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THIS MONTH, WE'RE MAKING A NEW CONNECTION

Welcome to the first issue of the newly updated bioMérieux *Connection* newsletter. This updated version is the result of our ongoing efforts to make sure that *Connection* delivers the kind of content you're looking for, in a friendly, easy-to-read format. That process involved a great deal of feedback from our readers, and we'd like to thank everyone who took the time to offer comments and suggestions.

While the format may be new, our goal remains the same. With all of the exciting things taking place in laboratory medicine, *Connection* provides a single source you can turn to as a way to keep up with new products, and issues of concern to medical laboratorians. We will also feature stories on customers that demonstrate best practices and improve patient care through innovative healthcare solutions.

We hope that you'll continue to find the articles in *Connection* interesting, informative and useful. And, if you have any suggestions on how we can make further improvements, please let us know – you can contact your local bioMérieux representative or visit our web site at www.biomerieux-usa.com. ■

BLOOD CULTURE COLLECTION VIDEO ANNOUNCEMENT

bioMérieux is pleased to announce that its Blood Culture Collection Video will be released in the first quarter of 2007. This video will review the proper technique for blood specimen collection and inoculation of the BacT/ALERT® culture bottles. Details on how to get your copy will be provided in the next issue of *Connection*.

continued on page 2



BacT/ALERT 3D™
PERFORMANCE IN EVERY DIMENSION.™



continued from page 1

Dr. Cynthia Fowler is the head of Global Medical Affairs for bioMérieux. As an Infectious Diseases Physician and a Clinical Microbiologist, she knows how important accurate blood culture results are for diagnosis and treatment of patients with septicemia.



"We know that septicemia occurs in approximately 200,000 patients each year, and between 30 and 50% of those patients die. Because the consequences of septicemia are so serious, rapid and accurate diagnosis of this disorder is critical. The blood culture is the best diagnostic tool for detecting septicemia, and it's absolutely imperative that the blood specimen be collected properly to provide clinically valuable results." ■



ICAAC SAN FRANCISCO

bioMérieux was present at the 46th Interscience Conference on Antimicrobial Agents and Chemotherapy Conference in San Francisco, and the emphasis was on the influence its diagnostic family of products has on infection control issues.

The recent acquisition of **Bacterial Barcodes, Inc.** gave bioMérieux the opportunity to incorporate the DiversiLab™ system into our expanding offering of molecular diagnostic products. Used for DNA fingerprinting and analysis, DiversiLab™ is a powerful tool for tracking the spread and source of both community and hospital acquired infections.

bioMérieux also announced the recent 510(K) clearance of **Fluconazole susceptibility** testing on the VITEK® 2 platform. The Fluconazole (MIC) susceptibility test card provides an accurate, rapid and automated method for the susceptibility testing of systemic yeast infections, a leading cause of hospital-acquired infections.

Both of these exciting announcements herald bioMérieux's ability to provide hospitals and labs with the tools needed to aid in infection control and slow the growth of hospital-acquired infections. ■

DiversiLab™ is a powerful tool for tracking the spread and source of both community and hospital acquired infections.

Microbial
Genotyping System
diversilab™

COMPARISON OF PHOENIX™ AND VITEK® 2 COMPACT



FOR PERFORMANCE OF IDENTIFICATION AND SUSCEPTIBILITY TESTING, WORKFLOW, AND TIME TO REPORT

Background

Several options exist for performance of identification (ID) and susceptibility testing (AST) in clinical laboratories. We evaluated the Phoenix™ (PHX) (BD Diagnostic Systems, Sparks, Md.) and the new VITEK® 2 Compact (V2C) (bioMérieux, Marcy l'Étoile, France) for performance of ID and AST, workflow, and time to result.

Methods

Three hundred consecutive clinical isolates from a tertiary care pediatric hospital were tested including 131 Gram positives and 169 Gram negatives (127 *Enterobacteriaceae*, 42 non-fermenters). All discrepancies were resolved using the API® system (bioMérieux) and Sensititre® panels (Trek Diagnostic Systems, Cleveland,

Ohio). Workflow analysis consisted of a time study conducted by an independent consultant measuring total time for set up per isolate. Time to result was also determined for each isolate tested.

Results

Overall, the same ID was obtained from both systems for 282 isolates (94%). In total, PHX correctly identified 286 isolates (95.3%) and V2C correctly identified 294 isolates (98%). However, PHX had significantly more incorrect ID for Gram positives (PHX-5 vs V2C-0, $p=0.03$). The overall category agreement for all organisms was 95.7% for PHX and 97.2% for V2C. The very major, major and minor error rates were 0.8%, 1.3%, 3.1% and 1.5%, 0.6%, 2.1% respectively for PHX and V2C. The total manipulation time

per isolate was 47.9% faster with V2C (6.19 minutes for PHX versus 3.60 minutes for V2C). The average time to report complete ID and AST results was 13.0 hours for PHX and 8.36 hours for V2C ($p < 0.0001$).

Conclusion

PHX and V2C are comparable for ID and AST testing with the exception of Gram positives where PHX had a higher number of incorrect ID. Manipulation times and time to reporting of results are longer using PHX. ■

Blondel-Hill E., Jang W., Lee I., Borton N., Book L., Thomas E. BC Children's Hospital, Vancouver, BC, Canada. Presented on Poster D-691 at ICAAC 2006.

**“Manipulation times and
time to reporting of results are
longer using BD's Phoenix.”**



VITEK® 2
—compact

STILL STANDING

In the aftermath of Hurricane Katrina, the labs of New Orleans' East Jefferson General Hospital have never stopped testing.

There are 64 hospitals in the New Orleans area, according to the Louisiana Hospital Foundation (LHF, Baton Rouge, La). Hurricane Katrina forced 61 of these institutions to close. Approximately one year later, the LHF reported that 18 had still not reopened their doors. Only three hospitals managed to continue operations throughout the entire crisis: the Ochsner Clinic Foundation in New Orleans, West Jefferson Medical Center in Marrero, and East Jefferson General Hospital in Metairie.

Doing so was no easy feat. The hospitals did experience some damage and weathered extreme conditions. Communications were down, electricity was out, and staff was unable to come into or out of the area. "We were isolated from the world," says Mike Lattier, microbiology supervisor at East Jefferson.

Workflow and volume changed, but the East Jefferson lab was able to adjust, even with many of the staff living on the premises. "We never shut our doors, and the lab never stopped testing. We didn't lose one patient as a result of the hurricane," says Lattier. He credits a great emergency preparedness plan and high staff morale for seeing the hospital successfully through the crisis.



The hospital was not accepting many new admissions, surgery was not performed for about two weeks, and the outpatient workload had dropped to almost nothing. "Once people started moving back, though, it picked up pretty quickly. We are back to about the same volume now," he says.

In the immediate aftermath of the storm, however, the hospital felt like an island. Homes in the area were flooded by as much as three feet, and East Jefferson was surrounded by water. The hospital is up just enough that they had some seepage under thresholds but no flooding.

There was some damage to the roof and windows, but the bigger problems were the lack of communications and power. "Communications were horrendous. We lost Internet and phone service. Cell phones weren't working because the cell phone towers were down," he explains. Hospital generators kept needed systems running, but the elevators were inoperable, the lights were off in hallways, and the air conditioning was out. "The a/c chillers were turned off to conserve power, and it was very hot, even in patient rooms."

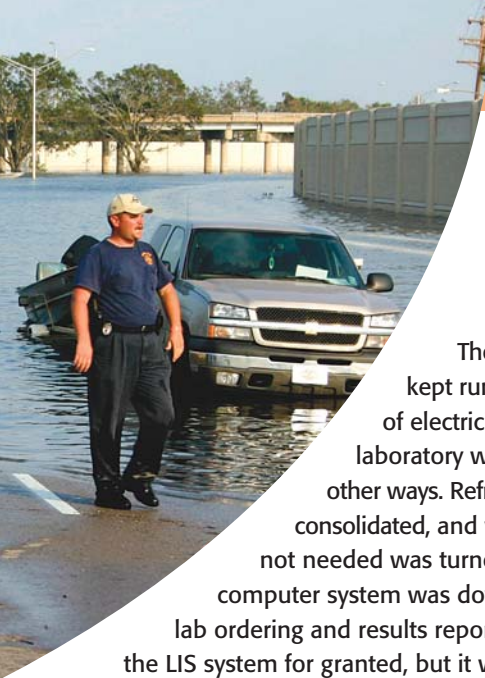
In the lab, the temperature reached 90 degrees. Lattier became concerned that the microbiology instruments would stop functioning. The laboratory uses VITEK® 2 and Bact/ALERT® 3D instruments for microbiology testing.

"We did set up some fans and were pleasantly surprised that both instruments never missed a beat," he says, adding that chemistry kept its analyzers functioning in the same way.



Storm Conditions

East Jefferson General Hospital is a community-based facility licensed for 450 beds. Lattier estimates the microbiology lab handled about 7,000 tests a month prior to Katrina. "There was a severe dip in the month of September [following the hurricane] – volume dropped by about half."



Though the tests kept running, the lack of electricity impacted laboratory workflow in other ways. Refrigerators were consolidated, and whatever was not needed was turned off. The computer system was down, which affected lab ordering and results reporting. "We take the LIS system for granted, but it was challenging to operate without it," says Lattier.

The hospital servers, normally stored on the first floor, had been relocated to higher floors in case the hospital did flood. After the storm passed, the servers were returned to the first floor and turned back on as power was restored.

In the meantime, orders and specimens were hand carried to the lab; results were given by phone, when possible, or hand delivered. According to Lattier, "Chemistry and hematology were able to print out manual reports, which could be easily brought to the floors, but in micro, it's difficult to do manual reports. So we used the phone when possible, or the doctor would come down to see results."

Team Players

The new, more intense workflow was managed with smaller teams. Each laboratory department had team members, designated by the hospital emergency preparedness plan, who were required to be on duty during a disaster. Lattier recalls that the microbiology lab was manned by just two people for about a week and a half after the storm.

Lattier became concerned that the microbiology instruments would stop functioning. The lab uses VITEK® 2 and BacT/ALERT® 3D instruments to perform microbiology testing.

The entire management team was also present, having been deemed essential personnel. "People questioned this rationale," he says, "but it allowed the techs to perform the testing while we helped out delivering specimens and results, even serving in the cafeteria and taking out garbage."

What the plan didn't anticipate was not having anyone to relieve the disaster team. "We were here pretty much around the clock, but since the workload had dropped off significantly, it was doable," says Lattier. A bigger challenge was being on-site for that length of time. "It took people a while to get back in, and some had no homes to return to. As they started trailing in, many stayed at the hospital." Lattier himself lived in his office for three weeks while waiting for power to be restored in his neighborhood.

Despite the hardships, morale remained high, and the team pulled together to help in many ways. Those who didn't lose their homes pitched in to help those who did. The hospital held counseling sessions, chaplains remained on duty to service patients and staff, and an employee in the compliance and legal department was assigned the task of finding housing for employees displaced by the hurricane. "She's done a great job of finding apartments or obtaining FEMA [Federal Emergency Management Association of Washington, DC] trailers for those who needed them," says Lattier. Some of the lab personnel are still living in trailers a year after the storm.

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"We... were pleasantly surprised that both instruments never missed a beat..."

Plan 'A' Still Good

While the hospital fared better than other institutions in the area, there were still some lessons learned, and adjustments have been made to the emergency preparedness plan. What worked will be kept: security and clean water posed no problems, for instance; IDs were needed to gain entry, and the hospital was able to draw water from its well.

To address communications issues, the hospital has now installed satellite phones. Future emergency electricity needs will be met through a direct feed established with the hospital's energy company. The hospital servers will eventually be permanently moved to higher floors to avoid having to move them in case of flooding.

Future emergency staffing plans will also provide for a team A, to be in place during the disaster, and a team B, to handle recovery. "Names will be selected on a rotational basis, although management will still be a part of every team," says Lattier.

The hospital didn't have to evacuate as a result of Hurricane Katrina, but it would have if it had flooded. "After the storm, we looked at the number of patients still in the hospital at the time of the hurricane and determined that it would have been a major undertaking to evacuate," he says.

The hospital does have a helipad, which was used to bring patients in during and after the storm, and which could be used to get patients out if needed. "We realized after a mock drill, however, that it would be extremely difficult to evacuate all of our patients, even with prior arrangements with other hospitals and transportation companies," says Lattier. "There is just not enough notice."

As a result, the hospital has decided to keep the same evacuation plan that it had in place before Katrina. As one of the three hospitals to continue functioning during the crisis, it is one of the few institutions that can proudly do so. ■

Source: Mike Lattier, microbiology supervisor, East Jefferson General Hospital (Metairie, La), 504.454.5569, mlattier@ejgh.org

EMERGING RESISTANCE

The evolutionary ability of microorganisms to alter their genetic makeup and become resistant to antimicrobial therapy poses a constant challenge to microbiologists and clinicians involved in the management of patients with infectious diseases. The scientists in our Research & Development and Medical Affairs departments also share this challenge.

Emerging resistance and the presence of new resistance mechanisms create a need for new antibiotics and new detection methods. Recent developments from bioMérieux include a Fluconazole Susceptibility Test for yeast susceptibility testing, a Cefoxitin Screen Test and a VRSA Screen Test for accurate reporting of *Staphylococcus aureus* susceptibility tests, and the new antibiotic Daptomycin, a treatment for infections due to *S. aureus*. This article provides information on some of the products and projects in development at bioMérieux to address these important issues.

New Antibiotic Development

Everyone involved in the diagnosis and treatment of patients with infectious diseases wishes that the pipeline of new antibiotics were greater than currently exists. The R&D teams in St. Louis and in France are working diligently to validate for use on VITEK® those new antibiotics that have made it to market or are expected to make it to market in the future. In development:

- **Tigecycline.** This relatively new antibiotic is now available on the VITEK® 2 Gram negative GN15 card and the soon-to-be-available VITEK® 2 Gram negative GN16 card, and it is likely to be available on future VITEK® 2 Gram negative cards. It is also in development for Gram positive cards, and is expected to be available on VITEK® 2 Gram positive cards in the 4th quarter of 2007. Tigecycline has been mentioned in the microbiology and infectious disease literature as a therapeutic consideration for highly resistant organisms, most notably the multi-drug resistant (MDR) *Acinetobacter baumannii* and the carbapenemase-producing *Klebsiella pneumoniae* (KPCs).

You can see the October 2006 issue of *Connection* for more information on KPCs.





• **Polymyxin B.** Most microbiologists probably never thought they would see the revival of this agent as a treatment for patients with serious infections. At this time, there are not even FDA breakpoints for polymyxin B. However, the emergence of organisms that are resistant to virtually all antibiotics has led to renewed interest in this

Emerging resistance and the presence of new resistance mechanisms create a need for new antibiotics and new detection methods.

antimicrobial. Typically used as a treatment of last resort, physicians are asking laboratories to perform antibiotic susceptibility tests (AST) on this agent. The bioMérieux R&D team is working on the development of MIC tests for inclusion on VITEK® 2 Gram negative AST cards. The goal is to have Polymyxin B available by the 4th quarter of 2007.

• **ESBL Confirmatory Test for *Proteus mirabilis*.** Work is underway to include *P. mirabilis* in the list of organisms that can be reported using the VITEK® 2 ESBL Confirmatory test. While these organisms are not currently common or widespread in the United States, it may become important to have this capability

on VITEK® 2 and VITEK® 2 Compact. It should also be noted that a significant advantage of the VITEK® 2 instrument is the Advanced Expert System (AES) that assigns a phenotype to each organism tested; the ESBL-producing *Proteus mirabilis* is a phenotype identified by the Advanced Expert System.

• **“D Test.”** Knowing that resistance to the MLS (macrolide, lincosamide, streptogramin) antibiotics may be inducible has led to interest in detecting this mechanism of resistance. The most common application has been to detect potential inducible resistance in clindamycin. The so-called “D Test” refers to the pattern

observed in inducible clindamycin resistance when the disk-diffusion “D Test” is used. An erythromycin disk is placed a specified distance from a clindamycin disk on an agar plate inoculated with the test organism. When inducible resistance is present, there will be a flattening of the typically circular zone of inhibition near the erythromycin disk, resulting in the appearance of a “D.” The R&D scientists at bioMérieux are working on incorporating this principle into the VITEK® 2 card so that microbiologists will not have to perform an off-line test to detect inducible resistance to clindamycin. The goal is to incorporate the “D Test” on Gram positive VITEK® 2 and VITEK® 2 COMPACT AST cards by the 4th quarter of 2007.

• ***Clostridium difficile* A+B Test.** The emergence of increasingly virulent strains of *Clostridium difficile* has led to renewed interest in this important pathogen. Clinical trials are currently underway on the VIDAS *Clostridium difficile* A+B assay. The goal is to have this assay available in the 2nd quarter of 2007.

Surveillance of Resistant Organisms BORIS,

the bioMérieux Organism Surveillance Network, was detailed in the August 2006 issue of *Connection*. As discussed in that article, the ability of organisms to rapidly develop resistance poses a challenge to everyone involved in the diagnosis and management of patients with infectious diseases. BORIS was specifically established to insure that VITEK® and VITEK® 2 card development is kept current with these emerging issues in antimicrobial resistance. It also allows bioMérieux scientists to conduct research in the fields of bacterial pathogenesis and antimicrobial resistance mechanisms. ■



GET CONNECTED EVEN SOONER

Connection is all about keeping up with the latest industry news and product information. And of course it's a great educational tool to keep current with important scientific topics and diagnostic product improvements. So, you'll be pleased to know that we've made it possible for you to be among the first to know about everything that's going on – by signing up to receive a link to a printer-friendly version of *Connection* in your email in-box. Visit us online at www.biomerieux-usa.com/connectiononline, fill out the simple form, and you'll be all set to make all the right connections. ■

IMPORTANT PRODUCT NOTIFICATION YST QUALITY CONTROL PRODUCT NUMBER 21343

After reviewing internal and customer QC trending data, bioMérieux is implementing a change to the Quality Control expected results for the YST/Kloekera apis ATCC 32857/dGNTa reaction. This change increases the accuracy of the expected QC and will result in greater success in QC testing of these products.

If you are using the YST card in conjunction with the Quality Control program, you can use the 'comment' option within the program and state that the expected result has been changed to a +/- reaction by bioMérieux.

This change is effective immediately and will be made in a future software release for both the QC program and the VITEK® 2 Systems Product Information. You should store this information with your Quality Control records for documentation of the change. ■

BIOMÉRIEUX QUALITY CONTROL ISOLATE/BIOCHEMICAL CHANGES

TEST KIT	ORGANISM	BIOCHEMICAL	PREVIOUS EXPECTED RESULT	NEW EXPECTED RESULT
YST	Kloekera apis ATCC 32857	dGNTa	-	+/-

2007

SHOWS AND CONFERENCES

Lab Info Tech Summit (LITS)
Las Vegas, NV • Mar. 5-7

Society for Healthcare Epidemiology of America (SHEA)
Baltimore, MD • Apr. 14-17

Clinical Virology Symposium
Clearwater Beach, FL • Apr. 27-28

National Patient Safety Foundation (NPSF)
Washington, DC • May 2-4

American Society of Microbiology (ASM)
Toronto, Canada • May 21-25

Association for Professionals in Infection Control (APIC)
San Jose, CA • June 24-28

American Society of Health-System Pharmacists (ASHP)
San Francisco, CA • June 25-27

American Association for Clinical Chemistry (AACC)
San Diego, CA • July 15-19

Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)
Chicago, IL • Sept. 17-20

Infectious Disease Society of America (IDSA)
San Diego, CA • Oct. 4-7

American College of Emergency Physicians (ACEP)
Seattle, WA • Oct. 8-11

Association of Molecular Pathology (AMP)
Los Angeles, CA • Nov. 7-10

American Society of Health-System Pharmacists (ASHP)
Las Vegas, NV • Dec. 2-6

bioMérieux CONNECTION

bioMérieux Connection is published by bioMérieux, Inc., 100 Rodolphe Street, Durham, NC 27712. Please send address corrections and mailing list additions to biomerieux.connection@na.biomerieux.com. For customer service, call toll free 800-682-2666. Please visit our web site at www.biomerieux-usa.com.

Please share your comments and suggestions with us through your local account manager or by emailing us at the address above. As always, we thank you for being a bioMérieux customer.