ISO 9001:2000 | FDA REGISTERED | ISO 17025

NELSON LABORATORIES

MICRO NEWS

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OUTSOURCING LAB SERVICES

Nelson Laboratories Celebrates 20 Years of Service

We help the best companies in the world improve the quality of life by providing the highest standard in laboratory testing.

During the past few years we have witnessed a change in the relationship and responsibilities between contract labs and OEMs in the medical device, pharmaceutical and supplement industries. Several clients have switched from a vertical integration approach to a strategic outsourcing plan that helps them focus on their core competencies. In a recent Harvard Business Review article, the authors made an interesting observation about the strategic outsourcing approach:

> "..all companies need to rigorously assess each of their functions to determine in which they have sufficient scale and differentiated skills and in which they don't. Greater focus on capability sourcing can improve a company's strategic position by reducing costs, streamlining the organization, and improving quality. Finding more-qualified partners to provide critical functions usually allows companies to enhance the core capabilities that drive competitive advantage in their industries."

What matters most in an outsourcing relationship?

There have been several opinions and articles written on the subject of test services, but let us offer a few suggestions and considerations:

QUALITY:
Is the firm committed to quality at every level and does management support and implement programs for continuous improvement?

SERVICE:
Does the service provider offer the tangible service you require and the intangible customer service when problems/issues arise?

VALUE:
Does the service provider offer a reasonable price and high level of quality that creates value and confidence in the product?

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STRATEGIC SOURCING:
From *Periphery to the Core*.
Mark Gottfredson,
Rudy Puryear, and Stephen
Phillips. Harvard Business
Review, pg. 133, vol. 83, #2.
Feb 2005.
Harvard Business Review,
Harvard Business School
Publishing, Boston, MA.

TURN AROUND TIME:
Can the service provider deliver as promised and assist with urgent needs as they arise?

EXPERIENCE:
Do the staff and management of the service provider have the experience to understand the nuances of the test and the problem-solving ability for difficult situations? Do they participate on the committees that write the industry standards for your tests?

Why is Nelson Labs a highly qualified partner?

At Nelson Laboratories we recognize our responsibility as a highly qualified test partner and focus our core competencies on the management and delivery of quality test services. With extensive experience across several industries and product types, we are able to customize test services to each client's needs while also offering a large scope and scale of services. Clients who outsource lab services to Nelson find they benefit from our experience, expertise, economies of scale and our involvement with industry experts and standards organizations. Recently we have re-formulated our mission statement to reflect our key role and who we serve. In addition, we have redefined our values as they relate to the mission statement.

OUR VALUES

PEOPLE:
We select top tier people committed to our mission and values.

INTEGRITY:
We act with integrity in all that we do.

QUALITY:
We ensure quality in every step of our process.

NELSON LABORATORIES' MISSION STATEMENT

We help the best companies in the world improve the quality of life by providing the highest standard in laboratory testing.

Our Values

People: We select top tier people committed to our mission and values.
Integrity: We act with integrity in all that we do.
Quality: We ensure quality in every step of our process.

As stated in our mission statement and implied by our values, we strive to offer the best in test services because we know that our services impact more than our direct customers – our tests impact the lives that our customers' products touch. While we have excellent assets in building, equipment and quality systems, our core competency lies in the intangible scientific experience of our staff and the highly organized and disciplined manner in which our corporate management and quality assurance teams monitor and process lab studies. During the past year we have made several changes to improve the quality of our test service and enhance the customer experience. These changes include the addition of client services account representatives to assist clients with the management of their studies and customer-specific requests; the addition of a direct sales group to assist in the development of custom projects and corporate contract analysis; and an increase in quality staff to maintain high quality at every level of our organization.

At Nelson Labs, quality is not a loose phrase, but a personal commitment from each staff member. Our quality systems are rigorous and allow us to be third-party certified to ISO 9001:2000 (Quality Systems) and ISO 17025 (Lab Accreditation) as well as FDA registered. Several staff members actively participate on the committees that write test standards, including AAMI, ASTM, ISO, IEST, and others. We strive to offer the best possible service at a reasonable price, delivered on-time and with the high quality, value and confidence that comes from experience.

This October marks Nelson Laboratories' 20th anniversary as a highly-qualified test service provider. We invite you to consider Nelson Laboratories as your source for high quality test services – and extend an invitation for you to experience the Nelson difference.

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INTRODUCTION TO ANSI/AAMI PB70:2003:

LIQUID BARRIER PERFORMANCE AND CLASSIFICATION OF PROTECTIVE APPAREL AND DRAPES INTENDED FOR USE IN HEALTH CARE FACILITIES

Brynn Perkins, B.S.
Aerobiology Study Director

INTRODUCTION:

The Association for the Advancement of Medical Instrumentation (AAMI) standard was developed to establish a classification system based on the liquid barrier performance of surgical drapes, drape accessories, surgical gowns, and other personal protective apparel worn by health care personnel. The purpose of the classification system introduced in this standard is to assist end-users in selecting the product which will best protect them from blood borne pathogens, body fluids, or other potentially infectious materials. The standard recommends specific zones for testing and sampling sizes in order to ensure consistent labeling of barrier properties among the different manufacturers. Annex C of the standard lists examples of sampling plans based on code letter G (normal inspection) or ANSI/ASQ Z1.4.

All surgical gowns and protective apparel are ranked by a numerical classification system based on the performance of the critical zones. The critical zones are defined as the areas where direct contact with blood, body fluids, and other potentially infectious materials is most likely to occur. The designated critical zones vary between the different types of protective apparel. The critical zones of a surgical gown consist of the chest and forearm areas, forearm seam areas, and any tie attachments that are located in the reinforced area of the gown. For isolation gowns, the critical zone is the entire gown. The critical zone for surgical drapes is comprised of a large portion, usually reinforced, in the center of the drape.

CLASSIFICATION SYSTEM:

In order to classify and label surgical gowns and drapes, intended to meet the requirements of AAMI PB70, a series of barrier performance tests must be performed on the critical zones of the product. A classification level is determined when the product meets an acceptance quality level (AQL) of 4% for the designated test method(s). The critical zone with the lowest level of barrier performance will determine the overall classification of the gown or drape.

Level 1-Gowns and Drapes: To obtain a level 1 classification, the product must demonstrate the ability to resist ≤ 4.5 grams of water penetration, when tested in accordance with American Association of Textile Chemists and Colorists (AATCC) method 42 (Water resistance: Impact penetration test). This test procedure is designed to measure the resistance of materials to water penetration under contact with sprayed water. In order to measure the resistance, a pre-weighed blotter paper is placed under the test specimen. A spray head then delivers 500 milliliters of deionized water to the product. At the conclusion of testing, the water penetration is determined by comparing the initial blotter weight with the weight after exposure.

Level 2-Gowns and Drapes: To meet a level 2 classification, the critical zones of surgical drapes and other protective apparel must show the ability to resist ≤ 1.0 gram of water penetration with the AATCC 42 test, as well as reach a pressure of ≥ 20 cm of water with AATCC 127 (Water resistance: Hydrostatic pressure test). The AATCC 127 test determines gown and drape resistance to water penetration with the use of a hydrostatic head tester. The normal outside surface of the product is challenged directly with deionized water and the reverse side is observed for fluid penetration. With a steady increase of water pressure at 60 mbar per minute (1cm/sec.), an accurate rate of resistance can be determined for the product.

REFERENCES:

ANSI/AAMI PB70:2003, "Liquid Barrier Performance of protective apparel and drapes intended for use in health care facilities".

AATCC Test Method 42-2000. Water Resistance: Impact Penetration Test

AATCC Test Method 127-1998. Water Resistance: Hydrostatic Pressure Test

ASTM F 1670-03, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood".2003

ASTM F 1671-03, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System".2003

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INTRODUCTION TO ANSI/AAMI PB70:2003:

LIQUID BARRIER PERFORMANCE AND CLASSIFICATION OF PROTECTIVE APPAREL AND DRAPES INTENDED FOR USE IN HEALTH CARE FACILITIES

(cont.)

Level 3-Gowns and Drapes: A level 3 classification is obtained when the critical zones of the surgical gowns and drapes demonstrate ≤ 1.0 gram of water penetration for the AATCC 42 test, and reach a pressure of ≥ 50 cm of water with the AATCC 127 test.

Level 4-Drapes: A level 4 classification for drapes requires testing in accordance with ASTM F 1670 (synthetic blood penetration). In order for surgical drapes to attain a level 4 classification, the critical zones must pass the synthetic blood penetration test with an AQL of 4%. Specific time and pressure protocols are followed in this test method, which demonstrate a higher level of barrier performance than the AATCC 42 and AATCC 127 tests.

LEVEL	TEST	RESULT
1	AATCC 42	≤4.5 g
2	AATCC 42 AATCC 127	≤1.0 g ≥20 cm
3	AATCC 42 AATCC 127	≤1.0 g ≥50 cm
4	ASTM F 1670 (for drapes) ASTM F 1671 (for gowns)	Pass Pass

BARRIER CLASSIFICATION SYSTEM

Level 4-Gowns: In order for surgical gowns and other protective apparel to meet a level 4 classification, the critical zones must pass the ASTM F 1671 (viral penetration) test with an AQL of 4%. The viral penetration method is a more sensitive test than the ATCC127 and AATCC 42 methods. In this test system, the protective apparel is challenged with the Phi-X174 bacteriophage, a blood borne pathogen surrogate. Like the ASTM F 1670 test, the viral penetration test follows specific time and pressure protocols that qualify the protective apparel for a higher level of barrier performance.

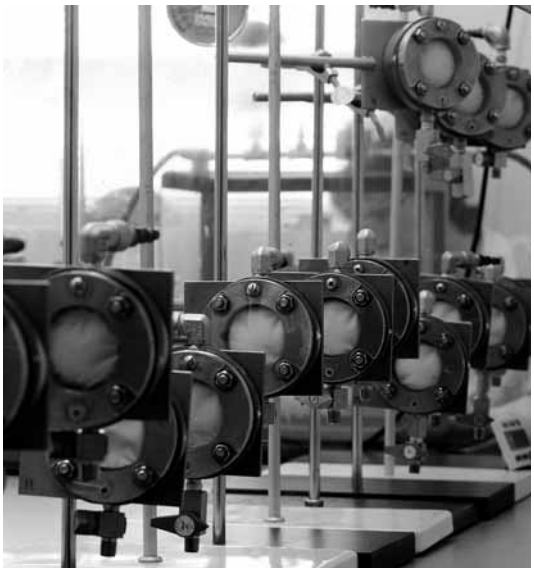
For surgical gowns and other protective apparel, the critical zones are based on the anticipated location in which health care personnel may come into contact with blood borne pathogens or other potentially infectious materials.

Because there is a chance that areas outside of the critical zones may come into liquid contact, the entire front of the gown is required to meet at least a level 1 classification. The back of a gown is expected to stay dry during surgical procedures, thus, there is no minimum level required. Isolation gowns and drapes have a more unpredictable area of liquid contact, due to inadvertent splashing or spraying in general patient care; therefore, the entire gown must meet at least a level 1 classification.

APPLICATION:

Each surgical gown, surgical drape, drape accessory, and other protective apparel shall be labeled with its proper barrier classification level. If the back does not meet the level 1 requirement, the package should contain a statement that labels the back as non-protective. Manufacturers are ultimately responsible for educating the end-users on the barrier classification system. This will enable the end-users to make more informed decisions on the level of protection necessary for their anticipated level of exposure to blood borne pathogens, body fluids, and other potentially infectious materials.

To order a complete copy of the AAMI PB70:2003 standard, visit the AAMI web site at www.aami.org. Nelson Laboratories, Inc. has validated each of the test methods presented in this standard and performs them on a regular basis. Contact us at sales@nelsonlabs.com, to see how we can evaluate the barrier performance of your protective products.



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GLOVE TESTING

Nelson Laboratories (NLI) is committed to the continuous improvement of our test services. For many years NLI has been testing medical gloves in accordance with ASTM and FDA guidance documents. The test results can be used in support of 510K submission, materials files, and lot release quality control.

Nelson Labs is now able to offer the glove leak test at a new discounted rate. Our many dedicated staff members with numerous years of experience in glove testing are ready to assist you with your various glove test needs. Some of the many glove testing capabilities include: tensile, physical dimension, puncture resistance, whole viral barrier, degradation testing, and much more.

NLI is also able to assist with FDA glove detentions. The sampling paperwork, sampling plan, glove leak test with GLP report makes Nelson Laboratories your single source provider.

Nelson Laboratories Ethylene Oxide & Radiation Sterilization Workshop Re-Cap

In August, Nelson Laboratories held the Ethylene Oxide & Radiation Sterilization Workshop in San Diego, California. The seminar was very well attended. It began with an overview of the sterilization methods (EO and Radiation) and progressed to an in-depth presentation of the intricacies of both methods. Each day ended with examples and case studies to enhance the learning which had occurred. Lunches, breaks and after-workshop activities provided opportunities for one-on-one discussions regarding the workshop content. The information shared truly resulted in the most in-depth training ever performed by Nelson Laboratories. If you were unable to attend this workshop we hope you take advantage of future opportunities. For information on future Nelson workshops contact Clarence Baker at:

seminars@nelsonlabs.com.

FOLLOWING IS SOME FEEDBACK WE RECEIVED FROM ATTENDEES:

"I had the opportunity to attend your workshop shop in August and would like to thank you and your team for providing me an in-depth understanding of ETO / Gamma sterilization methods and validation of sterilization / manufacturing processes. I enjoyed listening to all your speakers, they were extremely knowledgeable and the information was presented very clearly."

"It was a pleasure spending two days with your team, looking forward to future workshops and will recommend your services to my colleagues."

TONY ROSE – KINAMED, INC.

Excellent presentation & content-well worth the time and money. Excellent people and very knowledgeable.

"The seminar has been extremely helpful in bringing me up to speed in a very short time frame."

ADRIENNE MUQTASID – CARDIOMEMS, INC.

Great seminar! Speakers did great job addressing both basic & advanced concepts.

"I just wanted to send you a quick note of appreciation for your recent Seminar in San Diego. I have never written to a presenter of any seminar before, but yours was exceptional and deserved some recognition. Your speakers were not only knowledgeable, but possess excellent presentation skills. It was a true pleasure attending."

KEVIN CHINERY – KINAMED, INC.

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"Great tournament, great tradition"

2005 GOLF OUTING

"Great tournament, great tradition", was one of the comments after the 2005 Nelson Laboratories golf tournament held August 27th at Riverbend Golf Course in Riverton, Utah. The field consisted of thirty teams competing for the championship and other individual contests such as longest drive and closest-to-the-pin. During lunch the prize drawing was a hit where golf bags, clubs, golf equipment, gift certificates, and many other prizes were given out.

Nelson Laboratories would like to thank all employees, clients, and sponsors who helped make the 2005 tournament a great time and success.

Celebrating 20 Years of Test Service Excellence

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