 om-89 [Surface wettability of paper (angle of contact method), also known as the Goniometer contact angle test]. Here a droplet of water has been placed on the surface of a repellent textile. The Goniometer (scope) is used to magnify the droplet and determine the contact angle at the liquid/solid textile interface.

the surface of textile materials. Two examples are given in Figure 13 to illustrate textiles exhibiting hydrophilic behavior, where γ_{SL} is less than 90 degrees, and hydrophobic behavior, where γ_{SL} is greater than 90 degrees. Contact angle measurements for other potential challenging liquids can be made in this fashion and used to help determine their relative resistance to wetting. The higher the contact angle measurement between a liquid and a textile, the more resistant the textile will be to wetting and penetration of the liquid.

Figure 13
Contact angle measurements of water ($\gamma \approx 0.072$ N/m): left, water placed on a hydrophilic surface, contact angle less than 90 degrees; right, water placed on a hydrophobic surface, contact angle greater than 90 degrees.

In order to further illustrate how different textiles and different liquids can interact Figures 14–17 were prepared. Four liquids, which span a broad range of surface tensions, Were selected and sessile drops were placed on the surfaces of textiles. (The textiles used are illustrated in Figures 3–10.) The liquids are water ($\gamma \approx 0.072$ N/m), synthetic blood ($\gamma \approx 0.042$ N/m), mineral oil ($\gamma \approx 0.031$ N/m), and 70% isopropyl alcohol ($\gamma \approx 0.024$ N/m).

Some of the conclusions that can be drawn about the interactions between each textile and each liquid from this simple demonstration are:

1. Lower surface tension liquids developed lower contact angles (the sessile drops were more flattened on the surface of the textiles) than higher surface tension liquids on all four textiles.

2. Water behaved similarly on the surface of all four textiles, developing a high contact angle (the sessile drops stood higher on the surface of the textiles).

3. The behavior of water on a textile may not predict the behavior of other liquids. Some textiles exhibiting hydrophobic behavior allowed lower surface tension liquids to spontaneously wet and penetrate through while other textiles did not allow spontaneous wetting and penetration of those same liquids. The most obvious examples of the same liquids exhibiting different contact angles on different textiles are mineral oil and isopropyl alcohol.

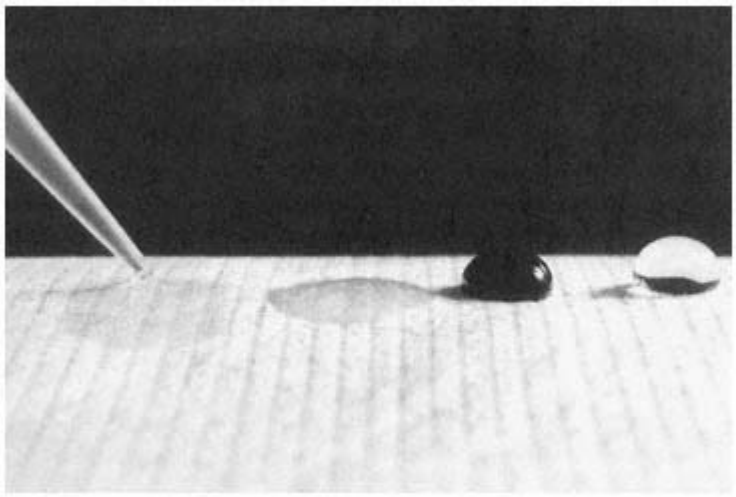

Figure 14
The wettability behavior of four liquids placed on the surface of spunbonded plexifilamentary linear high-density polyethylene nonwoven. From left to right, the liquids are 70% isopropyl alcohol ($\gamma \approx 0.024$ N/m), mineral oil ($\gamma \approx 0.031$ N/m), synthetic blood ($\gamma \approx 0.042$ N/m), and water ($\gamma \approx 0.072$ N/m).

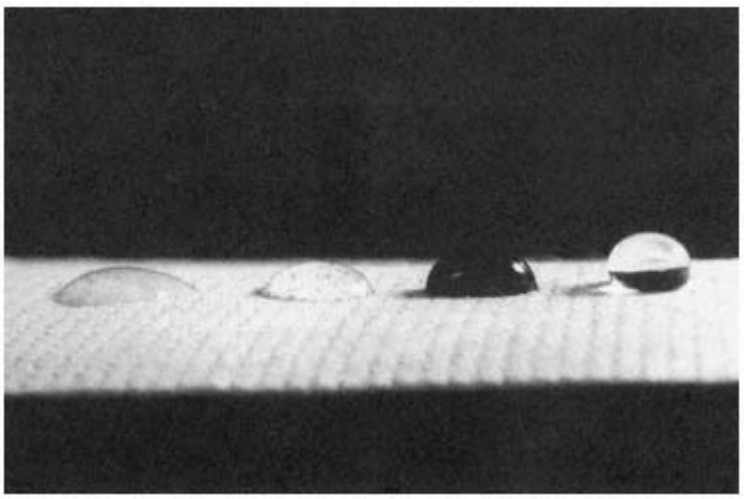

Figure 15
The wettability behavior of four liquids placed on the surface of spunbond/ meltblown/spunbond (SMS) polypropylene nonwoven. From left to right, the liquids are 70% isopropyl alcohol ($\gamma \approx 0.024$ N/m), mineral oil ($\gamma \approx 0.031$ N/m), synthetic blood ($\gamma \approx 0.042$ N/m), and water ($\gamma \approx 0.072$ N/m).

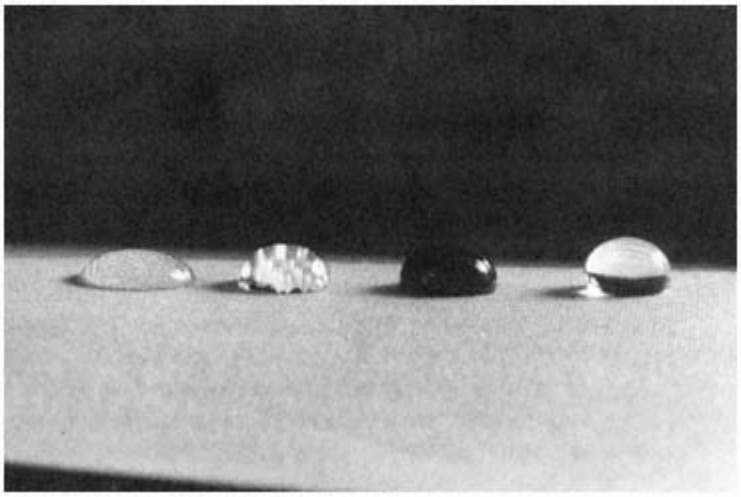

Figure 16
The wettability behavior of four liquids placed on the surface of woven continuous filament polyester microfiber. From left to right, the liquids are 70% isopropyl alcohol ($\gamma \approx 0.024$ N/m), mineral oil ($\gamma \approx 0.031$ N/m), synthetic blood ($\gamma \approx 0.042$ N/m), and water ($\gamma \approx 0.072$ N/m).

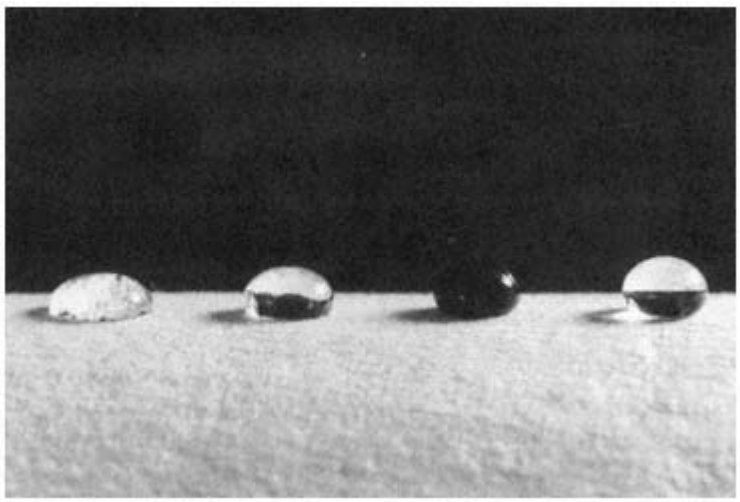

Figure 17
The wettability behavior of four liquids placed on the surface of spunlace woodpulp/polyester nonwoven. From left to right, the liquids are 70% isopropyl alcohol($\gamma \approx 0.024$ N/m), mineral oil ($\gamma \approx 0.031$ N/m), synthetic blood ($\gamma \approx 0.042$ N/m), and water ($\gamma \approx 0.072$ N/m).

3— Breakthrough Pressure

Breakthrough pressure refers to the pressure required to force liquid to penetrate through a textile. A very succinct treatment of the important variables was put together by Olderman [6]. Olderman expressed these variables in a word equation as follows:

The resistance of a textile to liquid penetration varies as

$$\frac{\text{surface tension, viscosity, contact angle, and pore length}}{\text{hydrostatic pressure, time, pore radius, and number of pores}} \qquad (4)$$

It is generally accepted that those liquids that develop low contact angles (less than 90 degrees) on the surface of a textile can wet and penetrate through the textile via capillary pressure and wicking forces more easily than those liquids that develop high contact angles (greater than 90 degrees). The capillary forces are described by the Laplace theory of capillarity, which defines the pressure that is necessary to push or draw a liquid through a uniform channel or pore [14,15].

$$P = \text{capillary pressure} = \frac{2\gamma \cos \theta}{r} \qquad (5)$$

where

γ = surface tension of the liquid

θ = contact angle of the liquid on the surface of the textile

r = pore radius

Further modifications can be made to the Laplace theory of capillarity to account for the relationship between capillary pressure (P), the height of the liquid column (h), the gravitational acceleration constant (g), and the density of the liq. uid (ρ): P = hgp [14]. This produces the following equation:

$$h = \frac{2\gamma \cos \theta}{rg\rho} \qquad (6)$$

From this equation it is apparent that as the challenging liquid surface tension and contact angle values get lower, the resistance of the textile to wetting and penetration is also reduced. Challenging liquid surface tension can be plotted against breakthrough pressure to graphically illustrate this relationship. Figure 18 graphically depicts the theoretical impact of decreasing the surface tension of the challenging liquid on the break-through pressure for porous textiles. Reductions in the resistance of the textile to wetting and penetration can also result from increasing the pore radius.

When a liquid either spontaneously wets or is forced to wet the textile by hydrostatic pressure, the rate of liquid penetration can be described by the law of Poiseuille and the Washburn equation [16]. The Washburn equation introduces two

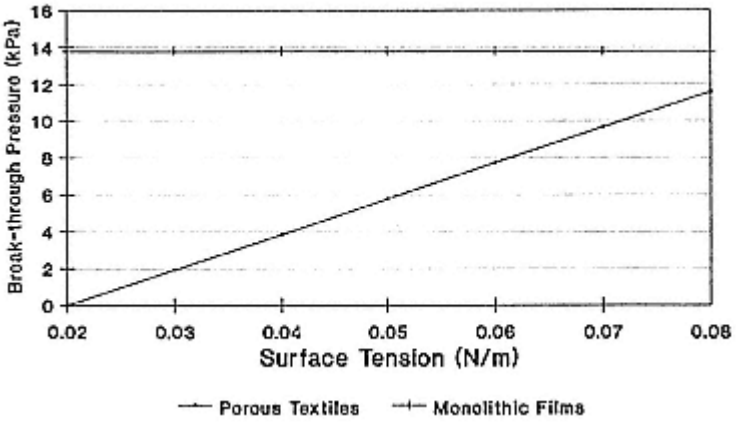

Figure 18
The relationship between the surface tension of various challenging liquids and the penetration resistance for any given textile can be plotted as illustrated. This graph shows the contrast between the theoretical behavior of porous textiles and the theoretical behavior of textiles that are reinforced with monolithic (nonporous) films.

new variables: the length of the pore and the viscosity of the liquid. As the values for pore length (influenced by the thickness of the textile and tortuosity of the path) and viscosity increase, the rate of entry for the liquid decreases. This equation is stated as follows:

$$V = \frac{r\gamma \cos\theta}{4\ell n} + \frac{P_A r^2}{8\ell n} \qquad (7)$$

where

V = rate of entry of a liquid in a capillary

r = pore radius

γ = surface tension of the liquid

θ = contact angle of the liquid on the surface of the textile

P_A = hydrostatic pressure

ℓ = length or depth of the pore

n = viscosity of the liquid or resistance of the liquid to flow

C—
Air Penetration Resistance

In most cases involving known biohazardous aerosol generation, rigorous engineering controls, such as negative-air-pressure rooms and biosafety cabinets, are employed in order to isolate and/or eliminate the risk. However, if textiles are intended to limit or prevent the penetration of hazardous airborne microorganisms, understanding whether those textiles allow air to penetrate through is the first analyrical step. If the textiles or the films used to reinforce the textiles are porous, the pores will allow air to penetrate through the structure. Textiles that are reinforced with monolithic (nonporous) films that are free from defects will not allow air to penetrate. Two of the standard test methods used to characterize the air penetration resistance of textiles are outlined next.

1—
Low Air-Penetration Resistance

The air-penetration resistance of low resistance textiles can be determined using ASTM D 737-75, Standard Test Method for Air Permeability of Textile Fabrics (Fig. 19). Some textile structures, such as the plexifilamentary linear high-density polyethylene nonwoven (Figs. 3 and 4) and the woven continuous-filament polyester microfiber (Figs. 7 and 8), can yield false negative results using this test procedure. High-density/low-porosity textile structures like these, which yield results of less than 0.5 $cm^3/cm^2 \cdot s$ (cubic centimeters per square centimeter per second), should be evaluated with the high-resistance test method.

2—
High Air-Penetration Resistance

The air-penetration resistance of high-resistance textiles can be determined using Federal Test Method Standard 191A, Method 5452 (Permeability to Air; Cloth;

Figure 19
The air penetration characteristics of textiles with low resistance can be determined using ASTM D 737-75 (Standard Test Method for Air Permeability of Textile Fabrics, also known as the calibrated orifice method). This method determines the volume of air that can penetrate through a textile with a pressure differential of 0.12 kPa. The higher the volume of air the more permeable the textile. (Photo courtesy of the Institute for Environmental Research, Kansas State University, Manhattan, KS.)

Falling Cylinder Method) (Fig. 20). Typically results are recorded as the time (in seconds) necessary to pass 300 cc (cubic centimeters) of air through the textile. The test method can be modified to accommodate textiles or textiles with various film reinforcements with very high resistance to air penetration by reducing the air volume penetration end point (<300 cc) and by extending the observation time period (hours). In order to obtain accurate measurements for some of the higher resistance textiles with film reinforcements, special sealing techniques may need to be employed in order to ensure that the air is flowing through the film and not escaping through the textile interface. Microscopy may also be used to confirm that the textile structure contains a monolithic (nonporous) element.

Other methods of determining air penetration resistance of textiles are being developed in order to document flow resistance changes with varying pressure drops [17]. The filtration of biohazardous aerosols through textiles is discussed later in this chapter.

D—
Moisture Vapor Permeability and Thermal Insulative Properties

Depending on the end-use application for the textile, it may be necessary to characterize the moisture vapor permeability and thermal insulative properties. Bal-

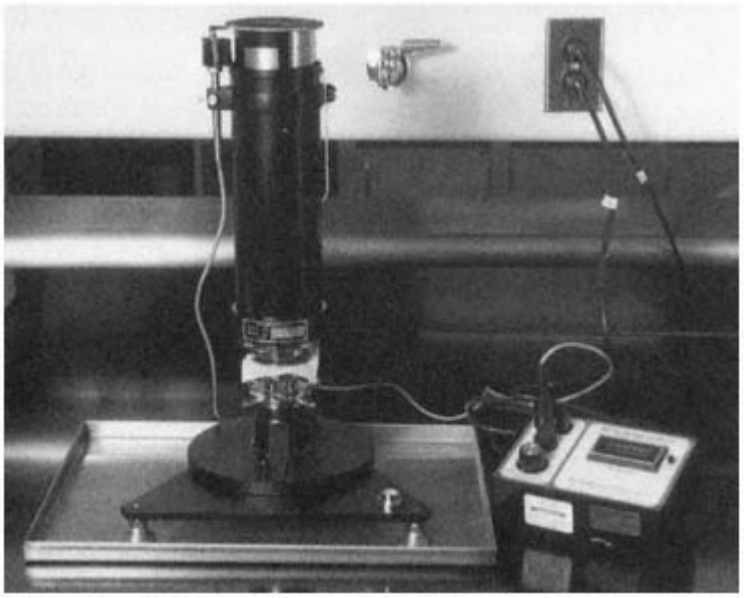

Figure 20
The air penetration characteristics of textiles with high resistance can be determined using Federal Test Method Standard 191A, Method 5452 (Permeability to Air; Cloth; Falling Cylinder Method). This method determines the time that is necessary to allow a certain volume of air to penetrate through the textile. The shorter the time interval, the more permeable is the textile.

ancing the thermal comfort properties against the microbial barrier properties can be very important for textiles intended to be used in personal protection and infection control clothing. Allowing the human body to maintain thermal equilibrium can lower heat stress and result in better job performance (physically and mentally), improve productivity (work longer with fewer breaks), reduce the risk of noncompliance (not wearing protective clothing because it is too hot), and increase job satisfaction (make work more enjoyable). Different work environments, physical labor, and clothing styles (gown vs. coverall, zoned vs. complete reinforcement) can place different demands on textiles in order to achieve the thermal comfort balance. The comfort versus protection paradigm has presented a longstanding problem in personal protection and infection control clothing textile applications; however, this paradigm can be broken with breathable film reinforced textiles.

Institutes developing excellence in this area are utilizing two main research tools: the sweating guarded hot plate and the thermal (heated) manikin [1,2,3,18]. When textiles are required to minimize or prevent the penetration of hazardous microorganisms and allow the human body to maintain thermal equilibrium, the

resistance to evaporative heat transfer should be determined using the sweating guarded hot plate. The sweating guarded hot plate is preferred over other simpler methods for making comparative analyses of the moisture vapor permeability of textiles because it simulates the heat and mass transfer characteristics of the human body fairly accurately, Textiles exhibiting lower resistance values R(et) against the transfer of moisture vapor with this text can be utilized to construct more comfortable garments.

Generally speaking, most textiles that do not include film reinforcements exhibit low resistance values R(et) against the transfer of moisture vapor. However, new developments in the field of monolithic film reinforcements can also provide low resistance values R(et) against the transfer of moisture vapor. As an example, one of these film-reinforced textiles that exhibits low R(et) can be found in Figure 36.

The thermal manikin is used to assess the impact of the end garment as influenced by the geometry of the human body (clothing fit, design, and layering) on heat and mass transfer. Human subjects are also used to evaluate clothing systems to more directly measure the physiologic factors important to thermal comfort and to qualitatively assess comfort variables that are difficult to determine in the laboratory.

E—
Penetration Versus Permeation

The terms penetration and permeation are often used interchangeably when describing the transfer of air, liquids, and microorganisms from one side of a textile barrier to the other side. There is a fundamental difference between penetration and permeation that should be understood when evaluating the barrier properties of textiles in the laboratory. Penetration is defined as the bulk flow of gases, vapors, or liquids through porous materials and is driven by a pressure gradient across the bartier. Permeation can be defined as the diffusion of gases or vapors through porous materials and dissolved gases, vapors, or liquids through nonporous materials on a molecular level, and is driven by a concentration gradient across the barrier.

Permeation testing is usually employed on textiles that are intended to protect against the diffusion of hazardous gases and vapors. The basic equation for diffusion can be derived from Fick's law, stated as follows [18]:

$$\frac{m}{A} = \frac{\Delta c}{R} \qquad (8)$$

where

m = mass flow

A = area

Δc = concentration difference

R = resistance to diffusion

If penetration can occur, through the interstices between the yarns/fibers in a textile or through the pores in a porous film reinforcement, then permeation can also occur. However, the rate of transfer will most likely be more dependent on bulk flow rather than diffusion. Currently, microorganisms are thought to penetrate and not permeate through materials, mainly due to their large size in comparison to gas and vapor molecules. Even the smallest known human pathogenic viruses, as depicted in Figure 21, are almost two orders of magnitude larger in diameter than the molecular diameters of CO_2 and H_2O. (The molecular diameters for gas molecules, such as carbon dioxide and water vapor, have been calculated and determined to be in the range of 0.0004 µm [19].) This size difference is one of the reasons why monolithic (nonporous) films can act as such effective

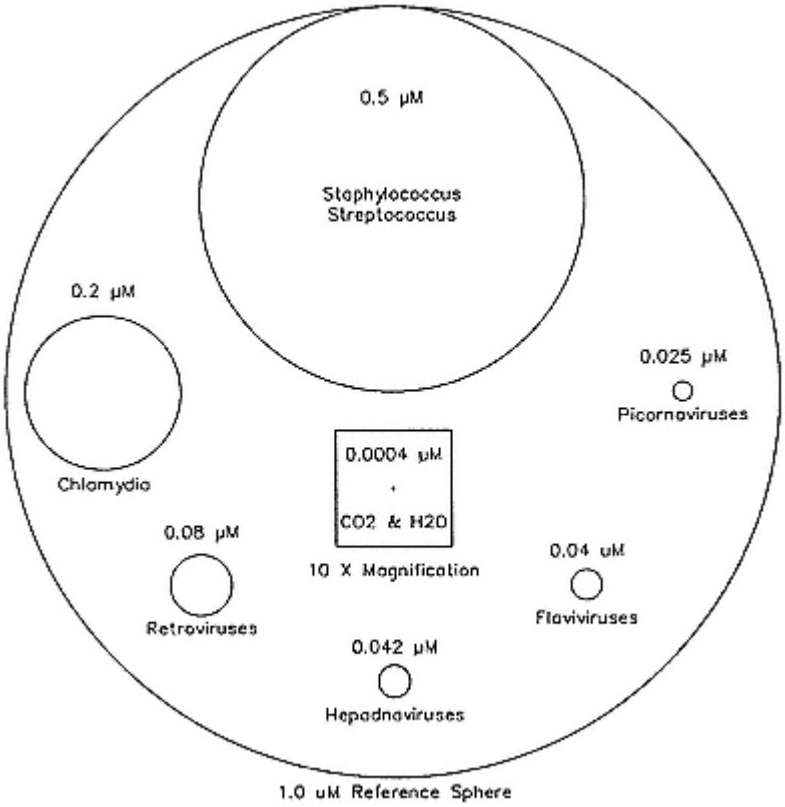

Figure 21
Examples of the sizes for various selected microorganisms are depicted to illustrate the difference between viruses, bacteria, and fungi. Even the smallest fungal spores would be larger than the outer 1.0-µm reference sphere. The molecular diameter for carbon dioxide and water has been added in the box at the center of the diagram for comparison.

microbial barriers. This is also one of the reasons why it is possible to create "breathable" monolithic film reinforcements, as the small size of water vapor allows it to diffuse through on a molecular level, while microbes are excluded due to their larger size.

Microbial challenge testing has fundamentally different requirements than permeation testing. Some of the important differences are as follows.

1. For many types of microorganisms, given the correct inoculation route, very few infectious units are necessary to cause infection [20,21]. Under these circumstances, where the acceptable number of viable infectious microbes that can penetrate through a textile is extremely small (i.e., 1–100), determining the penetration rate is of little or no real value.

2. Infection is an absolute process. Either infection occurs or it does not occur. Beyond a certain number, related to the number of infectious units necessary to cause infection to occur, quantification and determination of steady state are moot points.

3. Molecular diffusion is currently not recognized as a mode of transfer for microorganisms through textile barriers. The major mechanism of transport for microbes is to move with the bulk flow of the air and liquid vehicles. Pressure gradients across the textiles can cause the penetration of the air and liquid vehicles, whereas permeation testing can be performed with little or no pressure differential across the barrier as permeation is the result of a concentration gradient.

Test cells that are designed to measure the chemical permeation resistance of textiles, such as ASTM F739-91 (Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids or Gases Under Conditions of Continuous Contact), unless modified to apply pressure, are not appropriate for use in assessing the microbial barrier characteristics of textiles.

F—
Time of Test

Time is an important parameter to understand when conducting challenge tests of various types on textiles in the laboratory. Some penetration mechanisms are time dependent and others are not time dependent. When considering air-based challenge testing, depending on the filtration mechanisms acting on the aerosols, the time to travel through the textile can influence the filtration efficiency. The time necessary to travel through will be proportional to the pressure differential, which influences the flow rate of the air.

When considering liquid-based challenge testing, the time of the tests is secondary in importance as compared to pressure. If the hydrostatic pressure exerted on the liquid does not cause the liquid to overcome the resistance of the textile, then the time variable could be infinite, as wetting and penetration may never oc-

cur. It has been suggested that if the test pressure exceeds the average applied pressure that would normally be exerted on the textile during use, then the test time may be shorter than the time of use [22]. Historically, the pressures used in liquid based microbial challenge tests have been quite low. As an example, in one study, when using a constant, very low hydrostatic test pressure (≈0.06 kPa), time periods greater than 60 min did not increase bacterial penetration through barrier materials [23]. However, this conclusion is only valid if the hydrostatic pressures challenging the textiles during use do not exceed 0.06 kPa. Depending on the enduse application, hydrostatic pressures far in excess of 0.06 kPa and probably as high as 13.8 kPa can be exerted on textile barriers during use [24,25,26].

Assuming that the hydrostatic pressure exerted on the liquid causes the liquid to wet and penetrate into the textile barrier, the Washburn equation identifies two variables that can influence the flow rate of liquids through the textile: the pore length (influenced by thickness of the textile and tortuosity of the path) and the viscosity of the liquid. As the hydrostatic pressure on the penetrating liquid is increased, the flow rate of the liquid through the textile barrier will increase and the corresponding time to penetrate through the textile will decrease.

Each personal protective clothing and infection control end-use application may have different requirements for the period of time that the textile barriers are expected to meet the barrier performance expectations. The true goal of laboratory testing is to discriminate among the barrier properties in a meaningful way. This does not mean that the challenge time in the laboratory has to equal the challenge time in each end-use application, but that the challenge time in the laboratory is controlled in a way that provides data that can be used to make reasonable predictions of barrier performance in each end-use application.

If the reason for considering increasing the time interval of the test in the laboratory is to determine how long the textile will act as an effective microbial barrier in actual use, then other types of use factors that can significantly impact barrier integrity and induce other modes of failure should be considered. Factors influencing microbial penetration in use could include a whole list of physical, chemical, and thermal stresses. These stresses may need to modeled in the laboratory and used as preconditioning steps prior to microbial barrier integrity testing. As an example, flexing or abrading a textile sample for 1 min may cause an immediate failure at very low pressure during barrier integrity testing. However, without flexing or abrading, that same textile may not demonstrate failure over long periods of time at high pressure.

G—
Liquid Challenge Testing

Liquid challenge testing has been used over the years as a means to predict the liquid-borne microbial barrier properties of textiles [6,24]. A lot of the work done in this area focused on the need for infection control in the surgical end-use

applications. However, when health-care workers became aware of the personal risks associated with direct contact with blood and body fluids, textile and garment manufacturers, academia, regulatory agencies, and the medical community became much more critical of barrier integrity testing. Recent work has demonstrated that there are significant limitations in the industry standard liquid challenge test methods [24,27]. This work has led to the conclusion that liquid challenge tests can be useful prescreening tools in determining which protective fabrics warrant further investigation with microbiological challenge tests, but should never be used alone to infer absolute microbial barrier properties. The most common liquid challenge test methods are briefly reviewed and some of the more significant limitations are discussed next.

1— Review of Common Standard Liquid Challenge Tests

The INDA Standard Test IST 80.5-92 (Saline Repellency of Nonwovens) is illustrated in Figure 22. This test is designed to measure the amount of time required for saline to penetrate through textile barriers under defined conditions. Specimens of the textile are cut and fit into the lid of a Mason jar, which is inverted and placed on a glass surface over a mirror. Saline is added through a hole in the bottom of the jar and adjusted to a height of 115 mm (1.13 kPa hydrostatic pressure). The test is terminated when visible penetration of the saline through the textile is observed and the time (in minutes) is recorded. The longer the time interval the more repellent the textile. (Normally this test is terminated if no visible penetration occurs in 60 min.) Here the saline has been substituted with synthetic blood as part of a study to determine the effect of liquid type on the outcome of the results.

AATCC Test Method 42-1989 (Water Resistance: Impact Penetration Test) is illustrated in Figure 23. This test is designed to measure the amount of water that can penetrate through a textile under defined conditions. A preweighed piece of blotter paper is placed under a specimen of the textile barrier that is oriented at 45 degrees to a funnel situated 61 cm above. After 500 ml of distilled water is poured through the funnel, impacting the top surface of the textile, the blotter is reweighed. Any weight gain in the blotter is attributed to water penetrating through the textile barrier. The lower the weight gain in the blotter, the more water impact resistant the textile is. Here the water has been substituted with synthetic blood as part of a study to determine the effect of liquid type on the outcome of the results.

AATCC Test Method 127-1989 (Water Resistance: Hydrostatic Pressure Test) is illustrated in Figure 24. This test is designed to measure the hydrostatic pressure necessary to force water to penetrate through a textile under defined conditions. A specimen of the textile barrier is clamped over the end of a water column. The height of the water in the column is raised at the rate of 1.0 cm/sec until penetration of the water is visible through the textile. The standard column height is 100 cm (maximum hydrostatic pressure = 9.8 kPa). The higher the column height achieved before water penetration, the greater the water resistance of the textile is.

Figure 22
The saline repellency of textiles can be determined using INDA Standard Test IST 80.5–92 (Saline Repellency of Nonwovens, also known as the Mason jar test). (Photo courtesy of the Institute for Environmental Research, Kansas State University, Manhattan, KS.)

2— Limitations of Standard Liquid Challenge Tests

Detecting liquid penetration through the use of the naked eye or by weight gain in a paper blotter is significantly less sensitive than a microbiological assay. A significant number of microorganisms can be carried in a very minute volume of liquid, which may not be visible to the naked eye or measured by weight gain in a blotter (refer to Fig. 25).

The liquids normally used in these liquid challenge tests, water and saline, have high surface tensions, exhibit high contact angles (>90 degrees) on most textile barriers, and consequently do not wet or penetrate through textile barriers as easily as some of the liquids that are potentially contaminated with hazardous microorganisms.

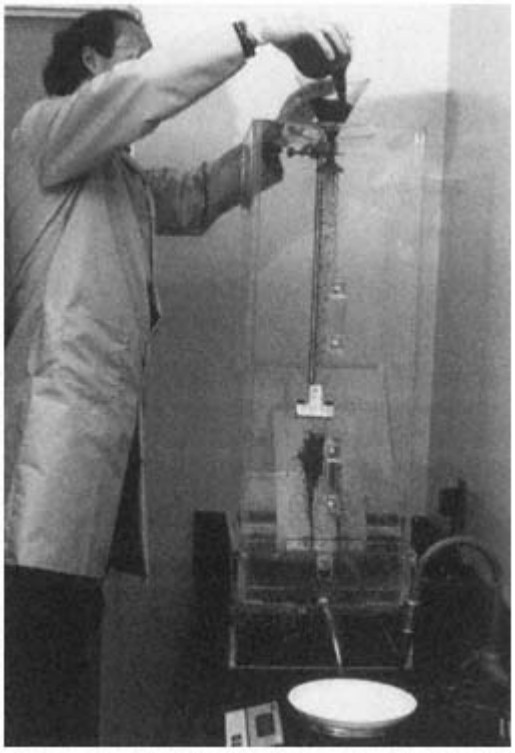

Figure 23
The water impact resistance of textiles can be determined using AATCC Test Method 42-1989 (Water Resistance: Impact Penetration Test).
(Photo courtesy of the Institute for Environmental Research, Kansas State University, Manhattan, KS.)

These test devices have limitations on the amount of pressure that is applied to the liquid during the challenge procedure and may not be indicative of the pressures that can be exerted on liquids in contact with textile barriers during use.

These liquid challenge tests are normally conducted for shorter periods of time than the anticipated time of liquid challenge in some end-use applications. A short time in combination with low liquid challenge pressure may render misleading test results.

3—
Development of New Tests

Recognizing the inadequacies of the industry standard liquid challenge tests prompted two manufacturers to respond and attempt to develop new liquid challenge tests. Each one of these new test methods is briefly described next.

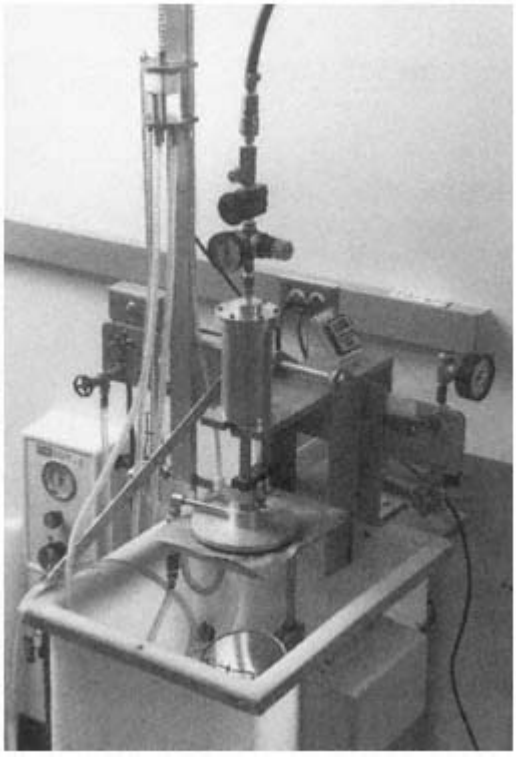

Figure 24
The penetration resistance of textiles to water at low pressure can be determined using AATCC Test Method 127-1989 (Water Resistance: Hydrostatic Pressure Test).

The Kimberly-Clark blood strikethrough test is illustrated in Figure 26. This test was designed to measure the amount of heparinized bovine blood that could penetrate through textile barriers under defined conditions. This procedure is performed by placing a small amount (1.4 g) of bovine blood on the surface of the textile. The jack stand is then raised, compressing the textile between the water bottle and the top plate of the test apparatus. The pressure on the water bottle is increased to 6.9 kPa. After a specified period of time the pressure is released and a paper blotter is removed from under the textile and weighed. The lower the weight gain in the blotter, the more resistant the textile is to the penetration of bovine blood.

This test procedure was considered for standardization through the American Society for Testing and Materials (ASTM); however, it was found that certain types of absorbent nonbarrier fabrics, such as surgical gauze, would pass this test by preventing the penetration of bovine blood. Therefore, ASTM discontinued its effort with this method [28].

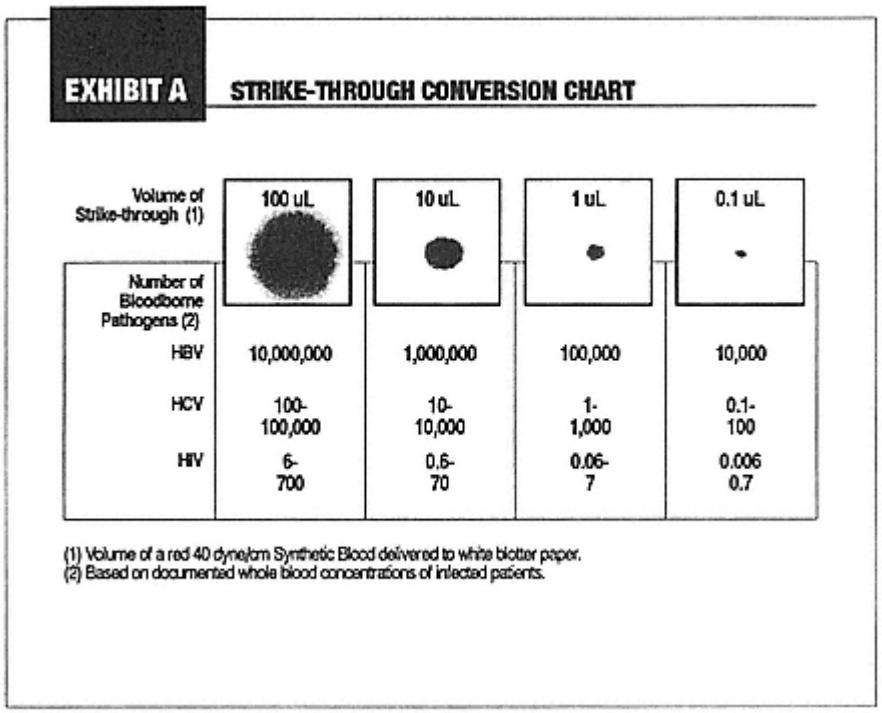

Figure 25
Strike-through conversion chart.

The GORE elbow lean test is illustrated in Figure 27. This test was designed to determine if a body fluid model (synthetic blood) could visibly penetrate through textile barriers during simulated pressing and leaning activities. The body fluid model was selected because the whole blood of humans or other animals may not be predictive of the wetting and penetration characteristics of the entire range of potentially infectious human body fluids. Excluding saliva, the surface-tension range of human blood and body fluids is 0.042–0.060 Nlra (refer to Table 1). A more appropriate body fluid model would have a surface tension approximating the lower end of the blood and body fluid range and would be more predictive of the penetration characteristics of body fluids and other liquids with higher surface tensions. Researching the literature led to a synthetic blood formulation [29]. The synthetic blood contains 10 g direct red 081 dye (CI 28160, colorant with surfactant), 25 g Acrysol G-110 (thickening agent), and 1.0 L normalized distilled water. The surface tension of the synthetic blood is 0.042 N/m. The synthetic blood has been evaluated in comparison to other test liquids, including heparinized whole bovine blood, for penetration through a variety of commercially available textile barrier fabrics and has been found to be the preferred test liquid [27].

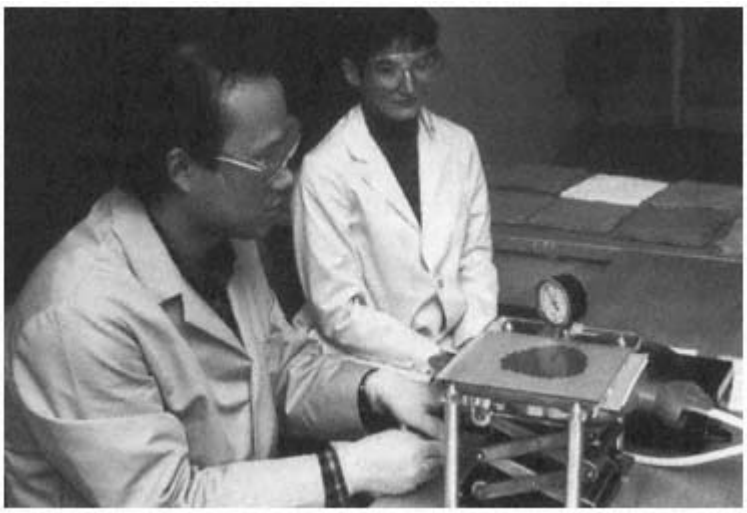

Figure 26
Kimberly-Clark blood strike-through test.
(Photo courtesy of the Institute for Environmental Research,
Kansas State University, Manhattan, KS.)

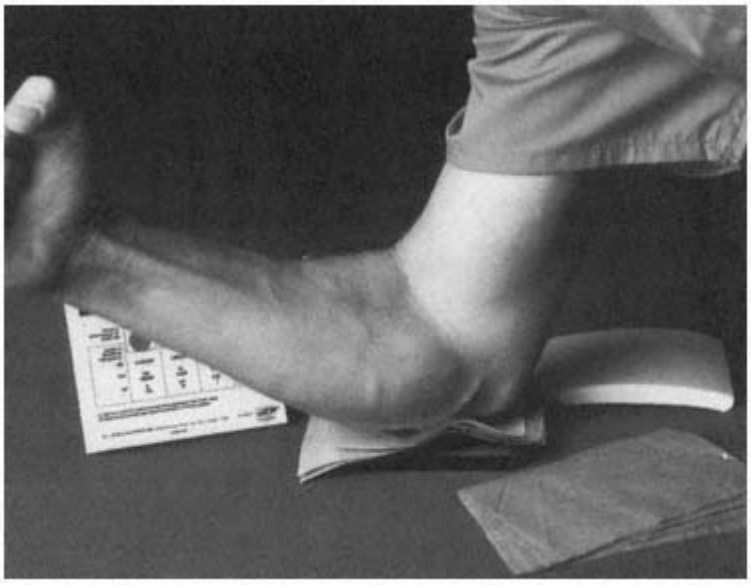

Figure 27
The GORE elbow lean test. Contact W. L. Gore & Associates, Inc.,
for details on how to order test kits [11].

The GORE elbow lean test is performed by saturating a foam pad with the synthetic blood, laying the textile barrier over the soaked pad (face side down), placing a white paper blotted over the textile (the paper is backed by a polyethylene film to prevent penetration of the synthetic blood if the textile fails), and then pressing and leaning on the textile. Pressing and leaning can be done in various ways to simulate the types of stresses and pressures that the textile barrier would be exposed to during use. Leaning with the elbow can easily apply direct mechanical pressures on the textile in excess of 345 kPa. Visible penetration of synthetic blood through the textile to the paper blotter denotes failure. If desired, the volume of penetrating blood and the respective number of infectious microorganisms can be approximated by comparing the blotter to the strike-through conversion chart (refer to Fig. 25). Textiles that prevent the visible penetration of synthetic blood during pressing and leaning are considered to be more protective against the penetration of blood and body fluids.

Although the GORE elbow lean test has not been standardized, the results of this simple pressing and leaning experiment have served as a benchmark to compare with other more complicated scientific laboratory tests and to develop new standardized liquid and microbial challenge procedures (ASTM ES21-92 and ASTM ES22-92). This test serves as a classic example of how to apply knowledge of the real-world end-use application for textile barriers to the development of challenge test methods in the laboratory that would be more likely to reduce risk. The GORE elbow lean test can also be used by end users in the field, simulating many different types of personal protection and infection control end-use applications, to help determine the visible liquid barrier properties of textiles.

Typically, textile barriers that are not film-reinforced will fail and textile barriers that are film-reinforced will pass the GORE elbow lean test [2,3,24,27]. (Those textiles found in Figs. 3-10 consistently demonstrate failing results, and those textiles found in Figs. 35 and 35 consistently demonstrate passing results.) Illustrations of failing and passing results are given in Figures 28 and 29.

The resistance of textiles to the visible penetration of synthetic blood can also be determined by using ASTM ES 21-92 (Emergency Standard Test for Resistance of Protective Clothing Materials to Synthetic Blood). The development of this method is based on correlation studies that were done, comparing the results obtained when testing the synthetic blood resistance of a variety of commercially available textile barriers, using the GORE elbow lean test and the ASTM ES 21-92 test [24,27] (refer to Table 2).

The test was developed as a prescreening test for ASTM ES22-92 (discussed later in this chapter). ASTM ES21-92 is designed to determine if textiles can prevent the visible penetration of synthetic blood under defined test conditions. Textile specimens are clamped into the penetration ceil with the face side oriented toward the cell cavity. Then the penetration cell in attached to the apparatus and the cell cavity is filled with 60 ml of synthetic blood. An air line is connected to

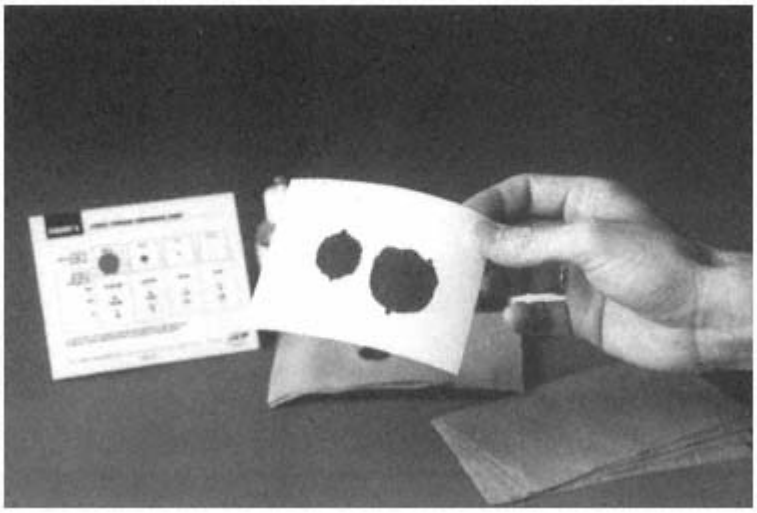

Figure 28
A failing result on the GORE elbow lean test. The specimen tested was cut from a fabric-reinforced surgical gown. The textile type is spunlace woodpulp/polyester nonwoven (refer to Figs. 9 and 10). The penetrating synthetic blood on the left of the paper blotter is the result of one finger press, and on the right is the result of one elbow lean.

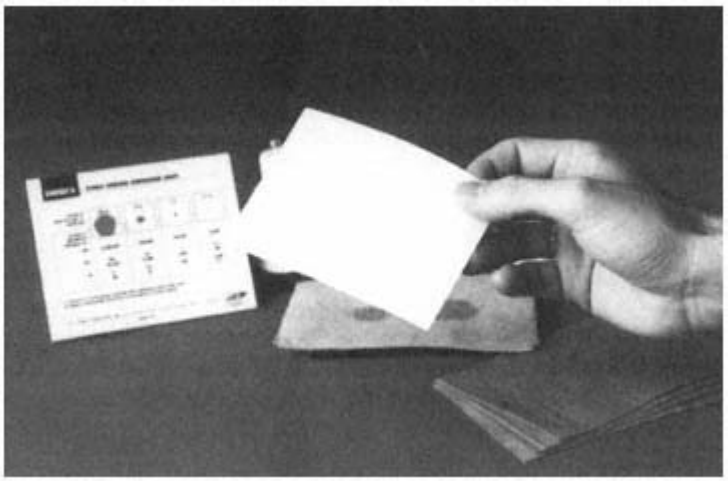

Figure 29
A passing result on the GORE elbow lean test. The specimen tested was cut from a film-reinforced surgical gown. The textile type is spunlace woodpulp/polyester nonwoven with film reinforcement (refer to Fig. 35). No visible penetration of the synthetic blood is noted on the paper blotter as a result of the finger press or the elbow lean. Multiple leans can be performed and yield the same results.

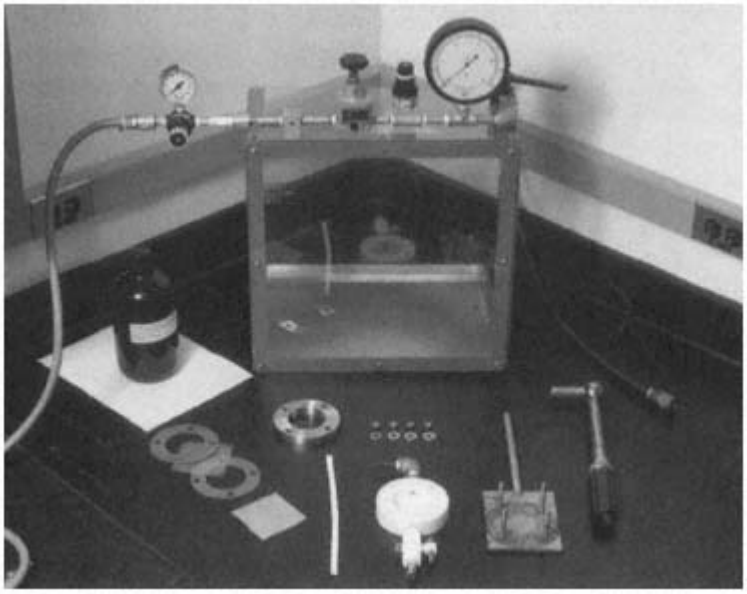

Figure 30
The resistance of textiles to the visible penetration of synthetic blood can be determined by ASTM ES21-92 (Emergency Standard Test for Resistance of Protective Clothing Materials to Synthetic Blood).

the cell and a specific time and hydrostatic pressure protocol is followed: 5 min at ambient pressure, 1 min at 13.8 kPa, and 54 min at ambient pressure. The back side of the textile specimen is observed through the viewing port, and any visible sign of synthetic blood penetration through the textile denotes a failure. Examples of failing and passing results are illustrated in Figures 31 and 32. Textiles that demonstrate passing results should then be tested with ASTM ES22-92 to confirm the microbial barrier integrity.

The results of the ASTM ES21-92 test (Figs. 31 and 32) can be directly compared to the results for the GORE elbow lean test (Figs. 28 and 29). Once again, textile barriers that are not film-reinforced typically fail and textile barriers that are film-reinforced typically pass the ASTM ES21-92 test [2,3,24,27]. (Those textiles found in Figs. 3-10 consistently demonstrate failing results and those textiles found in Figs. 35 and 36 consistently demonstrate passing results.)

A comparison of the six liquid challenge tests already listed was performed using synthetic blood and nine different single-use and multiple-use barrier textiles. (This necessitated replacement of the standard liquid challenge reagents with synthetic blood for some of the tests.) The results of this analysis can be found in Table 2. The highest correlation found between any two tests was between the

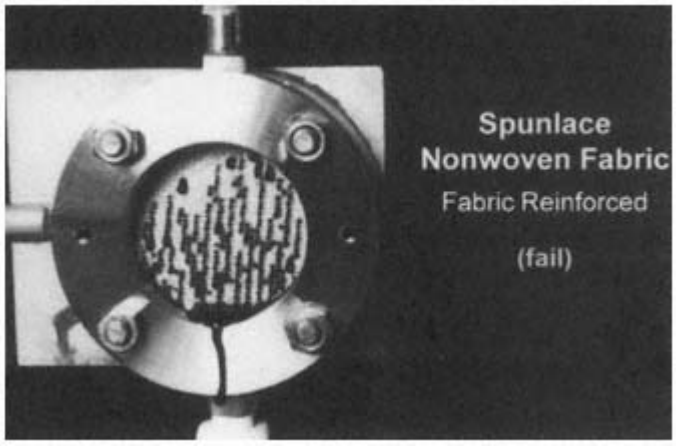

Figure 31
Failing test result for ASTM ES21-92. The specimen tested was cut from a fabric reinforced surgical gown. The textile type is spunlace woodpulp/polyester nonwoven (refer to Figs. 9 and 10).

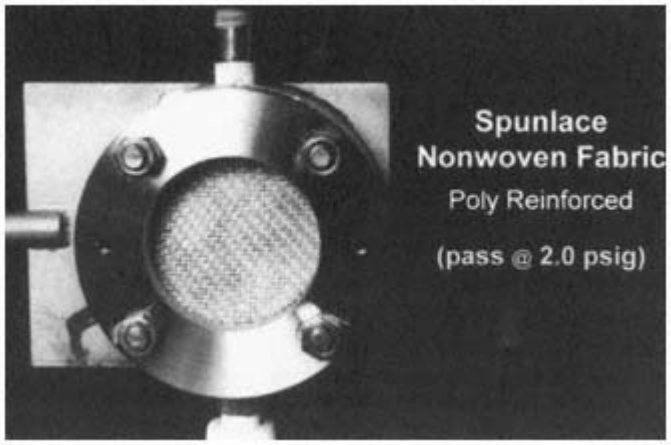

Figure 32
Passing test result for ASTM ES21-92. The specimen tested was cut from a film-reinforced surgical gown. The textile type is spunlace woodpulp/polyester nonwoven with film reinforcement (refer to Fig. 35).

Table 2 Spearman Correlation Coefficients for Liquid Barrier Tests Using Synthetic Blood

Comparative liquid barrier tests	KC blood strik-through test	AATCC 42-1989 impact penetration test	IST 80.5-92 Mason jar test	ASTM ES21-92 synthetic blood resistance test at 6.9 kPa	ASTM ES21-92 synthetic blood resistance test at 13.8 kPa	AATCC 127-1989 hydrostatic resistance test
KC blood strike-through test	N/A					
AATCC 42-1989 impact penetration test	0.92[b]					
IST 80.5-92 Mason jar test	0.69[a]	0.75[a]				
ASTM ES21-92 synthetic blood resistance test at 6.9 kPa	0.38	0.25	0.54[b]			
ASTM ES21-92 Synthetic blood resistance test at 13.8 kPa	0.60	0.49	0.37	0.59		
AATCC 127-1989 hydrostatic resistance test	0.92[b]	0.75[a]	0.56	0.63	0.74[a]	
GORE elbow lean test	0.61	0.50	0.38	0.60	0.98[b]	0.75[a]

[a]Significant to the .05 level.
[b]Significant to the .01 level.
Source: Ref. 27.

GORE elbow lean test (dubbed the "human factors test") and the ASTM ES21-92 test. This high correlation (.98 correlation coefficient, significant at the .01 level) demonstrates that these two tests were able to discriminate among the nine different barrier textiles in the same way. The ASTM ES21-92 test, a laboratory bench-top test, discriminated among the nine different barrier textiles in the same way as the GORE elbow lean test, a simulated use or "human factors" validation test. The other five tests were not able to discriminate among the nine different barrier textiles in the same way as the GORE elbow lean test. This finding is very important for the laboratory evaluation and determination of which types of textiles might be capable of resisting visible liquid penetration in end-use applications involving soaking with blood and body fluids and pressing and leaning pressures.

H—
Pressure

As mentioned previously, the pressure placed directly on the challenging air and liquids can significantly influence the flow rate of those fluids through porous textile barriers. However, quantifying the pressures actually applied on these fluids in the real world during exposure situations is difficult. Each end-use application will bring a different set of dynamic uncontrolled circumstances that can change the factors that are important in calculating the pressures applied to the air and liquids challenging the barrier textiles. Pressure is defined [9] as:

Pressure (P) = force per unit area

SI unit: Pascal (Pa) (9)

1 Pa = 1 N/m^2 (newton per square meter)

Most of the work done to date has focused on quantifying the mechanical pressures applied to the textiles as they are compressed between the human body and the work space. For example, the pressures exerted on surgical gowns during pressing and leaning activities in surgery can range from less than 6.9 kPa to more than 414 kPa [31]. The hydrostatic pressures exerted on the liquids in contact with the surgical gowns during pressing and leaning have not yet been quantified, but are thought to easily exceed 6.9 kPa [24,25].

As discussed earlier, when comparing the resistance of many different barrier textiles against synthetic blood, there is a strong correlation between the 13.8 kPa hydrostatic pressure used in the ASTM ES21-92 test and the much higher direct mechanical pressure (≈345 kPa) used in the GORE elbow lean test. This correlation was confirmed again in a more recent study involving an even higher direct mechanical pressure (427 kPa) on the textile [26]. Under most end-use conditions the hydrostatic pressure exerted on the challenging liquid will be lower than the direct mechanical pressure applied to the textile as the liquid is not contained but free-flowing and able to escape from the forces being applied to it. In an attempt to illustrate this point, Figures 33 and 34 were prepared. Figure 33 is a

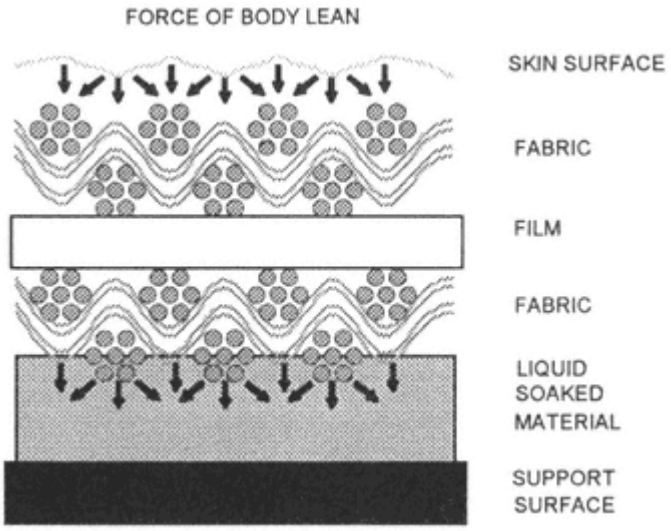

Figure 33
Orientation of a textile (three-layer film-reinforced laminate) between the human body and a wet contaminated work environment. Here the liquid is adsorbed into a porous compressible material, such as a foam pad. As the force of the body increases, the textile is pressed into the liquid-soaked pad. While a direct mechanical pressure is exerted on the textile and the foam, a corresponding hydrostatic pressure is exerted on the liquid. Since the liquid is free flowing, pressure will only remain on the liquid until the structural elements of the textile align themselves to provide a solid support for the force of the body against the work surface. The range of direct mechanical pressures exerted on the textile can be calculated and controlled; however, the range of hydrostatic pressures exerted on the liquid has only been approximated and cannot be controlled.

representation of the GORE elbow lean test and Figure 34 is a representation of the ASTM ES21-92 test.

I—
Textile Composites

Film-reinforced textiles, as a group, can offer a much higher level of resistance to airborne and liquid-borne microbial penetration. When textiles include film rein-forcements, the films become the overriding factor in determining the air, liquid, and microbial barrier properties. The textiles mainly serve to support and protect the films. The types of textiles that are used for this purpose and the ways in which the textiles and films are combined can have a direct influence on the initial barrier properties and the in-use durability of the those barrier properties. As an example, two-layer composites (film combined with one textile) where the film is oriented out to the work environment would subject the film structure directly to potentially damaging physical stresses, such as abrasion, scoring, etc.

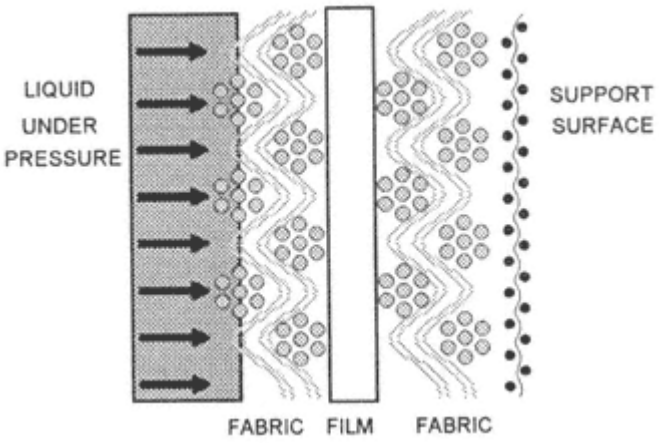

Figure 34
This diagram illustrates the orientation of a textile (three-layer film-reinforced laminate) in a hydrostatic test device such as ASTM ES21-92 and ASTM ES22-92. Here the liquid represents the contaminated work environment and is placed in direct contact with the textile. The hydrostatic pressure placed on the liquid is known and can be very precisely controlled. As the hydrostatic pressure on the liquid is increased, the liquid is compressed against the textile. In some cases, if the textile is weak or subject to distortion-related failures, a retaining screen can be used to add support. Liquid penetration through the textile occurs if the hydrostatic pressure exceeds the ability of the textile to resist wetting.

Concerning the evaluation of the protective properties of films, there are two major film reinforcement categories, monolithic and microporous, which are defined by fundamental structural differences that can influence the airborne and liquid-borne microbial barrier properties. Other subcategories exist that are defined more by the chemical nature of the films and how the films interact with liquids, such as hydrophobic, hydrophilic, oleophobic, etc., which may further influence the airborne and liquid-borne microbial barrier properties.

The inherent differences between the two major categories of textile film reinforcements are that (1) porous film reinforcements allow the bulk flow of air through the pores, relying on filtration mechanisms against air-borne biohazards, and resist the penetration of challenging liquids to varying degrees based on the laws and equations discussed earlier [Eq. (2)–(7)] and (2) monolithic (nonporous) textile film reinforcements do not allow the bulk flow of challenging air or challenging liquids.

The major types of film reinforcements being used today for microbial barrier textiles rely either entirely or partially on a monolithic structure to impart the air, liquid, and microbial barrier properties. Representative structures are depicted in Figures 35 and 36. Three major studies have been conducted, using the most

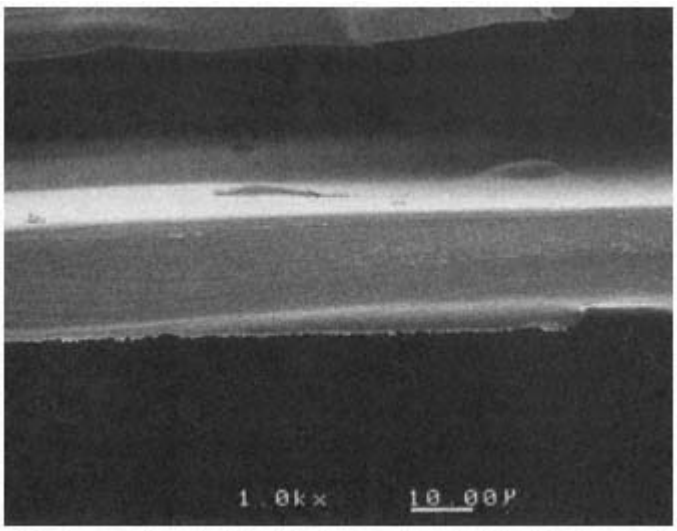

Figure 35
Scanning electron micrograph: cross section at 1000× magnification, Optima (polyreinforced), supplied by Baxter Healthcare Corp., described as spunface woodpulp/ polyester nonwoven with film reinforcement; weight 115.44 g/m^2, thickness 0.65 mm, bulk density 177.60 g/m^3. Description of film: monolithic (nonporous) polyethylene.

stringent liquid and liquid-borne microbial challenge procedures available today, which have demonstrated that these two film-reinforced textiles provide excellent barriers to liquids and liquid-borne microorganisms [2,3,26].

Unlike porous film reinforcements, the liquid penetration resistance of monolithic film reinforcements is only influenced by one variable in Eq. (4), hydrostatic pressure. In reference to Figure 18, the line that has been plotted for monolithic films simply represents the strength of the film. The breakthrough pressure of monolithic film reinforcements, across the whole range of liquid surface tensions, will be the result of the film bursting. Porous films, on the other hand, will behave similarly to the line represented for porous textiles as the breakthrough pressure will be proportional to the wetting characteristics of the challenging liquid and subject to all of the variables in Eq. (4).

1—
Film Strength

One method of distinguishing between monolithic film reinforcements is to evaluate the bursting strength. Bursting strength may also be determined after various different types of preconditioning steps, such as flexing, abrading, etc., to simulate the impact of actual use. However, the bursting strength test is not intended as a measurement of the integrity of monolithic film reinforcements against airborne

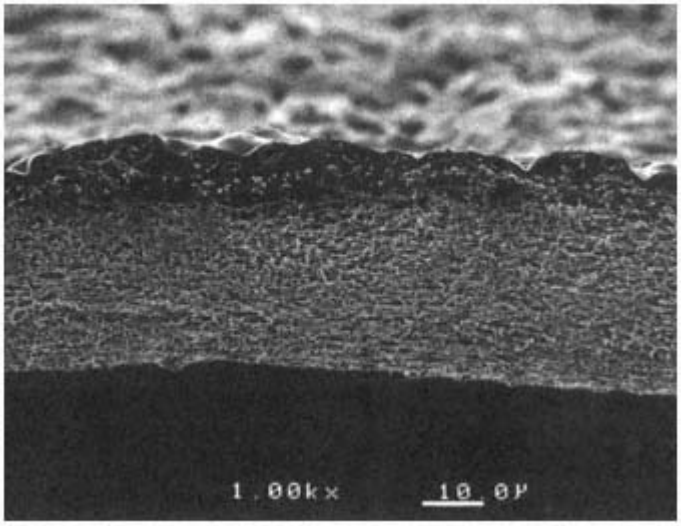

Figure 36
Scanning electron micrograph: cross section at 1000× magnification, GORE surgical barrier fabric, supplied by W. L. Gore & Associates, Inc. described as woven polyester/film/knitted polyester laminate; 184.88 g/m^2, thickness 0.47 mm, bulk density 393.36 g/m^3. Description of film: bicomponent; expanded polytetrafluoroethylene membrane partially impregnated with a monolithic (nonporous) hydrophilic/oleophobic polymer.

or liquid-borne microbial penetration. With the exception of pressure, this test suffers from all the same limitations of many of the other liquid challenge tests discussed previously. Also, the results obtained on liquid challenge tests of this type have been found to be sensitive to the ramping speed [32].

The burst strength of film-reinforced textiles can be determined by using ASTM D751-89 (Standard Test Methods for Coated Fabrics; Procedure A). The test device is depicted in Figure 37. Figure 38 shows a specimen being observed for leakage.

2—
Film Integrity Testing

Characterizing the maximum pore size in porous film reinforcements or the size of defects in either monolithic (nonporous) or porous film reinforcements can be done by using ASTM F316-86 (Standard Test Methods for Pore Size Characteristics of Membrane Filters by Bubble Point and Mean Flow Pore Test). This procedure is illustrated in Figures 39 and 40. The maximum pore or defect size is calculated using the following equation:

$$d = C\gamma/p \qquad (10)$$

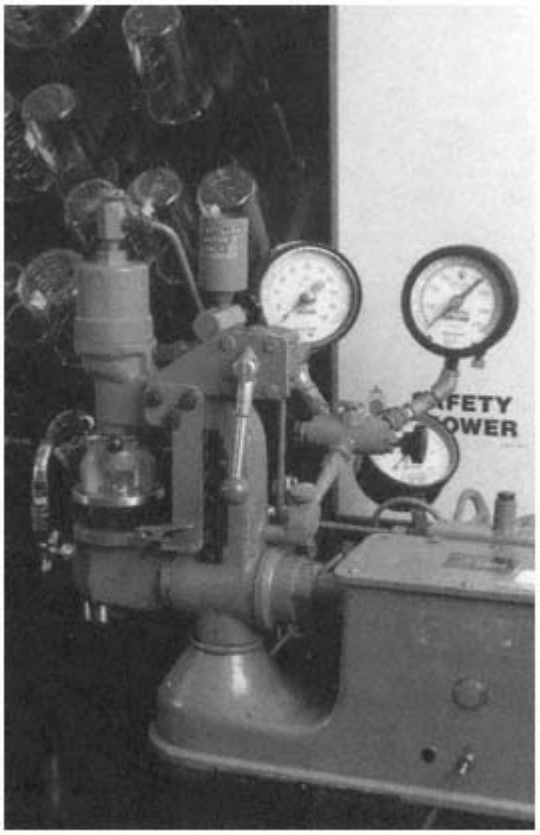

Figure 37
The penetration resistance of textiles to water at high pressure can be determined using ASTM D751-89 (Standard Test Methods for Coated Fabrics; Procedure A). The hydrostatic pressure of the water on the textile is steadily increased until visible penetration occurs or until the 6984 kPa pressure limit is reached. The higher the pressure achieved before water penetration, the greater is the water resistance of the textile. (This test is also known as Mullen's burst test.)

where

d = limiting diameter

C = constant (2860 when p is in pascals)

Υ = surface tension, mN/m

p = pressure, Pa

Results of this test may not be a direct indication of the particle retention characteristics of a film but may be used as a quality control tool or for comparative

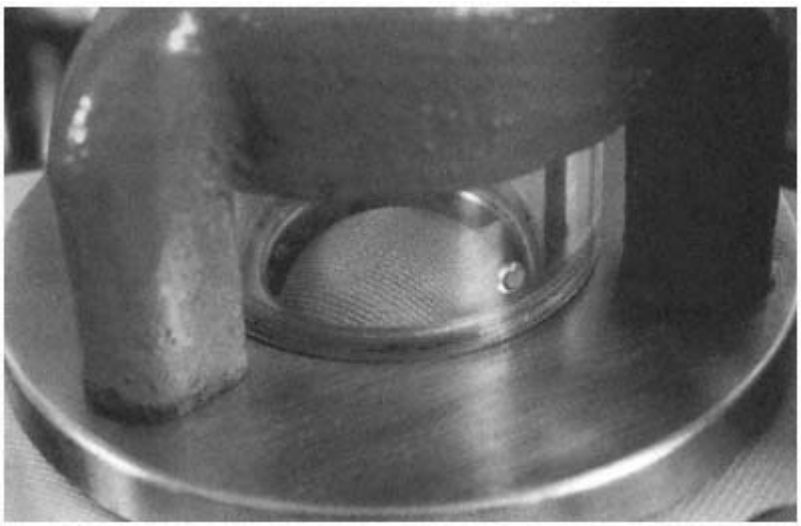

Figure 38
ASTM D751-89, procedure A. Test specimen is observed until leakage or bursting is determined. Note how the textile specimen is distorted (ballooning up) by the hydrostatic pressure of the water.

analysis. The microbial retention characteristics of porous film reinforcements should always be validated using filtration test methods.

J— Microbial Challenge Testing

1— A Brief Historical Review

Historically, even with the urging of such noted authorities as William C. Beck, M.D., F.A.C.S., dating back to 1952, the medical fabric industry was unable to reach a consensus regarding microbiological barrier performance standards [33]. The plethora of different test methods being used to assess the "barrier" properties of materials, including both industry standard and corporate-sponsored methods, resulted in a significant state of confusion among the members of the health-care community concerning product performance. The literature was replete with comparative analyses of scientific laboratory bench-top liquid and microbiological barrier evaluations [6,22]. However, the objective was always to compare and rank product performance and not to identify which products might actually be capable of preventing microbial penetration. In the past, laboratory testing was mainly intended to identify those materials that might reduce postoperative wound infection rates but not to identify those materials that could prevent the transmission of infectious microorganisms in use. Comparative in-use analyses of barrier products followed a similar theme [34].

Figure 39
The maximum pore size of nonfibrous porous film reinforcements used in textiles can be approximated using ASTM F316-86 (Standard Test Methods for Pore Size Characteristics of Membrane Filters by Bubble Point and Mean Flow Pore Test).

Recently, the focus for preventing transmission of infectious microorganisms through barrier materials has grown to include both infection control and personal protection. One major reason for this growth is the significant risk associated with occupational exposure to bloodborne pathogens perceived by the health care community. The Occupational Safety and Health Administration (OSHA), under the U.S. Department of Labor, published its Final Rule on protecting health care workers from occupational exposure to bloodborne pathogens. The OSHA Final Rule [35] states:

> When there is occupational exposure, the employer shall provide at no cost to the employee, appropriate personal protective clothing, such as, but not

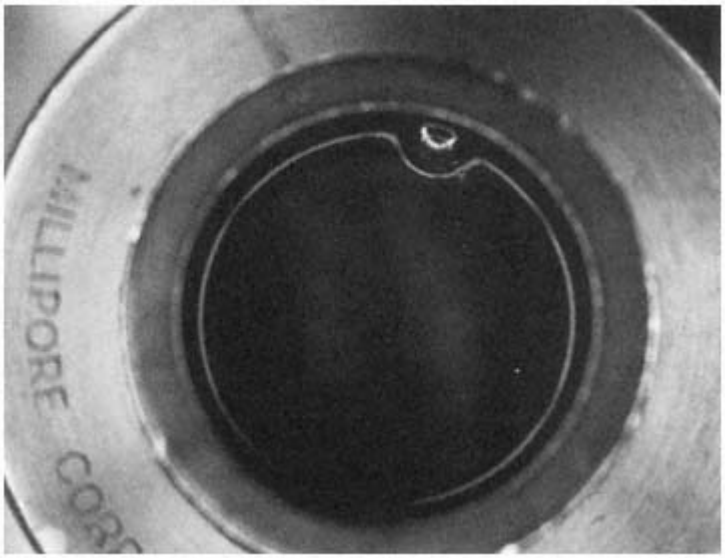

Figure 40
Test result for ASTM F316-86. This is an example of the first stream of continuous air bubbles breaking through a microporous membrane. Calculations would be made as to the maximum pore size of this film and compared to filtration test results using particles and/or microorganisms of various types and sizes.

limited to, gloves, gowns, laboratory coats, face shields or masks, and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employees' work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time in which the protective equipment will be used.

In the last decade the medical literature has exploded with research studies reporting on bloodborne pathogen exposure rates based on various occupational risk factors, on risk reduction strategies, and on compliance issues [36–43]. There have also been a number of significant new standards, books, recommended practices, and technical reports published. Many of these references are listed in the Appendix.

Beyond bloodborne pathogens looms the threat of other potentially hazardous microorganisms: prions (Creutzfeldt-Jakob agent), *Escherichia coli* 0157:H7, Muerto Canyon virus (hantavirus), and multiple-drug-resistant forms of *Mycobacterium tuberculosis*, staphylococci, and enterococci, to name a few.

Workers can also face other significant microbiological hazards than bloodborne pathogens, such as biotechnology workers dealing with recombinant DNA (rDNA), laboratory workers handling concentrated cultures of human pathogens (other than bloodborne), and veterinary or agriculture workers dealing with zoonotic agents. Each work environment and potential microbiological hazard may require a different strategy of experimentation and risk reduction decision logic. Similar strategies and risk reduction decisions may be made for microbes falling into similar classifications.

2— Classification Schemes for Biohazards

Many of the key variables important to assessing the degree of hazard associated with exposure to biohazards have already been discussed. Specifically, with respect to determining the most appropriate type of microbial challenge, the following factors are important:

1. The type of microbe(s): size, shape, concentration, environmental viability/ stability, resistance to inactivation, compatibility with the textile material (no antimicrobial effects), binding mechanisms, motility, and limit of detection.

2. The susceptibility of the host: host immunity, virulence of the microbe(s), the dose necessary to cause infection, and the risk to the lab technician.

3. The nature of the exposure(s): transport modes (direct or vehicle dependent), vehicle type (air or liquid), associated carders, forces and pressures applied directly to the vehicles.

4. The state of the textile when exposure occurs: environmental conditions, and physical, chemical, and thermal stresses.

With respect to handling the actual human pathogenic microbial agents there are a number of good references that should be consulted prior to beginning any experimentation (refer to the Appendix).

3— Transfer of Vehicles Versus Transfer of Microbes

Internal research at W. L. Gore & Associates, Inc., and research published by others regarding the viral barrier properties of protective clothing products have demonstrated that viral penetration can occur in the absence of any perceivable liquid penetration [2,11,44]. Similar results have also been found with latex surgical gloves [45,46]. Therefore, testing the penetration characteristics of textiles to air and liquids does not rule out the possibility of the transmission of infectious microorganisms. Certainly, those materials that appear to be highly resistant are probably much better barriers to microorganisms. However, since the real hazard is infectious microorganisms, the goal should be to demonstrate that the textiles are effective microbiological barriers. The only truly definitive test is a microbiological challenge.

The one significant limitation of air and liquid penetration testing of textile barrier products is the limit of detection for fluid transfer. With respect to liquid penetration, this can be graphically illustrated by referring to Figure 25; the strike-through conversion chart. This chart converts the amount of strike-through to the amount of bloodborne pathogen contamination. The four spots at the top of the chart were formed from premeasured droplets of synthetic blood and are marked in microliters, ranging from 100 µ1 to 0.1 µ1. Listed on the left are the three primary bloodborne pathogens: hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency (HIV) viruses. The approximate number of infectious units that could be present in each spot was calculated from the known blood serum concentration of infected patients and is shown for each type of virus. For example, the number of infectious units of hepatitis B virus in a 0.1 µm1 droplet of infected blood serum can be 10,000 or higher; this is one of the reasons why hepatitis B is so highly infectious and easily transmitted.

When considering the high concentrations of hepatitis B virus (HBV) [20], hepatitis C virus (HCV) [47], and the human immunodeficiency virus (HIV) [48] in the whole blood and blood serum of infected patients, it is clear that very minute amounts of liquid, which may not be visible to the naked eye, can carry significant quantities of infectious disease. (Other microorganisms with concentrations of 1×10^8 infectious units/ml would be comparable to the HBV results on this chart.) When thinking in these terms, even very small amounts of liquid strike-through may represent an unacceptable risk.

4—
Characteristics of Pathogenic Microbes

It has been estimated that there are at least 193 important biological agents that show infectious, allergenic, toxic, or carcinogenic activities in the working population [43]. The following diagrams and charts are not represented to be complete, but are based on the references cited. They are provided in an attempt to illustrate the magnitude of the problem associated with hazardous microorganisms and to illustrate the diversity of shapes and sizes.

Figure 41 illustrates the morphology of animal virus families including human pathogens, and Table 3 gives other details of pathogenic viruses. Figure 42 shows the morphology of bacterial ultrastructure, with Table 4 giving for other details of pathogenic bacteria. In Figure 43 are shown different types of spores in fungi, accompanied by Table 5 for other details of pathogenic fungi.

5—
Possible Models for Pathogenic Microbes

With the impending OSHA Final Rule focusing on reducing the risk of occupational exposure to hepatitis B and C and the human immunodeficiency viruses, the medical fabric industry expended significant efforts to develop a new barrier integrity test. One of the primary factors in the design of this new test was the

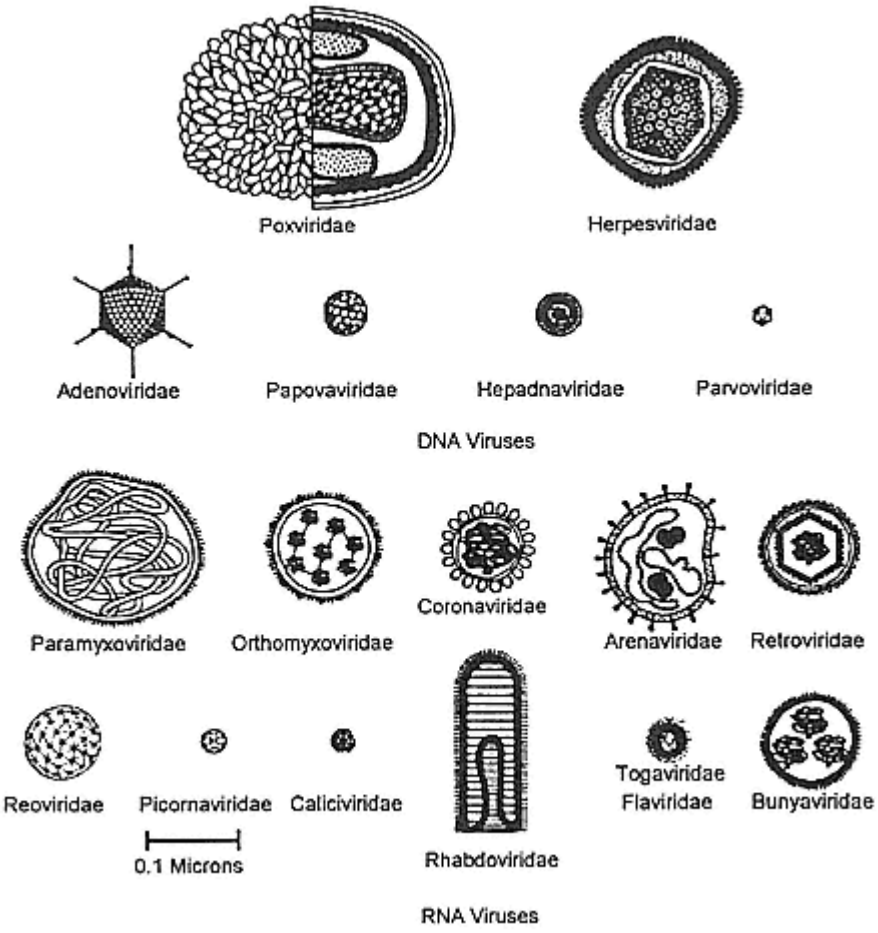

Figure 41
Morphology of animal virus families including human pathogens.
(From Ref. 49.) Refer to Table 3 for other details of pathogenic viruses.

selection of an appropriate model that was capable of determining the "viral" barrier properties of protective clothing materials. Table 6 provides a brief summary of some of the various types of options that were considered.

The phi-X174 bacteriophage was selected as the most appropriate bloodborne pathogen model because it has no envelope (similar to HCV), is 27 nm in size (similar to HCV, the smallest pathogen), has icosahedral or nearly spherical morphology (similar to all three pathogens), can be cultivated to reach very high titers [$>10^8$ placque-forming units (PFU)/ml, similar to HBV, the most concentrated

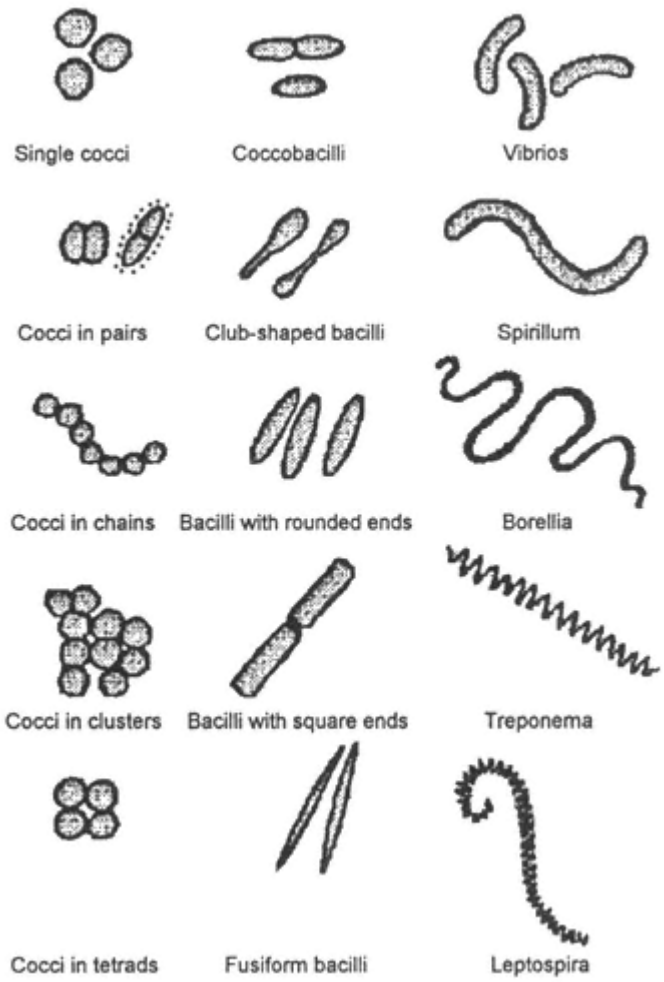

Figure 42
Morphology of bacterial ultrastructure. (From Ref. 69.) Refer to Table 4 for other details of pathogenic bacteria.

pathogen], has excellent environmental stability (similar to HBV), is noninfectious to humans (low risk), has an extremely low limit of detection (approaching 1 viral particle/ml), and grows very rapidly (assay results can be read in as few as 6–18 hrs). Further research has also demonstrated that the phi-X174 bacteriophage has fewer compatibility problems than alternative surrogate viruses, is less subject to binding, and the filtration behavior of phi-X174 is as expected (based on the size determined by scanning electron microscopy, SEM) [56,57].

Table 3 Characteristics of Pathogenic Viruses

Viral organisms	Associated disease(s)	Morphology	Smallest diameter (µm)	Shortest length (µm)	Other important factors
Adenoviruses	Pharyngitis, respiratory disease, keratoconjunctivitis, hemorrhagic cystitis, gastroenteritis, cervicitis, urethritis	Icosahedral	0.07	N/A	No envelope, DNA genome
Arenaviruses	Lassa fever, hemorrhagic fever, lymphocytic choriomeningitis	Spherical (pleomorphic)	0.05	N/A	Envelope, RNA genome
Bunyaviruses	Hemorrhagic fever (Hataan), encephalitis	Spherical	0.09	N/A	Envelope, RNA genome
Calciviruses	Hepatitis (E), Norwalk gastroenteritis	Icosahedral	0.035	N/A	No envelope, RNA genome
Coronaviruses	Respiratory, colds	Spherical (pleomorphic)	0.06	N/A	Envelope RNA genome
Delta virus	Hepatitis (D) (superinfection of HBV carriers)	Spherical	0.036	N/A	No envelope, RNA genome
Filoviruses	Marburg and Ebola hemorrhagic fevers	Filamentous	0.08	0.8	Envelope, RNA genome
Flaviviruses	Hepatitis (C), yellow fever, hemorrhagic fever, encephalitis	Spherical	0.04	N/A	Envelope, RNA genome
Hepadnaviruses	Hepatitis (B)	Spherical	0.042	N/A	Envelope, DNA genome
Herpesviruses	Herpes, chicken pox, cytomegalovirus infection, mononucleosis	Spherical	0.12	N/A	Envelope, DNA genome
Orthomyoviruses	Influenza	Spherical or filamentous	0.08	N/A	Envelope, RNA genome

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Viral organisms	Associated disease(s)	Morphology	Smallest diameter (μm)	Shortest length (μm)	Other important factors
Papovaviruses	Warts, cancer	Icosahedral	0.045	N/A	No envelope, DNA genome
Paramyxoviruses	Measles, mumps, parainfluenza, respiratory syncytial virus infection,	Spherical (pleomorphic)	0.15	N/A	Envelope, RNA genome
Parvoviruses	Erythema infectiosum, rheumatoid arthritis	Icosahedral	0.018	N/A	No envelope, DNA genome
Picornaviruses	Hepatitis (A), polio, colds, meningitis, paralysis, myocarditis, leurodynia, herpangina, acute hemorrhagic conjunctivitis, hand, foot, and mouth disease, pancreatitis, gastroenteritis	Icosabedral	0.025	N/A	No envelope, RNA genome
Poxviruses	Smallpox, *molluscum contagiosum*, monkeypox, cowpox and milkers nodes, Orf	Brick	0.1×0.24	0.3	Envelope, DNA genome
Reoviruses	Infantile gastroenteritis, diarrhea, Colorado tick fever	Icosahedral	0.06	N/A	No envelope, RNA genome
Retroviruses	Cancer, acquired immune deficiency syndrome	Spherical	0.08	N/A	Envelope, RNA genome
Rhabdoviruses	Rabies, hemorrhagic fever, vesicular stomatitis	Bullet	0.075	0.18	Envelope, RNA genome
Togaviruses	Rubella, fever, hemorrhagic fever, arthritis, eastern, western and Venezuelan equine encephalitis	Spherical	0.06	N/A	Envelope, RNA genome

Source: Refs. 49–51.

Table 4 Characteristics of Pathogenic Bacteria

Bacterial organisms	Associated disease(s)	Morphology	Smallest diameter (µm)	Shortest length (µm)	Other important factors
Acinetobacter calcoaceticus	Pneumonia, sepsis, endocarditis	Rod, coccoid rod	0.9	1.5	Gram negative, nonmotile, endotoxin
Aeromonas hydrophila	Wound infection, gastroenteritis, septicemia	Rod	0.3	1.0	Gram negative, motile, endotoxin
Alcaligenes faecalis	Urogenital tract, wound infections, abscesses, pleuritis	Rod, coccoid rod, or cocci	0.5	0.5	Gram negative, motile, endotoxin
Bacillus spp.	Anthrax, eye infections, urinary tract infections, septicemia, meningitis, otitis	Rod	0.5	1.2	Gram positive, sporulating, motile
Bordetella pertussis	Pertussis (whooping cough)	Coccoid rod	0.2	0.5	Gram negative, motile and nonmotile
Brucella spp.	Brucellosis, Mediterranean fever, Bang's disease	Coccoid or rodlike	0.5	0.5	Gram negative, nonmotile
Campylobacter spp.	Enteritis, septicemia, meningitis	S-shaped rod	0.2	1.5	Gram negative, motile
Chlamydia psittaci	Psittacosis	Coccoid or pear	0.2	N/A	Gram negative, nonmotile
Citrobacter spp.	Urinary tract and wound infection, septicemia, nosocomial infections	Rod	1.0	2.0	Gram negative, motile

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Bacterial organisms	Associated disease(s)	Morphology	Smallest diameter (µm)	Shortest length (µm)	Other important factors
Corynebacterium diptheriae	Diptheria	Rod	0.3	1.0	Gram positive, nonmotile
Clostridium spp.	Tetanus, botulism	Rod	0.5	1.3	Gram positive, sporulating, motile
Enterobacter spp.	Opportunistic, septicemia, nosocomial infections, meningitis	Rod	0.6	1.2	Gram negative, motile, endotoxin
Enterococcus spp.	Endocarditis, septicemia, urinary tract infection, nosocomial infections	Cocci, ovoid	0.5	N/A	Gram positive, some are motile
Escherichia coli	Diarrhea, dysentery, urinary tract infection, meningitis, nosocomial infections	Rod	1.1	2.0	Gram negative, some are motile
Francisella tularensis	Tularemia	Rod	0.2	0.2	Gram negative, nonmotile
Haemophilus spp.	Respiratory infections	Pleomorphic rod	0.3	0.5	Gram negative, nonmotile
Klebsiella pneumoniae	Pneumonia, urinary tract infection, meningitis, nosocomial infections	Rod	0.3	0.6	Gram negative, nonmotile
Legionella pneumophila	Legionnaires disease, pneumonia	Rod shaped or filamentous	0.3	2.0	Gram negative, motile
Leptospira interrogans	Leptospirosis (anicteric and icteric)	Helical rod	0.1	6.0	Gram negative motile

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(Continued)

Table 4

Bacterial organisms	Associated disease(s)	Morphology	Smallest diameter (µm)	Shortest length (µm)	Other important factors
Listeria monocytogenes	Listeriosis, meningitis, meningo-encephalitis, septicemia, endocarditis	Rod	0.4	0.5	Gram positive, motile
Mycobacterium spp.	Tuberculosis, skin ulcers, leprosy, soft tissue infections	Rod	0.2	1.0	Gram positive nonmotile
Mycoplasma spp.	Pneumonia, arthritis, pelvic inflammatory disease, postpartum fever; wound infections	Pleomorphic	0.3	N/A	Gram negative, nonmotile
Neisseria spp.	Gonorrhea, meningoencephalitis	Cocci	0.6	N/A	Gram negative, nonmotile
Proteus spp.	Urinary-tract infections, septicemia, meningitis, nosocomial infections	Rod	0.4	1.0	Gram negative, motile
Pseudomonas spp.	Glanders, endocarditis, respiratory and urogenital tract infection, septicemia, nosocomial infections	Straight or curved rod	0.5	1.5	Gram negative, motile
Rickettsia spp.	Q fever, typhus, Rocky Mountain spotted fever	Pleomorphic coccoid or rod	0.3	1.5	Gram negative nonmotile

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Bacterial organisms	Associated disease(s)	Morphology	Smallest diameter (μm)	Shortest length (μm)	Other important factors
Salmonella spp.	Food poisoning, typhoid fever	Rod	0.7	2.0	Gram negative, motile, endotoxin
Serratia spp.	Wound, urinary tract, and pulmonary infections, septicemia, meningitis, nosocomial infections	Rod	0.5	0.9	Gram negative, motile
Shigella spp.	Dysentery	Rod	1.0	2.0	Gram negative, nonmotile
Staphylococcus spp.	Inflammation, suppuration, nosocomial infections	Cocci	0.5	N/A	Gram positive, nonmotile
Streptobacillus monili formis	Rat bite fever	Pleomorphic rod	0.1	1.0	Gram negative, nonmotile
Streptococcus spp.	Inflammation, scarlet fever, pneumonia, toxic shock, nosocomial infections, endocarditis	Cocci	0.5	N/A	Gram positive, nonmotile
Treponema pallidum	Syphillus	Spirochete	0.1	6.0	Giensa stain, motile
Vibrio spp.	Cholera, gastroenteritis	Curved rod	0.5	1.4	Gram negative, motile
Yersinia pestis	Bubonic plague	Pleomorphic rod	0.5	1.0	Gram negative, nonmotile

Source: Refs. 52–55.

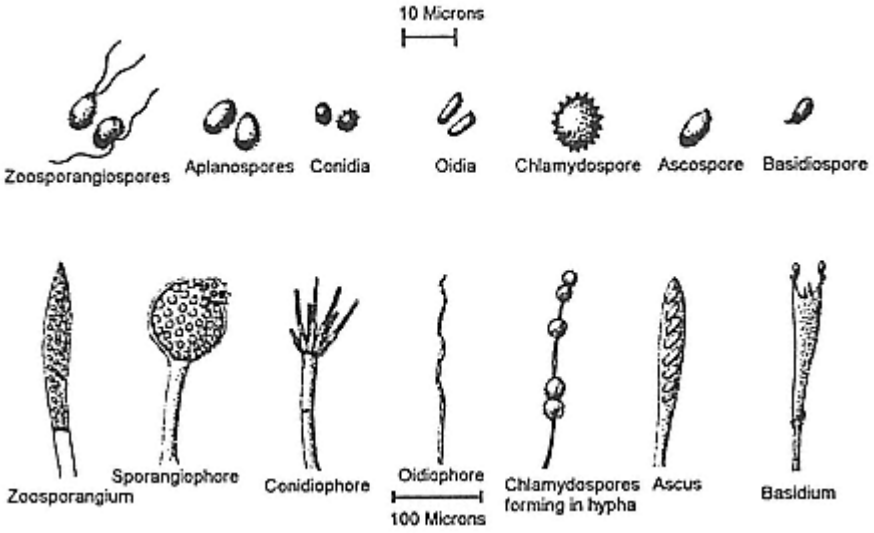

Figure 43
Different types of spores in fungi. (From Ref. 70.) Refer to Table 5 for other details of pathogenic fungi.

The phi-X174 bacteriophage could potentially be used as a conservative model for a variety of other viruses (other than HBV, HCV, and HIV) and larger pathogenic microorganisms.

K—
Liquid-Borne Microbial Challenge Testing

Historically, the hydrostatic pressures used to evaluate the liquid-borne microbial barrier properties of textiles have been very low. Most of the work in this area was done in an effort to try to reduce the likelihood of postoperative wound infection rates associated with bacteria. Therefore, the laboratory devices were designed to simulate the pooling of fluids on surgical drapes. Figure 44 illustrates the GORE diffusion technique of bacterial challenge testing [65]. Techniques such as this were proposed for standardization; however, as previously mentioned, no consensus could be reached [33]. This test was used to assess the bacterial barrier properties of textiles in both surgical and clean-room applications, becoming recognized in the industry and adopted for use by such prestigious organizations as the Shirley Institute and the University of Massachusetts [66,67]. However, like other bacterial challenge test devices of that period of time, the GORE diffusion technique was designed to apply only minimal hydrostatic pressure.

Recently, a new and highly stringent test method has been developed and approved as an emergency standard test method by the American Society for Testing and Materials (ASTM). This effort was undertaken by ASTM in response to

questions regarding the performance of personal protective clothing posed in the Announced Notice of Public Rulemaking by the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA), concerning occupational exposure to bloodborne pathogens. The objective was to develop a test method that took the most important variables, relevant to bloodborne pathogen exposure, into consideration and provided a higher level of assurance in the barrier qualities of protective clothing for health-care workers [24].

The following ASTM emergency standard test method, ASTM ES22-92 (Emergency Standard Test Method for Resistance of Protective Clothing Materials to Penetration by Bloodborne Pathogens Using Viral Penetration as a Test System) uses a specific time and pressure protocol that is identical to the ASTM ES21-92 test (which has been highly correlated to the GORE elbow lean test). ASTM ES22-92 also uses appropriate body liquid and microbial models to overcome some of the most significant weaknesses that were outlined in the industry standard liquid challenge test methods. The ASTM ES22-92 procedure can be used alone or as a confirmatory test for those textile barriers which pass ASTM ES21-92. ASTM ES21-92 can be used to prescreen textiles, eliminating those textiles that are easily penetrated.

The ASTM ES22-92 is illustrated in Figure 45. This test is designed to determine if textiles can prevent the penetration of liquid-borne viruses under defined test conditions. This method has been specifically designed for modeling the viral penetration of hepatitis (B and C) and the human immunodeficiency viruses. The utility of the method for other purposes (modeling the penetration characteristics of other microbes) must be assessed on a case-by-case basis. The microorganism that is utilized is the phi-X174 bacteriophage at a minimal challenge concentration of 1×10^8 PFU/ml. The bacteriophage is suspended in a liquid media with a surface tension that simulates the lower end of the surface tension range for blood and body fluids, 0.042 N/m.

To perform the test, textile specimens are clamped into the penetration cell with the face side oriented toward the cell cavity. Then the penetration cell is attached to the apparatus and the cell cavity is filled with 60 ml of phi-X174 bacteriophage challenge suspension. An air line is connected to the cell and a specific time and hydrostatic pressure protocol is followed: 5 min at ambient pressure, 1 min at 13.8 kPa, and 54 min at ambient pressure. The back side of the textile specimen is observed through the viewing port. The test is terminated if there are any visible signs of liquid penetration through the textile or at 60 min. At the end of the test a very sensitive microbial assay is performed to determine if viruses penetrated through, even in the absence of visible liquid penetration. Any evidence of viral penetration constitutes a failure. Examples of failing and passing results are illustrated in Figures 46 and 47.

Textiles that pass the ASTM ES22-92 test are considered to be highly protective against liquid and microbial penetration. Textile barriers that are not

Table 5 Characteristics of Pathogenic Fungi

Fungal Organisms	Associated disease(s)	Sporophore or spore type(s)	Smallest spore diameter (µm)	Shortest spore length (µm)	Other important factors
Absidia spp.	Zygomycosis	Sporangiosphore	N/A	N/A	
Alternaria spp.	Skin nodules, lesions	Conidiophore	N/A	N/A	
Aspergillus spp.	>Aspergillosis, pneumomycosis, bronchmycosis, pulmonary infiltration	Conidiophore	N/A	N/A	Mycotoxin, carcinogenic
Blastomyces dermatitidis	North American blastomycosis, Gilchrist's disease	Conidia, budding cells	3.0 5.0	N/A N/A	
Candida spp.	Candidiasis, endocarditis (involving prosthetic devices)	Blastospore, chlamydospore, budding cells	4.0 N/A 4.0	6.0 N/A N/A	
Chaetomium spp.	Onchomycosis	Ascus	5.0	8.5	
Cladosporium spp.	Subcutaneous phaeohyphomycosis and possible systemic infection, chromoblastomycosis	Conidiophore	8.0	N/A	
Coccidioides immitis	Coccidioidomycosis, San Joaquin Valley fever	Arthrospore, spherules with endospores	2.0	N/A	

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Fungal Organisms	Associated disease(s)	Sporophore or spore type(s)	Smallest spore diameter (µm)	Shortest spore length (µm)	Other important factors
Cryptococcus neoformans	European blastomycosis, cryptococcosis, crytptococcal meningitis	Budding cells with capsules	2.5	N/A	
Fusarium spp.	Localized infections of skin, implicated in esophageal cancer	Conidiophore	N/A	N/A	Mycotoxin
Histoplasma capsulatum	Histoplasmosis, Darling's disease	Microconidia, macroconidia, budding cells	2.0 7.0 1.5	N/A N/A 3.0	
Mucor spp.	Zygomycosis	Sporangiophore	N/A	N/A	
Penicillium spp.	Generalized reticulosis, subcutaneous mycosis	Conidiophore	N/A	N/A	Mycotoxin
Sporothrix schenckii	Sporotrichosis	Conidia, cigar-shaped budding cells	3.0 2.0	6.0 6.0	
Trichophyton spp.	Skin infections, athlete's foot	Chlamydospore, microconidia, macroconidia	5.0 N/A N/A	N/A N/A N/A	

Source: Refs. 51, 52, and 55.

Table 6 Comparison of Possible Models for Human Pathogenic Viruses

Class of model	Type of model	Advantage(s)	Disadvantage(s)	Other factors to consider
Microbial	Actual pathogen	True measure	Health hazard, long analysis time, expense	Viability, compatibility
	Bacteriophage (phi-X174)	Microbe (virus), spherical shape, 0.027 µm in size, high titer possible, robust/stable, no health hazard, short analysis time, LOD (limit of detection) ≈ 1.0 PFU/ml		Viability, compatibility nonmotile, no envelope
Biological; nonmicrobial	Antibodies (ELISA)	Short analysis time	Not a microbe, developmentcost, high LOD	Small size; permeability behavior
	Blood (hemoglobin)	Short analysis time, refined method, LOD ≈ 5–20 cell/ml	Not a microbe, large size of red blood cell	
Particles	Latex spheres (laser diffraction).	Short analysis time, variety of sizes; 0.014 µm and larger (ultraclean)	Not a microbe, development cost, high LOD	Penetration behavior
Chemicals	Indicators and dyes	Short analysis time	Not a microbe, high LOD	Small size; permeability behavior
Gases	Helium Nitrogen	Short analysis time	Not a microbe, high LOD	Small size; permeability behavior

Source: Refs. 11, 56–64.

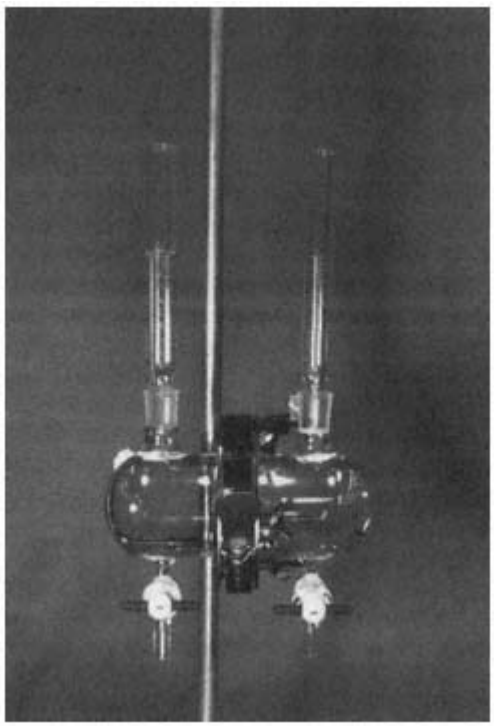

Figure 44
The GORE diffusion technique of bacterial challenge testing. This test device serves as an example of the state of the art in bacterial challenge testing in the 1980s. The textile sample acts as a partition between the two halves of the cell, with the left side containing the bacterial challenge (normally *Escherichia coli* at 10^8 CFU/ml) and the right side containing sterile detector media. A low hydrostatic pressure (~ 1.0 kPa) was placed on the bacterial challenge media in left side of the cell, and at the end of a predetermined time interval the detector media in the right side of the cell was assayed for the presence of the challenge bacteria.

film-reinforced typically fail and textile barriers that are film reinforced (with high quality continuous films) typically pass the ASTM ES22-92 test [2,3,24,26]. (Those textiles found in Figs. 3-10 consistently demonstrate failing results and those textiles found in Figs, 35 and 36 consistently demonstrate passing results.)

Two ASTM emergency standard test methods (ASTM ES21-92 and ASTM ES22-92) were developed and published to meet a demand for more rapid is, suance. The Executive Committee of ASTM Committee F23 on Protective Clothing recommended this publication, and the ASTM Committee on Standards concurred in the recommendation. These emergency standards differ from full

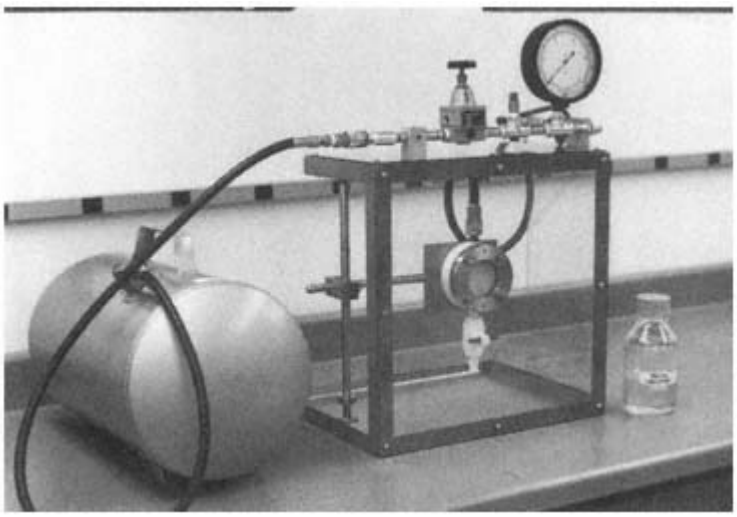

Figure 45
The resistance of textiles to viral penetration can be determined by ASTM ES22-92 (Emergency Standard Test Method for the Resistance of Protective Clothing Materials to Penetration by Blood-borne Pathogens Using Viral Penetration as a Test System). (Photo courtesy of Nelson Laboratories, Inc., Salt Lake City, UT.)

Figure 46
Failing test result for ASTM ES22-92. This is an example of the type of result typically exhibited by the positive control (0.04 µm) hydrophilic nylon microfiltration membrane). The clear spots, known as plaque-forming units, that are apparent in the surface of the lawn of *Escherichia coli* C (host bacterium) in the petri dishes were made by penetrating bacteriophage.
(Photo courtesy of Nelson Laboratories, Inc., Salt Lake City, UT.)

Figure 47
Passing test result for ASTM ES22-92. This is an example of the type of result typically exhibited by the negative control (medical packaging grade of monolithic nonporous polyester film). Note the absence of any plaque-forming units in the surface of the lawn of *Escherichia coli* C in the petri dishes.
(Photo courtesy of Nelson Laboratories, Inc., Salt Lake City, UT.)

consensus standards in that they are only balloted through the subcommittee level as per the regulations governing ASTM technical committees. These documents were published by ASTM through August 1994. At the time of this writing, ASTM was in the process of developing full-consensus standard test methods for the evaluation of the resistance of protective clothing materials to synthetic blood and to bloodborne pathogens. As with any standard, these test methods may be revised to some extent as a result of this process.

L—
Aerosol-Borne and Liquid-Borne Microbial Filtration Testing

1—
The Mechanisms of Filtration

The process of filtration is complicated, and although the general principles are well known there is a substantial gap between theory and experiment. A common misconception is that aerosol filters work like microscopic sieves in which only particles smaller than the holes can get through. This view may be appropriate for the liquid filtration of solid particles, but it is not how aerosol filtration typically works [19]. An aerosol is defined as a suspension of solid or liquid particles in a gas that range in size from 0.001 to 100 μm in diameter. Microbes that are suspended in air are, by definition, an aerosol.

The necessary condition for filtration in textiles protecting against airborne microbiological agents is a pressure drop across the material causing air to flow through. If there is no air flow (as with monolithic nonporous films), the transport of microbes through the textile will not occur. (This assumes that molecular diffusion does not play a roll in transport.) Porous textiles and porous film reinforcements, with pores larger than the size of the aerosol particles, will depend on the mechanisms of filtration for determining the degree of separation of the biohazardous particles from the air passing through.

In considering airborne transmission of microbes, although it is certainly possible that individual microorganisms can be transported alone, it is generally agreed that in most cases the organisms are associated with larger aerosol particulates and droplets. However, the size of these particles and droplets may depend on the means with which they were generated. Recent studies have shown that the median aerodynamic diameter of particles generated during laser surgery is 0.3 μm, with a range of 0.1–0.8 μm [68]. This finding illustrates how important it is to investigate the nature of each microbiological hazard.

The most important parameters for characterizing aerosols are the aerodynamic diameter of the particles and the velocity of the particles in the air. Velocity is presumably very low in most cases of protection against biological agents, as the pressure drop on garments in most situations is thought to be very small. When the aerodynamic diameter of the aerosol is smaller than the pores through the textile, there are five basic mechanisms by which they can be stopped [19]:

1. Interception: Occurs when a particle follows an air streamline that happens to come within one particle radius of the surface of the fiber. The particle impacts the fiber and is captured.

2. Inertial impaction: Occurs when a particle, because of its inertia, is unable to follow abrupt changes in the flow of the air streamlines traveling around the fiber, crosses the streamline, and impacts the fiber. This mechanism is important for particles with a diameter >0.5 μm.

3. Diffusion: Occurs when the Brownian motion of the small particles (<0.5 μm in diameter) is sufficient to greatly enhance the probability of their impacting a fiber while traveling past in a nonintercepting streamline.

4. Gravitational settling: Occurs when the sedimentation velocity of a particle causes the trajectory of the particle to deviate from the air streamline and impact a fiber. This mechanism is important to particles with a diameter >3.0 μm.

5. Electrostatic attraction: Occurs when a charged particle is attracted to an oppositely charged fiber by coulombic attraction or when a charged particle induces an equal and opposite charge in an uncharged fiber surface

by image forces. This mechanism is important for particles with a diameter <3.0 μm.

Particles that impact a fiber surface must stick to the surface in order to be captured. Particles will be retained if the forces directing the particle away from the surface are smaller than the forces attracting the particle to the surface. Forces attracting the particle to the surface of the fiber are known as van der Waals intermolecular forces. Forces directing the particle away from the surface of the fiber are elastic energy stored when the particle impacts the fiber, macroscopic external forces (shaking, abrading, etc.), and the inherent mobility of the microorganisms. For particles with aerodynamic diameters < 1.0 μm, the attractive forces are expected to overcome the dispersive forces.

In considering the filtration of liquid-borne microorganisms it is important to recognize that when microbes are suspended in a liquid medium they are surrounded by a boundary layer of liquid. This is one of the major differences that exists between airborne and liquid-borne microbial filtration testing. This boundary layer of liquid can nullify many of the capture mechanisms relied upon in the filtration of airborne particles. The predominant mechanism relied upon in liquidborne microbial filtration is size exclusion (sieving). This means that the difference between the hydrodynamic diameter of the hazardous liquid-borne microbes and the pore size of the textiles or film reinforcements will be the major determining factor as to whether the microbes will be effectively retained. Therefore, porous textiles and porous film reinforcements that are intended to filter hazardous microorganisms out of a penetrating liquid stream should have the pore size well characterized. Pore size measurements should also be validated against performance in a liquid-borne microbial filtration test to demonstrate effective retention properties against the microbes of concern.

2—
Filtration Testing

The aerosol-borne bacterial filtration efficiency of textiles can be determined by using the MIL-M-36954C (Military Specification; Mask, Surgical, Disposable) test illustrated in Figure 48. Although this test was originally designed for determining the protective qualities of masks against bacterial aerosols, it is currently being used to assess both the bacterial and viral (phi-X174 bacteriophage surrogate) filtration efficiencies of textiles for a variety of end-use applications. This test is designed to determine how many challenging microbes can penetrate through under defined test conditions. Textile samples are challenged with a microbial aerosol of a controlled concentration and a fixed air flow rate (28.3 L/min). After passing through the textile, the aerosol is separated according to aerodynamic size and is deposited onto agar surfaces in an Anderson particle fractionating viable sampler for enumeration. Results are recorded in terms of logarithmic reduction values (LRV). The higher the LRV, the higher is the filtration efficiency.

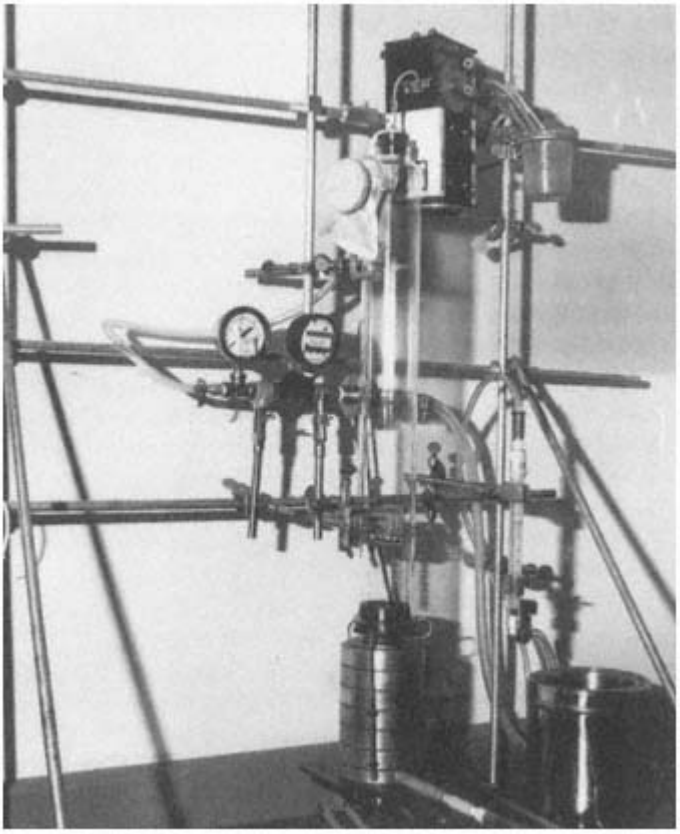

Figure 48
MIL-M-36954C (Military Specification; Mask, Surgical, Disposable) test device. This test is also known as the Anderson sampler test.
(Photo courtesy of Nelson Laboratories, Inc., Salt Lake City, UT.)

The liquid-borne bacterial filtration efficiency of textiles can be determined by using ASTM F838-83 (Reapproved 1993) (Standard Test for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration). This test is normally employed to test the bacterial filtration characteristics of sterilizing liquid filtration membranes. ASTM F838-83 is designed to determine how many challenging organisms (*Pseudomonas diminuta*) can penetrate through under defined test conditions. Film samples are challenged with a known concentration of bacteria (to deliver 10^7 CFU/cm^2 of film surface area) and a maximum pressure differential (206 kPa) to deliver a controlled flow rate. The flitrate is collected for

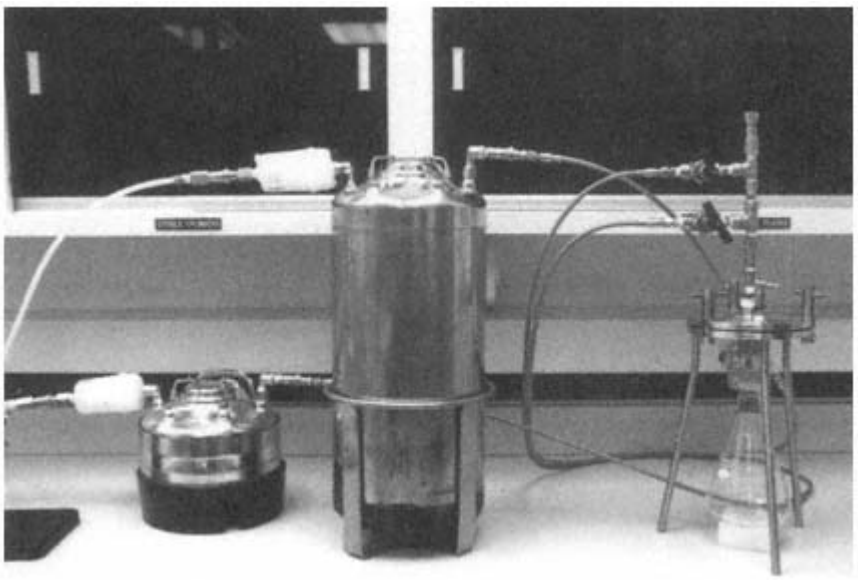

Figure 49
ASTM F838-83 (Reapproved 1993); Standard Test for Determining
Bacterial Retention of Membrane Filters Utilized for Liquid Filtration.
This test is also known as the HIMA challenge.
(Photo courtesy of W. L. Gore & Associates, Inc., Flagstaff, AZ.)

enumeration, and the results are recorded in terms of logarithmic reduction values (LRV). The higher the LRV, the higher is the filtration efficiency.

IV—
Limitations of Laboratory Test Methods

A—
End-Use Conditions

Each intended end-use application for textiles in personal protection and infection control applications may impose different microbial, physical, chemical, and thermal stresses. Selecting a single laboratory test that simulates all of the possible combinations of these variables is practically impossible. Most of the laboratory tests that have been reviewed make a determination about the air, liquid, and microbial barrier properties of textiles under defined and controlled laboratory conditions. It is important to recognize the inherent limitations in each test, as well as the relationship between the laboratory test and the real world.

Most laboratory tests evaluate specimens (not whole end products) "in the condition in which they were received." Each end-use application will impose a distinct set of requirements, as there will very likely be exposures to different

microbial, physical, chemical, and thermal stresses in each real-world environment. There are many examples of actual end-use stresses that Should be considered when testing the barrier properties of textiles in the laboratory. Many of these stresses may be required as preconditioning options for barrier testing in order to make a more accurate prediction of actual performance in use. Some of the important variables that should be considered are:

1. Physical stresses: flexing, abrasion, puncture, tear, and tensile.

2. Chemical stresses: chemical resistance, chemical degradation, and contamination resistance; acids, bases, solvents, lubricants, disinfectants, surfactants, etc.

3. Thermal stresses: flame resistance, melt point, thermal insulation.

4. The impact of laundering (and sterilizing if required) should be assessed for multiple-use products. Process parameters that could accelerate the deterioration of the products should be identified (chlorine bleach, high temperature, high pH, long time, etc.)

5. The impact of sterilization (if required) should also be assessed for single-use products.

6. The impact of transportation, storage conditions (time, temperature, and relative humidity), and shelf life should be assessed. There may be geographical and seasonal fluctuations that will need to be considered.

B—
Finished Products

Laboratory tests typically evaluate two-dimensional specimens and may not be indicative of the performance of finished products. Finished textile products are normally manufactured from roll goods by cutting and sewing (or gluing, fusing, etc.). The continuity of the two-dimensional structure of the textile is compromised as it is cut. When textile pieces are put together in a finished product, seams are created. If the seams are intended to possess the same barrier characteristics as the original textile, then the same laboratory tests that were performed on the textile should be performed on the seams.

Most end products are not used in a two-dimensional form. As an example, garments must conform to the human body, which requires that the design of closures (such as zippers) and interfaces (such as cuffs) also provide effective barriers. Sometimes end products are manufactured from different types and/or multiple layers of textiles. Each area of the end product, representing a different textile or layering, that is required to be a barrier will need to be evaluated.

C—
Single-Use Versus Multiple-Use Products

Due to the demand for cost controls (or reductions) and the concern over the potential negative environmental impact of using single-use products (incineration

and sterilized biohazardous solid waste), multiple-use products should be given serious consideration. Whether the multiple-use products are provided via contract services or processed for reuse in-house, there must be a reliable system of quality control in order to maintain barrier integrity. Appropriate systems would include dependable reprocessing controls, monitoring the number of uses (via check grids, bar codes, etc.), inspecting before reuse, barrier testing, repairing damaged items, and replacing worn out items.

D—
Quality Assurance/Quality Control

Manufacturers of roll goods and manufacturers of finished products should recognize that proper statistical design and analysis of larger data sets than those specified in many of the laboratory test methods may be required in order to establish reasonable confidence limits concerning barrier properties. Many of the textile products intended for use in personal protection and infection control applications will be classified as medical devices and subject to the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990. These products may also be subject to the FDA [510(k)] premarket notification and medical device reporting (MDR) regulations. In addition, good manufacturing practices (GMPs) may be necessary in the manufacture and reprocessing of these devices, and they may need to be labeled in accordance with FDA requirements.

V—
Conclusion

Our society is becoming increasingly concerned about being protected from exposure to human pathogenic microorganisms. Many people are faced with having to make a decision about how to reduce the risk of exposure to potentially hazardous airborne and liquid-borne microbes every day. Textiles are often employed in an effort to reduce the risk of exposure by helping to avoid direct contact with the biohazards. Considering the variety of different types of textiles, types of end-use applications, and types of biohazards, the decision logic required to help reduce the risk may not be obvious.

Determining which textiles will perform adequately in each application against the biohazards of concern often involves the use of laboratory testing. Understanding the performance requirements of each personal protective clothing and infection control end use application is important in making this assessment. The list of technical attributes that results from the end-use survey will lead to the development of a strategy of experimentation in the laboratory. This attributes list often includes physical, chemical, and thermal performance requirements, as well as microbial barrier properties. Each personal protection and infection control application may require different strategies of experimentation to determine if the textiles will perform adequately against the anticipated

Table 7 Summary of Standardized Air, Liquid, and Microbial Challenge Tests

Class of test	Challenge type	Test method(s)	Important test variables
Air penetration resistance	Ambient air	ASTM D737-75 FTMS 191A method 5450 IST 70.1-92	Calibrated orifice (0.12 kPa ΔP)
	Ambient air	FTMS 191A method 5452	Falling cylinder
Porosity	Solvent/air	ASTM F316-86	Bubble point; maximum pore size determination
Contact angle	Various liquids	TAPPI T458 om-89	Sessile drops
Liquid repellency	Saline	IST 80.5-92	Direct contact 1.13 kPa hydrostatic)
	Water	AATCC 22-1989 FTMS 191A method 5526 IST 80.1-92	Spray/impact (15.2 cm height)
	Various Oils	AATCC 118-1992 IST 80.7-92	Sessile drops
	Alcohol	IST 80.6-92	Sessile drops
Liquid penetration resistance	Water	AATCC 127-1989 ASTM D751 EDANA 120.1 FTMS 191A method 5514 IST 80.4-92	Direct contact (0-9.8 kPa hydrostatic)
	Water	ASTM D751-89 FTMS 191A method 5512	Direct contact (0-6984 kPa hydrostatic)
	Water	AATCC 42-1989 FTMS 191A method 5522 IST 80.3-92	Spray/impact (61 cm height)
	Synthetic blood	ASTM ES21-92	Direct contact (0-13.8 kPa hydrostatic)
Bacterial penetration resistance	Dry particulate	EDANA 190.0-89	*Bacillus subtilis* (10^7 CFU, vibration)
	Liquid	EDANA 200.0-89	*Streptococcus faecalis* (rotating finger)
Viral penetration resistance	Liquid	ASTM ES22-92	Phi-X174 bacteriophage (10^8 PFU/ml, 0-13.8 kPa hydrostatic)
Bacterial filtration	Aerosol[a]	MIL-M-36954C 6/12/75 EDANA 180.0-89	*Staphylococcus aureus, S. aureus/epidermidis* (2200 CFU, 28.3 L/min)
	Liquid[a]	ASTM F838-83	*Pseudomonas diminuta* (10^7 CFU/cm^2, 206 kPa hydrostatic maximum)

Note: Acronyms are ASTM (American Society for Testing and Materials); AATCC (American Association of Textile Chemists and Colorists); EDANA (European Disposables and Nonwovens Association); IST (Association of the Nonwoven Fabrics Industry Standard Test); FTMS (Federal Test Method Standard); MIL (Military Specification); and TAPPI (Technical Association of the Pulp & Paper Industry).

[a]The protocols for these two tests can be modified in order to accommodate other types of bacteria. Viruses such as the phi-X174 bacteriophage can also be used in these tests.

microbiological hazards. Challenge testing in the laboratory should produce data that can be interpreted and used to help reduce the risk of microbial exposure or contamination during actual use.

Simulating each set of actual end-use conditions in the laboratory may not be possible. Nevertheless, risk reduction strategies may be developed based on simulated use testing and reasonable worst-case exposure modeling. Determining how the textile is constructed and why the textile should act as a microbial barrier may help in deciding what type of testing will be necessary. Depending on the structure of the textile (porous vs. nonporous), the behavior against airborne biohazards and liquid-borne biohazards may be different. Also, the failure mechanisms for these two types of constructions may be different.

Conclusions should never be drawn about the absolute microbial barrier properties of textiles based on air and liquid challenge testing, Microbial challenge testing is the only truly definitive measurement of performance. Significant progress has been made in the area of liquid-borne microbial challenge testing with the development of ASTM ES22-92 (Emergency Standard Test Method for the Resistance of Protective Clothing Materials to Penetration by Blood-borne Pathogens Using Viral Penetration as a Test System). The utility of this extremely sensitive method for determining which textiles are capable of resisting viral penetration has been rapidly recognized by a number of important agencies and incorporated into several influential standards, guidelines, and reports (NFPA 1999, NFPA 1973, FDA Draft Guidance on [510(k)] Submissions, AAMI TIR No. 11-1994, and CSA Z314.10; references for these documents can be found in the Appendix).

Other very important factors to consider in the risk reduction analysis are the performance of finished products (as opposed to roll goods), any special requirements for the maintenance of multiple-use products, and performing properly designed, statistically valid microbial barrier integrity testing. A concise summary of the various air, liquid, and microbial challenge tests is provided in Table 7.

VI—
Appendix

A—
Publications from Regulatory Agencies and Associations

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