

## In this issue...

We'll share our insight on glove quality and the standards and tests used to ensure effective barrier protection.

## Barrier protection: illusion or reality?

Barrier protection is intended to help prevent the transmission of infection between clinical practitioner and patient. Today, the significant increase of bloodborne diseases has made the need for this protection critical for both health-care workers and their patients.

But is the quality of your gloves affected by the increasing financial pressures facing health-care providers? The drop in the price of natural rubber latex has made it easier for small manufacturers to enter the glove marketplace. This can result in an oversupply of exam gloves. Some glove distributors may "spot buy" these excess gloves and put them on the market at very low prices to make a quick profit. So, how do you determine the quality of these gloves and the level of protection they provide? Do they provide health-care workers with the reliable barrier protection that is increasingly important today?

## "All you need is glove"

Gloves are key in helping to control the spread of infectious microorganisms. After your own intact skin, the exam gloves you wear are the first line of defense against potentially infectious agents for both you and your patients. Recent reports of outbreaks and endemic infections caused by enterococci, including vancomycin-resistant enterococci (VRE), have indicated that patient-to-patient transmission of the microorganisms can occur either through direct or indirect contact via the hands of health-care workers or contaminated patient care equipment or environmental surfaces.

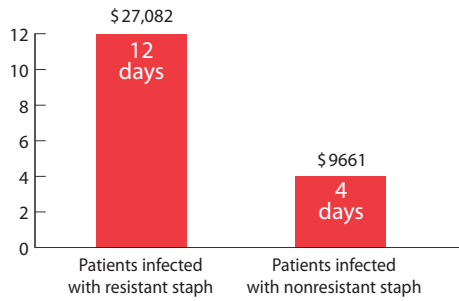
Robert A. Weinstein, M.D., director of Infectious Disease Services for the Cook County (Chicago) Bureau of Health Services and cochair of the Healthcare Infection Control Practices Advisory Committee (HICPAC), at a recent international conference on nosocomial infection, noted that 30% to 40% of resistant infections result from cross infection via the hands of hospital personnel.<sup>1</sup>

Dr. Weinstein cited studies of antimicrobial-resistant gram-negative rods, *Clostridium difficile* diarrhea and VRE hand carriage that showed a strategy of universal gloving resulted in effective control of resistant bacteria as well as *C. difficile* diarrhea.<sup>2,3</sup>

## The bad actors

Since their discovery in 1928, antibiotics have been hailed as miracle drugs and, therefore, have been used for a multitude of illnesses. Antibiotics have saved countless lives, but they are becoming less and less useful. Their overuse and misuse have caused the once rare antibiotic-resistant mutant bacteria to flourish and produce a large percentage of bacterial infections.

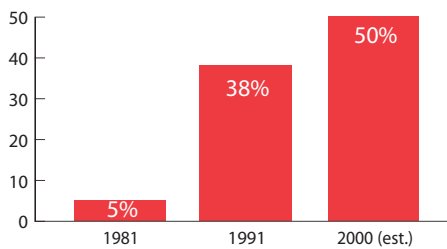
### Additional length of stay required



Methicillin-resistant *Staphylococcus aureus* (MRSA) is a resistant bacteria that has plagued hospitals for years. The only effective treatment is the antibiotic vancomycin. However, in 1988, another “super bug,” which is resistant to vancomycin, appeared in hospitals. VRE are extremely communicable and have a 40% mortality rate. *In vitro* studies have shown that VRE can transfer the vancomycin-resistant gene to other gram-positive bacteria, such as *Staphylococcus aureus*. This is a major concern to infectious disease experts since a vancomycin-resistant strain of MRSA (or VRSA) would be virtually untreatable.<sup>4</sup>

Today, nosocomial infections affect more than two million patients annually in the United States at a cost of more than \$4.5 billion. Patients infected with a strain of methicillin-resistant *S. aureus* were hospitalized for an average of 12 days longer than otherwise necessary at an average additional cost of \$27,082. In addition, infections caused by nonmethicillin-resistant *S. aureus* still lengthened hospitalization by an average of four days and added \$9661 to hospital costs.<sup>4</sup>

### Increase in methicillin-resistant *Staphylococcus aureus* over time



The phenomenal increase in methicillin-resistant *S. aureus* organisms is staggering. In 1981, about 5% of hospital *S. aureus* organisms were resistant to methicillin, and, by 1991, methicillin resistance had grown to 38%. Today, it may be as high as 50% in many hospitals.<sup>4</sup>

### How can you assure protection?

The U.S. Food and Drug Administration’s (FDA) Center for Devices and Radiological Health is responsible for regulating medical devices such as gloves. FDA requirements define performance properties, such as the minimum strength and barrier protection, that these products must exhibit. Additionally, consider that the FDA has proposed reclassifying natural rubber latex gloves from Class I to Class II medical devices. This will subject these products to new kinds of controls, including additional testing and labeling. Some manufacturers may not be able to meet these more stringent requirements.

Standards and test methods are developed by organizations such as the American Society of Testing and Materials (ASTM) and various international groups. Typically, the members of these organizations are scientists and engineers who have knowledge and experience in the behavioral properties of glove materials, manufacturing processes and testing methodologies. This helps assure that the tests are scientifically sound and appropriate and that the test methods fairly and accurately assess products made from a variety of manufacturing approaches, formulations and materials. Understanding the significance of these tests can help clinicians assess the performance of each product as well as its appropriate usage in a variety of situations and procedures.

### Barrier protection confidence tests

The Acceptable Quality Level (AQL) for freedom from holes typically refers to the barrier protection confidence level. A lower AQL number represents a higher quality product, in other words, a manufacturing process with fewer allowable defects. The AQL is used by manufacturers to identify the maximum number of allowable defects (pinholes) per hundred units. All gloves must be statistically sampled to meet specific AQLs.

Glove type	ASTM AQL limit
Latex exam	2.5
Synthetic exam	2.5

There are two tests used to verify AQL in gloves: the water leak test and the air inflation test. Resistance to chemicals is measured by the chemical permeation test.

**Water leak test** consists of filling a glove with 1000mL of water, suspending it for two minutes and then inspecting it for any leakage.

**Air inflation test** consists of inflating the glove with compressed air and visually inspecting it for holes.

**Chemical permeation test** measures the resistance of protective clothing materials to permeation by liquid or gaseous chemicals under conditions of continuous contact.

### Strength tests

Gloves are put under quite a bit of stress during actual usage. Glove strength is measured by resistance to tearing, puncturing and breaking and by stretchability.

**Tensile strength** refers to how much force in pounds per square inch (psi) is required to stretch a glove sample until it breaks. Higher numbers reflect superior performance.

**Elongation** relates to how far, in percentage of the original sample length, the glove stretches before it breaks. For example, if a 1" sample stretches to 9" before it breaks, the elongation is 800%. Higher numbers reflect superior performance.

**V-tear** measures the force in pounds per square inch (psi) necessary to start a tear.

**Trouser tear** measures the force in pounds per square inch (psi) necessary to continue tearing once an initial tear has been made.

**Puncture resistance** measures the force in newtons necessary to rupture the material using a pin of specified dimension.

### Biocompatibility

Medical gloves are required to undergo various tests that demonstrate the potential of the material to cause irritation to the skin. These tests include:

**Primary skin irritation test** demonstrates the potential for irritating abraded skin.

**Dermal sensitization test** demonstrates the potential for eliciting allergic contact dermatitis.

### Protection against microorganisms

While barrier tests are excellent indicators of performance, there is also a test that more specifically demonstrates surgical apparel's ability to prevent penetration by a microorganism.

**Bacteriophage penetration resistance test** assesses the effectiveness of materials used in protective clothing for preventing the penetration of a surrogate microbe (Phi-x174 bacteriophage) suspended in simulated body fluid under conditions of continuous contact. This is a pass/fail test.

## Using product performance testing to your advantage

Infection control is a vital concern in health-care today. Intelligent and informed use of personal protective equipment – especially exam gloves – is a critical component of your facility's infection control program. Understanding the standards and tests that are used to measure the performance of this equipment will allow you to choose the best barrier protection and performance for both yourself and your patients. Make certain the protection you get from the exam gloves you choose is real – not an illusion.

### Required minimums per ASTM standards D3578, D6319, D5250

Natural rubber latex exam gloves	2031 psi/14 MPa
Nitrile exam gloves	1813 psi/12.5 MPa
Vinyl exam gloves	1305 psi/9 MPa

### Required minimums per ASTM standards D3578, D6319, D5250

Natural rubber latex exam gloves	700%
Nitrile exam gloves	500%
Vinyl exam gloves	300%

## Performance tests at a glance

<b>Gloves properties</b>	<b>Standard/test method</b>
<b>Overall specifications</b>	
<b>Dimensions, physicals, AQL</b>	ASTM D3578 Standard Specification for Rubber Examination Gloves  ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Application  ASTM D5250 Standard Specification for Polyvinyl Chloride (PVC) Examination Gloves for Medical Application
<b>Bacteriophage penetration</b>	ASTM D1671 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Bloodborne Pathogens Using Phi-x174 Bacteriophage Penetration as a Test System
<b>Barrier tests</b>	
<b>Water leak</b>	ASTM D5151 Standard Test Method for Detection of Holes in Medical Gloves
<b>Air inflation</b>	(Procedure specific to equipment manufacturer)
<b>Chemical permeation</b>	ASTM F739 Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids or Gases Under Conditions of Continuous Contact
<b>Strength tests</b>	
<b>Tensile strength</b>	ASTM D412 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension
<b>Elongation</b>	ASTM D412 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension
<b>V-tear</b>	ASTM D412 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension
<b>Trouser tear</b>	ASTM D412 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension
<b>Puncture resistance</b>	ISO 1193, AS/NZ 4011 Requirement and Test Method for Glove Cuff Rupture Resistance
<b>Biocompatibility</b>	
<b>Dermal sensitization</b>	ASTM F720 Standard Practice for Testing Guinea Pigs for Contact Allergens; Guinea Pig Maximization Test
<b>Primary skin irritation</b>	ASTM F719 Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation
<b>Residual accelerators</b>	No standard method High performance or thin layer chromatography often used

## Your exam glove report card

When selecting a vendor to meet your exam glove requirements, the following product and company attributes must be considered. Cardinal Health's gloves provide outstanding barrier protection, strength and durability. And no other company can offer the wide array of products and services that Cardinal Health can offer. Use this grid to compare us to competitors.

	FDA required	Cardinal Health	Competitor
<b>Barrier protection</b>			
<b>AQL (pinhole) testing</b> Cardinal Health's standard for AQL is more stringent (1.5) than required by FDA (2.5)	yes	yes	
<b>Puncture resistance</b> The Australian standard test method is performed to ensure high resistance to puncture	no	yes	
<b>Chemical resistance</b> More than 25 different chemicals tested	no	yes	
<b>Bacteriophage penetration</b> Cardinal Health tests 32 gloves, which is a statistically significant sample size and much higher than the ASTM requirement of 3	no	yes	
<b>Aging/shelf life</b> Testing performed to estimate shelf life	yes	yes	
<b>Chemotherapy resistance</b> Cardinal Health tests many chemotherapy agents; specific results are available upon request	no	yes	
<b>Strength and durability</b>			
<b>Material thickness</b> Balances protection with dexterity and tactility	yes	yes	
<b>Tensile strength</b> Exceed or meet all requirements for tensile strength	yes	yes	
<b>Elongation/stretchiness</b> Exceed or meet all requirements for elongation	yes	yes	
<b>V-tear</b> Tested to ensure high V-tear value	no	yes	
<b>Trouser tear</b> Tested to ensure high trouser-tear value	no	yes	
<b>Allergen/protein/irritation related</b>			
<b>Powder levels (for powder-free claim)</b>	yes	yes	
<b>Protein levels (for lowest allowed protein claim)</b>	yes	yes	
<b>Antigenic protein/allergen levels</b>	no	yes	
<b>Residual chemicals</b> Processing reduces accelerators so they are not detectable in the final product using a liquid chromatography assay	no	yes	
<b>Manufacturer related</b>			
<b>Complies with Current Good Manufacturing Practice (CGMP) regulations</b>	yes	yes	
<b>ISO 9001/9002 certified</b>	no	yes	
<b>Rigorous design control, documentation and process control</b>	yes	yes	
<b>Product traceability</b>	yes	yes	

Note: Our gloves undergo a variety of testing as appropriate. Not all gloves are tested for every attribute listed above.

## References

1. Proceedings of the 4th Decennial International Conference on Nosocomial and Healthcare-Associated Infections; 2000 March 5-9; Atlanta, Georgia.
2. Johnson S., Gerding D.N., Olson M.M., et al. Prospective, controlled study of vinyl glove use to interrupt *Clostridium difficile* nosocomial transmission. *Am J Med.* 1990;88:137-140.
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4. Gaynes R.P. Surveillance of nosocomial infections: a fundamental ingredient for quality. *Infection Control and Hospital Epidemiology*, Volume 18(7), July 1997, Editorial.

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