



Message from bioMérieux

Welcome to the October issue of the *bioMérieux Connection* newsletter. In this issue we will continue our focus on infectious disease and news on the development of new solutions that promote lab safety, efficiency and minimize healthcare-associated infections (HAIs).



Herb Steward
*Executive Vice President
and General Manager,
bioMérieux North America*

According to the New England Journal of Medicine, between 5 and 10 percent of patients admitted to hospitals acquire one or more infections. Blood stream infections are among the most common, costing hospitals an estimated \$4.5 to \$5.7 billion per year in patient care costs. Blood culture collection is the first step in determining infection and contamination must be controlled to improve the efficiency of that first step.

The use of proper equipment and correct techniques can reduce blood culture contamination rates. Since the launch of bioMérieux's WorkSafe™ initiative in May 2007, we have developed an educational resource kit for laboratory professionals. In July, the WorkSafe Blood Culture Kit was launched, eliminating the need for nurses or phlebotomists to manually pull loose and disparate pieces together for blood culture collection and to help minimize blood collection contamination and the risk of false positives.

As an industry leader, bioMérieux looks forward to empowering healthcare professionals and encouraging best practices, through our WorkSafe initiative, in an effort to maximize lab performance and empower clinical decision making.

We at bioMérieux, thank you for continuing to let us bring you safe and reliable bioMérieux products and look forward to working with you in the future. ■

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A group of infectious disease specialists, headed by Shmuel Shoham M.D. at the Washington Hospital Center, revealed clinical data that demonstrated how PNA FISH™ significantly reduced mortality and hospital costs associated with staphylococcal bloodstream infections (BSI).

Diagnostic Breakthrough Addresses Cause Of 90,000 Deaths Each Year.

PNA FISH is a rapid, molecular-based test that identifies bacteria and yeast species directly from positive blood cultures. Results are available within hours instead of days, enabling labs to quickly report results to physicians and pharmacists to ensure optimal therapy and reduced death rates for patients afflicted with staphylococcal bloodstream infections. Dr. Shoham presented the data at the 2007 Annual Scientific Meeting of the Society for Healthcare Epidemiology of America.

The study occurred at the Washington Hospital Center,

a not-for-profit 926-bed acute care teaching and research facility. The flagship facility for the MedStar Health System, it is the largest hospital in the nation's capital and among the 25 largest hospitals in the United States.

By the numbers.

Every year, 350,000 patients acquire bloodstream infections in the U.S., resulting in more than 90,000 deaths and significant costs to the healthcare system. Rapid identification of the causative pathogen is crucial to ensuring early, appropriate, and effective therapy in order to improve patient outcomes.

During the study, 202 patients whose blood culture tested positive for Gram-positive cocci (indicating a staphylococcal bloodstream infection) were alternately assigned to a control or intervention group. In the intervention group, PNA FISH results and general organism information were relayed to the treating clinician via a call from a hospital liaison; clinicians treating control group patients did not receive a call.

According to the study, reporting of PNA FISH results led to:

- An 80% reduction in intensive care unit (ICU) related mortality due to *S. aureus* BSIs.

Every year, 90,000 deaths occur as a result of bloodstream infection. A new study shows one way this number can be cut: by utilizing AdvanDx's PNA FISH diagnostic test.



BORIS: Project Update

- Median hospital cost savings of \$19,441 per patient.
- A 61% reduction in patients receiving antibiotics for coagulase-negative staphylococci (CNS), which is often a blood culture contaminant that leads to unnecessary antibiotic therapy even though the patient does not have a true bloodstream infection.

Real-world implications.

"Rapid delivery of PNA FISH data from the laboratory to clinicians was associated with reduced mortality in ICU patients," said Dr. Shoham, Section of Infectious Diseases, Director, Transplant Infectious Diseases, Washington Hospital Center. "There was also a trend toward reduced length of hospitalization in non-ICU patients with *S. aureus*, and in patients with blood cultures growing CNS regardless of location within the hospital. AdvanDx, Inc's PNA FISH diagnostic tests provide rapid results that enable us to optimize antimicrobial therapy, improve patient outcomes and reduce hospital costs."

"We are extremely excited to see such powerful data regarding our PNA FISH tests, especially the reduction in mortality for patients with *S. aureus* bloodstream infections," said Dr. Henrik Stender, Vice-President for Research and Development at AdvanDx. "Extrapolating Washington Hospital Center's data to the rest of the U.S., more than 10,000 ICU patients with *S. aureus* bloodstream infections could potentially be saved every year. Combined with PNA FISH tests for other pathogens, we expect to see continued improvement in care for all bloodstream infections." ■

In the continuing effort to improve bioMérieux efforts in the area of bacterial identification and susceptibility testing, the bioMérieux Organism Resistance Surveillance (BORIS) project is making excellent progress in 2007.

A total of four U.S. sites are part of the laboratory network, representing clinical laboratories in the Northeast, Southeast, Midwest and Southwest regions of the country.

As of July 2007, with cooperation from our participating laboratories, we have collected a total of 225 *A. baumannii*, 97 *K. pneumoniae*, and 17 *P. aeruginosa*. As the majority of these contemporary clinical isolates exhibit increased levels of antibiotic resistance, as well as unusual resistance patterns, they comprise an extremely valuable culture collection for continued R&D efforts by bioMérieux.

In order to increase our knowledge of characteristics found among these isolates, the BORIS team has incorporated a number of phenotypic and genotypic methods in order to better characterize actual mechanisms of antibiotic resistance. In addition, strain typing using the Bacterial Barcodes system for rep-PCR, has allowed determination of clonal relationships within and between geographic regions.

We are pleased to announce the July 2007 addition of Dr. Jennifer Lavrrar as BORIS principal scientist. Dr. Lavrrar received her Ph.D. in Molecular Microbiology and Immunology from the University of Missouri-Columbia in 2002. She then completed two postdoctoral positions at the University of

Wisconsin-Madison in the areas of E2F proteins and their interactions with DNA, and post-transcriptional regulation of virulence factors in the pathogenic dimorphic fungus, *Histoplasma capsulatum*. Prior to joining bioMérieux, Dr. Lavrrar served as Lab Supervisor in the Pathology and Immunology department at Washington University School of Medicine. Dr. Lavrrar will work in conjunction with bioMérieux Senior Scientist, Jeanette Block, B.A., I(ASCP) to collect and characterize bacterial isolates on phenotypic and molecular levels.

In collaboration with our participating laboratories, two abstracts of original research from the BORIS were presented at the 2007 ICAAC meeting in Chicago, IL.

Both of these presentations address challenges in susceptibility testing of organisms resistant to multiple antimicrobial classes, and detection of emerging resistance mechanisms such as AmpC, KPC, and metallo β -lactamases. In addition, strain typing data generated with the Bacterial Barcodes system was used in analysis of clonal relationships in the organism collection.

Finally, BORIS needs labs! If you are interested in partnership with bioMérieux to increase knowledge for all microbiologists in the area of antibiotic resistance, we would certainly like to speak with you. Opportunities for publication and educational grants are available to clinical laboratories meeting criteria for participation. ■

▶ To read the complete article on BORIS, and to find out more information, go to www.biomerieux-usa.com/connection.

By Dr. LaBombardi, Chief of Microbiology, St. Vincent's Hospital, New York, NY

The Use of Expert Systems in an Era of

A worldwide increase in antibiotic resistance brings to mind how wrong that old saying, "What you don't know can't hurt you," is. I remember the "old days." To perform a susceptibility test, you would drop a Kirby-Bauer disk and measure the zone of inhibition the following day. You did not even need to look up the zone-size interpretation because chances are you had them memorized. You recorded the results and that was it. There was very little chance that you were missing something important. Obviously, this is no longer true. Susceptibility tests have given way to resistance detection assays. Due to the complexity involved in detecting certain resistance mechanisms and the fact that resistance to a particular antimicrobial may not be obvious, it is very easy to inadvertently release a false susceptible result. Therefore, it is an absolute necessity to utilize an up-to-date expert system to help recognize these resistance mechanisms.



We implemented the VITEK[®] 2 in my laboratory in 2000. The VITEK 2 comes with the Advanced Expert System (AES), which is based on the recognition of resistance phenotypes. At the time, ESBL-producing bacteria were a prime concern. After extensive validation utilizing fresh and archived isolates of ESBL-producing organisms, we were confident that the VITEK 2 was capable of recognizing this resistance mechanism. After establishing this, we set out to maximize the potential of the AES with the intention of using the AES to impact patient care. Below are some of the measures we have taken at St. Vincent's Hospital to utilize AES so that it has a meaningful impact on the care patients receive in our institution.

Auto-posting of Susceptibility Test Results

After gaining confidence in the ability of the AES to recognize resistance mechanisms and make appropriate

therapeutic modifications, we allowed all "green light" results (the MIC results are consistent with a known phenotype) to cross from the VITEK 2 to the Laboratory Information System (LIS) using auto-posting; that is, we released results to the LIS prior to technologist review if the AES assigned a known phenotype to the susceptibility test results. This allows the medical staff to view results as soon as the VITEK 2 makes them available. Important clinical decisions are not delayed because a technologist has not had the opportunity to review the VITEK 2 identification and antibiotic susceptibility test results. The following morning a technologist reviews the "auto-posted" results and the final report is issued. This change in workflow allows clinicians to make the earliest possible therapeutic interventions and maximizes the value of our microbiology laboratory results. It is our experience that changes to the final report rarely need

Increasing Antibiotic Resistance

to be made. Patients who are receiving inappropriate antibiotic therapy are switched to efficacious therapy sooner and this results in an improved patient care. It is important to note that not all results are auto-posted. Reports such as a vancomycin resistant *Staphylococcus aureus* (VRSA) would be held for review, as this would be an unusual result to say the least.

Using "Canned Messages"

In our laboratory, we append messages to the susceptibility report to help optimize antimicrobial therapy. Some of these messages already exist in AES and other messages we customized. These messages automatically post to the susceptibility report in the LIS when certain pre-determined conditions are met. Currently, we release customized messages for the inducible enterics to warn of the possibility of β -lactam resistance developing during therapy. Another message warns of the isolation of an ESBL-producing species and offers guides to appropriate therapy. Yet another message is used to explain aminoglycoside synergy in enterococcal isolates.

Modifications to AES

Out of the box, the AES can detect most of the currently recognized resistance mechanisms. The decision to review any therapeutic changes made by AES or to release the report without therapeutic changes is left to the discretion

of each customer. At St. Vincent's Hospital, we made the decision that it was to the benefit of patients to release data as soon as possible. Customers have the capability to make modifications to AES. There are several modifications that we made at St. Vincent's that we felt were necessary to optimize the impact of microbiology results. For example, bioMérieux is required to use FDA approved breakpoints. It is my opinion that these breakpoints may not be based on the most current data and, therefore, current FDA-approved breakpoints may not always be appropriate. So, with the concurrence of our Infectious

The VITEK 2 with AES is an indispensable tool in our laboratory. The Advanced Expert System has decided advantages over the rules-based system employed in the VITEK® 1. This hospital is embarking on an antibiotic stewardship program. Rapid reporting of antibiotic susceptibility test results, made possible by the Advanced Expert System and the modifications that we have made to this system, are an important component of our antibiotic stewardship program. I cannot imagine how difficult it would be to function in this era of antibiotic resistance without the aid of the Advanced Expert System. ■

I cannot imagine how difficult it would be to function in this era of antibiotic resistance without the aid of the Advanced Expert System.

Disease physicians and with our Pharmacy Department, we have made several modifications to the AES. We have also made modifications to the AES due to the recognition of new resistance mechanisms. These modifications are based on our experience at St. Vincent's Hospital and cannot be endorsed by bioMérieux, Inc. These modifications include:

- ESBLs
- *Pseudomonas aeruginosa*
- *S. aureus* and resistance to Macrolides, Streptogramins and Lincosamides (MSLB)
- KPC-Producing (Carbapenemase-Producing) Bacteria

References:

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Yigit, H., A.M. Queenan, G.J. Anderson, et al. 2001. *Novel carbapenem-hydrolyzing β -lactamase KPC-2*. Antimicrob. Agents Chemother. 45:1151-1161.

▶ To read the complete article on Expert Systems, and get more detail on some of the modifications that Dr. LaBombardi made at St. Vincent's Hospital, go to www.biomerieux-usa.com/connection.



What's New in Laboratory Safety

By Terry Jo Gile, MT(ASCP)MA Ed., The Safety Lady™

Today's hot topics in laboratory safety include personal protective equipment (PPE), training and safety improvement. At the July 2007, American Association for Clinical Chemistry (AACC), Terry Jo Gile, "The Safety Lady™" presented the following information.

Personal Protective Equipment

Laboratory PPE has been required since 1991, OSHA's compliance document 2-2.69 states that fabric for lab coats must meet the American Standards for Testing and Materials (ASTM) requirements. OSHA does not endorse any particular lab coat; however, vendors should provide labs with their specifications to be sure their coat meets ASTM requirements. So just what are these requirements?

Water repellency is the characteristic of fabric to resist wetting. The best rating is a 100. Ratings below 100 may be an indicator that the coatings on the fabric are beginning to fail.

Suter Hydrostatic Pressure Test measures the resistance of fabrics to the penetration of water under static pressure. Select a coat with a Suter rating in the 400 to 500 range.

The Break Test is a measurement of fabric durability. The more the fabric is washed and the condition under which it is washed (i.e.: detergent, fabric softener, bleach) determines the life of the garment. The break strength of a lab coat should be 150 inch pounds or more.

Laboratory coats must have air permeability for comfort, which is important to employee satisfaction. The ideal coat will have airflow of 12 or more cubic feet per minute.

Static discharge can damage the memory of computers or computer operated instrumentation. Insist on anti-static lab coats if you plan to wear fluid resistant coats.

Gloves must be made of a material that is hypoallergenic and comes in a variety of sizes for a snug fit. Latex gloves are most often used. Vinyl gloves are suitable for short term use such as 15 minutes or less but they do not provide long term protection. Nitrile gloves are a nice

alternative although they are more costly than latex gloves.

Shoes must have nonslip soles and cover the entire foot. Open-toes

shoes, sandals, shoes made of canvas and clogs are inappropriate as laboratory footwear. Shoes

must be made of materials that will not allow blood, body fluids or chemicals to soak through.

Podiatrists recommend a heel height of no more than 1.5 inches.

This allows for better distribution of weight on the foot so that proper body alignment can be maintained.

Training

Safety training is mandated for all lab employees. Spreading it out over a whole year keeps it fresh and new. To make sure safety training covers every aspect, divide up the issues and present one a month throughout the year. The following schedule takes into account national safety months that can provide you additional information for presentations.

January – Specimen Transport

February – Hoods and

Environmental Issues

March – Personal Protective

Equipment (National Eye

Safety Month)

April – Ergonomics

May – Bloodborne Pathogens

June – General Safety

(National Safety Month)

July – Compressed Gases

August – Safe Work Practices

September – Chemical Hygiene

October – Fire Safety

(Fire Safety Month)

November – Electrical Safety

December – Waste Management

So what makes safety training compelling? You need to make it entertaining and fun. Use posters developed by the various lab sections and make it a contest. Use a case study to get a safety point across. Try a word search that you can develop at www.discovery.com and search for puzzles. Use simple rewards such as a coupon for a free drink in the cafeteria or treats of some kind to help motivate the staff.

Safety Improvement

Sepsis is a big issue for hospitals. Over 750,000 patients in the United States are diagnosed with sepsis every year. The Centers of Disease Control and Prevention (CDC) says that the incident of sepsis is increasing 9% each year. As if that wasn't enough, lab contamination rates hover around the 3% mark and in many places it is much higher. Why is this an issue? A 2004 Medical Laboratory Observer (MLO) article reported that contaminated blood cultures can increase a patient's hospital stay by as much as 4.5 days and can add more than \$5,000 to the cost of treatment.

In many facilities blood collection, especially in the intensive care units

(ICU), is performed by nursing or patient care assistants that often have inconsistent training in proper blood culture collection.

WorkSafe™ is a bioMérieux initiative to provide education and training tools to improve proper blood culture collection. As part of the bioMérieux Bact/ALERT® system, WorkSafe is part of the overall concept of using plastic blood culture bottles instead of glass. Why is this important? OSHA's Richard Fairfax says: "Glass puncture wounds are among the most common injuries in healthcare, and glass that is contaminated with blood or other potentially infectious materials poses a more extreme danger."

The WorkSafe box includes a leader's guide to be sure the training is conducted properly, a 17 minute DVD on how to collect blood cultures from a variety of sites, a competency checklist to document proper training and knowledge of blood culture collection that can be used during skills days.

To learn more about WorkSafe go to www.biomerieux-usa.com/worksafe. ■

Product Highlight:

Blood Culture Collection Kit

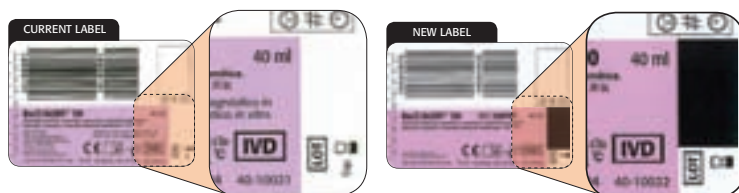
bioMérieux introduces a Blood Culture Collection Kit – all you need to collect a blood culture in one easy to use convenient package. Is your blood culture contamination more than 3%? Along with WorkSafe the blood culture collection kit can help you reduce contamination. Ask your bioMérieux sales representative how! ■



Improving BacT/ALERT® Bottle Labeling

Starting in Early December 2007 customers will be noticing a new BacT/ALERT label. The new BacT/ALERT bottle label will have the product reference # printed on the label.

The lot # and expiration date will now be etched on a black background instead of the lot # and expiration date being printed black on white background on the current label. Laser etching the lot code and expiration date produces a very durable and consistent print that can be inspected with automated equipment on our packaging line. ■



You Spoke and We Listened

bioMérieux is working hard to improve your service experience when calling into our customer service team. Our Mission: Improve Response Time. We are making changes to our phone system that will more quickly route your call to the appropriate specialist. Please refer to the new phone tree and listen for the changes coming in November.

Thank you for your continued business. We look forward to hearing from you! ■

bioMérieux Customer Hotline
800-682-2666

PRESS 1: If You Know Your bioMérieux Representative's Extension

PRESS 2: Place an Order

PRESS 3: Reagent & User Software Technical Support

PRESS 1: VITEK Systems and API Support

PRESS 2: Molecular Systems and MicroElisa Plate Support

PRESS 3: BacT/ALERT Systems Support

PRESS 4: Vidas Systems Support

PRESS 5: Stellara Support

PRESS 4: Instrument, Hardware & Computer Technical Support

PRESS 1: VITEK Systems and API Support

PRESS 2: Molecular Systems and MicroElisa Plate Support

PRESS 3: BacT/ALERT Systems Support

PRESS 4: Vidas Systems Support

PRESS 5: Credit and Collections

bioMérieux CONNECTION



2007 SHOWS AND CONFERENCES

**American College of
Chest Physicians (ACCP)**
Chicago • October 22-24
Booth #130

**Association for Molecular
Pathology (AMP)**
Los Angeles • November 7
Corporate Workshop: Innovative
Tools for Molecular Infectious
Disease Applications

**American Society of Health-System
Pharmacists (ASHP)**
Las Vegas • December 3-5
Booth #3217

WEBINARS

**Rapid ID of Sepsis Isolates
with PNA FISH –
Improving Patient Outcomes**
Dr. Margie Morgan
October 18
Visit www.biomerieux-usa.com/education for more details.