bioMérieux **onnection**

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New and Improved: 2nd Innovation in Motion Bus Tour Launches

bioMérieux's high-tech bus-board presentation theater and mobile laboratory recently launched its second nationwide tour from Orlando, Florida at the 106th American Society of Microbiology (ASM) General Meeting. The tour will be visiting more than 80 cities in the next six months.

Innovation in Motion is bioMérieux's way of putting the customer in the driver's seat. This laboratory on wheels has been developed to give hands-on experience with innovative microbiology systems that will show how integrated solutions can improve patient and financial outcomes. The focus is laboratories that could increase efficiencies, and reduce costs with state-of-theart identification and susceptibility testing systems, automated blood culture systems and clinical decision support software. This is a must-attend for microbiologists, lab professionals, lab managers, lab directors, pharmacists, pharmacy directors, medical/ pharmaceutical administrators, risk managers and infection control practitioners.

2006 Innovation in Motion Bus Tour, continued on page 2

ASM 2006 – A Book, a Bus, and a Bash

bioMérieux kicked their presence at ASM 2006 in Orlando into high gear with an author, a rolling lab, and a party that just wouldn't quit. And that was all outside the conference hall!

This year bioMérieux raised the bar at ASM making the event not only a complete showcase of their products and services, but their commitment toward education and growing knowledge as well as their unflagging appreciation for their customers. The Saturday prior to the conference at the Peabody, bioMérieux's annual Satellite Symposium got the nearly week-long schedule of events rolling. Featuring keynote speaker and award-winning author John Barry, his presentation on his book "The Great Influenza" captivated the audience. The first 300 registered attendees received a copy of Barry's book, while 25 randomly selected attendees won iPod®s containing the in-booth educational forums from ASM 2005. This was followed by a best practices presentation by Dr. Ellen Jo Baron that really struck a chord with the audience. Her insights were not only insightful, but helpful and actionable.





2006 Innovation in Motion Bus Tour, continued from page 1

The full-size luxury bus is equipped with the bioMérieux Integrated Solutions product portfolio, including: BacT/ALERT® 3D, VITEK® 2 Compact and STELLARA™, consisting of both diagnostic and IT equipment. New additions to the tour for 2006 are the NucliSENS® easyMAG™, mini VIDAS® and VITEK® 2. The products incorporate molecular diagnostics and automated immunoassay systems into the Integrated Solutions package. Personal demonstrations on-board will illustrate rapid results, increased productivity, automated bacterial identification, extensive clinical intervention, and improved safety that can be achieved by utilizing bioMérieux's suite of automated diagnostics equipment.



bioMérieux is offering special promotions and discounts to customers during the Innovation in Motion tour. For more information, visit www.biomerieux-usa.com/inmotion.







Launch Party, continued from page 1

Additional presentations included Herb Steward's update on bioMérieux current status and growth directions, while Doug Flammang updated ID/AST users on product information and upcoming features.

Following the symposium, attendees adjourned to the poolside reception where they mingled with the presenters.

Trade show highlights included:

- Congratulations to Janet Hindler on the 2006
 Sonnenwirth Award
- The 1,000th VITEK[®] 2 Compact placement
- Expansion of the NucliSENS[®] line adding five new ASRs during the show, to include *Chlamydophila pneumoniae*, *Mycoplasma pneumoniae*, Human Metapneumovirus, Respiratory Syncytial Virus and Enterovirus.
- A partnership with the Alliance for the Prudent Use of Antibiotics (APUA), a non-profit, international organization dedicated to promoting appropriate antibiotic access and use and curbing antibiotic resistance worldwide.
- The hugely popular speaker forums that left little standing room for overflow audiences



Forum topics included:

- Dr. Paul Bourbeau: Blood Culture Updates
- Dr. Steven C. Ebert: Antibiotic Stewardship
- Dr. Christine Ginocchio: Molecular testing for your lab: Are you Ready? Get set and go and "Real Time" Molecular Detection of RSV and hMPV in Pediatric Respiratory Samples
- Janet Hindler: CLSI™ Updates
- Dr. Vincent LaBombardi: Expert Systems
- Dr. Davise Larone: Fungal Update
- Dr. John Thomas: Measuring Microbiology's Value in a Pay4Performance Environment
- Dr. Ken Thomson: KPC Resistance Mechanisms

Most of the in-booth education forums are available at www.biomerieix-usa.com/interactive.

Customer appreciation party

Back by popular demand, Rockin' Dopsie and the Zydeco Twisters headlined the customer appreciation event at the largest Hard Rock Live in the world. BacTBuddies flew into the roaring crowd as Rockin' Dopsie led the charge in kicking off the second year of the Innovation in Motion bus tour. The infectious energy flowing through the party sent Rockin' Dopsie to blow past his scheduled finale at 10:30 p.m. and on into the early morning hours.

bioMérieux is already working on exciting forums and innovations to introduce at the 2007 ASM, so we'll see you in Toronto next year!







Quality control changes for the VITEK[®] 2 GN test cards

There have been three changes to the quality control performed on the GN test card:

- 1. The recommended medium for subculture of QC organisms is being changed from Columbia agar with 5% sheep blood to Trypticase Soy agar with 5% sheep blood
- 2. The expected results for Klebsiella oxytoca ATCC[®] 700324 with CMT has been changed to +/-
- 3. The expected results for Acinetobacter baumanii ATCC BAA-747 with AGLTP, IMLTa, ILATa and IHISa are being modified to +/-

If you are using the GN CARD in conjunction with the Quality Control program, please enter a comment in the "comment" option within that program to state that the expected result has been changed to a +/- reaction by bioMérieux, Inc.

These changes are effective immediately and will be made in a future software release for both the QC program and the VITEK[®] 2 Product Information manual. You will receive notification at that time.

The NH ID card is now available for VITEK[®] 2

Fastidious Gram negative cocci and fastidious Gram negative bacilli and coccobacilli can be problematic for the microbiology laboratory. Identification of these organisms can be time consuming and difficult.

bioMérieux is pleased to announce a significant expansion to the VITEK® 2 menu – the NH ID card. This card allows laboratories to use their automated microbiology instrument to identify the organisms listed at right. The result is improved laboratory productivity and accurate identification for a group of difficult to identify organisms.

Clinical trials were performed at three hospitals using 371 fresh clinical isolates. Correct identification was achieved in 96.5% of isolates. One choice was available for 86.3% of these isolates with low discrimination found in 10.2% of the correct identifications. An incorrect identification was found in 2.7% and unidentified organisms accounted for 0.8% of isolates. This is a very impressive performance considering the organisms listed in the database (right). The time-to-call is six hours for this card.

The NH ID card is available TODAY for VITEK 2 (Software 4.02 required). It will be available for VITEK[®] 2 Compact with the release of software version 2.01 in Q1 of 2007. To order, reference product number 21346.

The NH ID card reflects the commitment of bioMérieux to provide you with products that improve patient care, increase laboratory productivity and increase the value of your investment in VITEK 2 technology.

To keep you informed on progress with the development of an identification card for anaerobic bacteria and coryneform organisms, the ANC card is undergoing clinical trials and the results will be presented at the 2007 ASM meeting. We will present this data in a future newsletter.

You should store this information with your Quality Control records.

Test kit	Organism	Biochemical	Previous expected result	New expected result
GN	Klebsiella oxytoca ATCC 700324	CMT	-	+/-
GN	Acinetobacter baumanii ATCC BAA-747	AGLTp	+	+/-
GN	Acinetobacter baumanii ATCC BAA-747	IMLTa	+	+/-
GN	Acinetobacter baumanii ATCC BAA-747	ILATa	+	+/-
GN	Acinetobacter baumanii ATCC BAA-747	lHISa	+	+/-



Actinobacillus ureae Campylobacter coli Campylobacter fetus ssp. fetus Campylobacter jejuni ssp. jejuni Capnocytophaga sp. Cardiobacterium hominis Eikenella corrodens Gardnerella vaginalis Haemophilus actinomycetemcomitans Haemophilus aphrophilus/ Haemophilus paraphrophilus Haemophilus haemolyticus Haemophilus influenzae Haemophilus parahaemolyticus Haemophilus parainfluenza Haemophilus segnis Kingella denitrificans Kingella kingae Moraxella (Branhamella) catarrhalis Neisseria cinerea Neisseria elongata Neisseria gonorrhoeae Neisseria lactamica Neisseria meningitidis Neisseria sicca Oligella urethralis Suttonella indologenes

Performance of the New VITEK[®] 2 NH Card in a Routine Clinical Laboratory

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Abstract

Background: VITEK[®] 2 and VITEK[®] 2 COMPACT (bioMerieux, Marcy l'Étoile, France) are widely distributed automated identification systems. A new card (designated "NH") for identification of fastidious Gram negative or Gram variable organisms (HACEK group, *Campylobacter spp., Capnocytophaga spp., Gardnerella vaginalis, Haemophilus spp., Moraxella catarrhalis, Neisseria spp., Oligella urethralis, Suttonella indologenes*) has been developed but its performance under the conditions of a routine clinical laboratory has not been evaluated.

Methods: During a three-month period, 178 fresh, consecutive, clonally unrelated, fastidious organisms encountered in clinical specimens were identified using the NH card on the VITEK 2 instrument. Reference identification was achieved by a combination of phenotypical identification systems (API Campy, API 20E, rapid ID 32 STREP, API NH, rapid ID 32A [all from bioMérieux] and 16S rRNA gene sequencing. The older VITEK NHI card was tested on the VITEK instrument in parallel to the new VITEK 2 NH card for 71 isolates.

Results: Of the 178 strains, 147 (83%) were unambiguously identified and 27 (15%) were identified with low discrimination (i.e., correct identification with supplementary tests). Only two isolates (1 %) were not identified and two strains (1 %) gave discordant results regarding the reference identification. In contrast, the VITEK NHI card identified only 44% of the isolates without supplemental tests while 49% of the strains required additional tests for final identification, and 7% of the strains remained unidentified.

Conclusion: The new VITEK 2 NH card is a useful tool for the identification of fastidious Gram negative or Gram variable bacteria encountered in a routine clinical laboratory. The complete depth of the database needs to be evaluated in a separate study using a set of stored challenge strains.

Reprinted from ASM 2006. C-010

Rapid Automated Identification of *Neisseria gonorrhoeae* Fresh Isolates with the New VITEK[®] 2 NH Card.

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1. bioMérieux Inc, Hazelwood, MO, 2. Medical Microbiology Laboratory, University of Alberta Hospital, Edmonton, AB, Canada Abstract

Objectives: The new Advanced Colorimetry[™] NH card was developed for the rapid automated identification of *Neisseria*, *Haemophilus* and other fastidious species using VITEK[®] 2 Systems.

Methods: Fifty-two fresh isolates of *Neisseria gonorrhoeae* were collected at the University of Alberta Hospital and tested on the new NH card. Cards were filled with organism suspensions made in 0.45% aqueous NaCl to a turbidity equivalent to a McFarland #3 standard. Inoculated cards were incubated in the VITEK 2 for approximately 6 hours and a computer-assisted algorithm was used to generate test and identification results.

Results: Of the 52 fresh isolates tested, 51 (98.1%) gave a correct identification including 3 (5.8%) low discrimination results requiring supplemental testing to discriminate between multiple (up to three) choices. An incorrect identification was observed with 1 (1.9%) of the isolates and none were unidentified.

Conclusions: The new VITEK 2 NH card provides an accurate, rapid, and automated method for the identification of *Neisseria gonorrhoeae* isolates.

VRSA screen test for VITEK[®] 2 now FDA approved

bioMérieux is pleased to announce that the VRSA Screen for the VITEK[®] 2 has received FDA clearance. This test predicts the presence of high levels of Vancomycin resistance, meaning those strains of *Staphylococcus aureus* with an MIC of >16 µg/ml. The VRSA Screen is used in conjunction with the Vancomycin MIC, but not as a replacement for the MIC test.

The VRSA Screen will be available in September of 2006 on the new VITEK 2 Gram positive susceptibility card AST-GP64, Product #22107. In addition to the VRSA Screen, the GP64 card will also contain the Cefoxitin Screen test for oxacillin (methicillin) resistance detection and will contain the antibiotic daptomycin. VITEK 2 software version 4.03 must be installed to use the GP64 card.

The VITEK[®] 2 Compact will require software version 2.01 to utilize the GP64 card. Delivery of this software is expected in the first quarter of 2007.

This is the configuration of the GP64 Card:

	AST-GP64 #22107
	Ampicillin
	Penicillin
	Oxacillin
	Cefoxitin Screen
	Ciprofloxacin
	Levofloxacin
	Moxifloxacin
	Clindamycin
	Daptomycin
	Erythromycin
	Gentamicin
	Gentamicin High Level
	Streptomycin High Level
	Linezolid
	Quinupristin/Dalfopristin
t	Synercid®
5	Rifampin
	Tetracycline
	Trimethoprim/Sulfa
	Nitrofurantoin
	Vancomycin
	VRSA Screen Test

Analysis of the Comparative Workflow and ID/AST Test Result Accuracy of the VITEK[®]2 Compact and the PHOENIX[™] Systems

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Revised Abstract

Objective: The aim of this study was to analyse the impact of introducing into our laboratory the VITEK[®] 2 compact (V2C), (bioMérieux, France), a new automated identification (ID) and susceptibility testing (AST) system. The study consisted of two parts i) measurement of potential productivity gain, time and cost and; ii) analysis of ID and AST accuracy after Expert Systems validation. Methods: In total, 390 routine clinical isolates were tested: 215 Gram-negative (55%), 175 Gram-positive (45%) using our in-house method, PHOENIX[™] (PHX; Becton Dickinson, U.S.A), in parallel with the V2C. The strains were isolated from routine clinical samples; urine and blood cultures, stools, throat and genital samples. The following parameters were studied:

Productivity: Consultants audited the laboratory and performed time measurement of the general laboratory routine: from specimen reception, culture set up, ID/AST set-up and result validation.

ID and AST accuracy: Tests were performed in parallel on both systems and discordant results were tested by molecular technique and E-test (bioDisk). AST results were validated using the PHX Expert rule software and V2C Advanced Expert[™] System (AES) for results agreement. The medical microbiologist expertise provided final results on any discordant results.

Results: The global process time difference between V2C and PHX was mainly due to mean time to result for V2C being 7-13 h compared to 10-16 h for PHX. ID/AST test manipulation time was (1.53 min vs. 3.20 min). The overall identification agreement between the systems was greater than 97% for Gram-negative and 97% for Gram-positive. AST overall category agreement was more than 98% with both systems.

Conclusion: The VITEK 2 compact provided labor gains in our routine setting due to less manipulation steps and a faster time to result. Performance between two systems were comparable.

bioMérieux establishes an Organism Surveillance Network

It is understood that active epidemiologic surveillance is critical for the identification and control of emerging disease threats. Aware of the enormous challenge that microorganisms exhibiting unusual patterns of antimicrobial resistance pose to clinical laboratories in the form of accurate detection, treatment recommendations, and associated hospital costs, bioMérieux is pleased to announce the recently established bioMérieux Organism Resistance Initiative Surveillance (BORIS) network.

BORIS will work to specifically address the issues of emerging antimicrobial resistance and challenges in product development. Isolates will be sent to our St. Louis location for ID and AST confirmation, and additional testing. More importantly, these organisms will be available for use by bioMérieux in supplementary research activities and for future VITEK® card development sets. Because of the rapid pace at which bacteria develop resistance to antibiotics, access to a development set consisting of contemporary clinical isolates is crucial for VITEK product support.

With BORIS, bioMérieux can re-assess selected surveillance targets at six-month intervals, which allows for flexibility in response to rapidly changing pathogens, or rapid response to concerns from our customers. Some of the first organisms being targeted will be: *Pseudomonas aeruginosa* with increased MIC to: Piperacillin, Piperacillin/Tazobactam, *Staphylococcus aureus* resistant to: Linezolid, Tigecycline, Daptomycin and Multidrug resistant Acinetobacter.

As an industry leader in the field of diagnostic microbiology, bioMérieux acknowledges its responsibility to conduct research in the fields of bacterial pathogenesis and antimicrobial resistance mechanisms, in addition to continual support and improvement of its current range of microbiology diagnostic products. The establishment and long-term support of BORIS will ultimately result in increased knowledge for all microbiologists, better products, better customer service, and ultimately, better patient care.

- We will "Be the First to Know"

Update on fungal susceptibility testing

The number of serious infections due to yeasts continues to increase. Medical experts attribute this increase to therapeutic measures that can now be employed for advanced life support and increasing usage of antibiotics and indwelling catheters.

It is, therefore, also becoming important that laboratories provide physicians with guidance on the selection of an effective antifungal antibiotic. Clinical and Laboratory Standards Institute (CLSI) has established breakpoints for laboratories to report the category susceptibility result (Susceptible, Intermediate or Susceptible–Dose Dependent and Resistant) for the antifungal agents itraconazole, fluconazole and flucytosine.

To help laboratories meet this need for antifungal susceptibility testing, bioMérieux has been working toward the development of an antifungal susceptibility test card. This card has been developed to test and report the category and MIC results for fluconazole against *Candida sp.* A 501(k) premarket notification has been submitted to the FDA. Pending FDA clearance, the fluconazole antifungal susceptibility test card will be available for VITEK[®] 2 by late summer of this year and for VITEK 2 Compact by Q1 of 2007. We will keep you informed of the progress of this important new addition to the VITEK 2 menu in future editions of the *bioMérieux Connection* newsletter.

Message in a Bottle

Anne Beall, US Clinical Marketing Manager, Microbiology

As a bioMérieux customer for many years and recently new to the bioMérieux marketing team, I never realized all the effort and people involved in providing blood culture bottles to microbiology laboratories. Since joining bioMérieux in January 2006, I have learned so much about blood culture bottle manufacturing and felt compelled to share this knowledge. As customers and providers of healthcare solutions, we tend to be so focused on our own duties, tasks and our patients, that we frequently overlook how the products we use for diagnostic testing come together and the processes involved in the manufacturing of those products.

Until bioMérieux launched its plastic blood culture bottle in 2004, all blood culture bottles on the market were glass. It was not simply glass. Due to the bacterial metabolism and the technology involved in detecting septicemia in BacT/ALERT®, the glass had to be type One optical quality pharmaceutical glass. Making the switch to plastic was quite challenging. The first issue to overcome was finding a plastic bottle that had optical clarity; secondly, the plastic bottle had to be able to withstand a vacuum; there was also the issue of terminal sterilization. Finally, the plastic bottles had to maintain the integrity of the contents for a shelf life of 12 months or more.

Why Plastic?

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. In most cases, plastic can be easily substituted for glass, therefore OSHA (Occupational Safety and Health Administration) expects employers to use plastic where appropriate.

(Please see OSHA compliance Directive 2-2.69 available at www.osha-scl.gov/pls/oshawaweb/owadisp.show_document?pta ble+DIRECTIVES&p_ID=2570.)

Bottle Design

The plastic bottles are made of an innovative formulation that does not interfere with organism growth or metabolism.

The outer layer of the bottle is a polycarbonate layer and the inner layer is an amorphous nylon layer, which is not only transparent but also an excellent gas barrier. Together these

two layers make up the BacT/ALERT bottles, which are transparent, gas impermeable and virtually unbreakable.

Plastic is Fantastic

In 2004 bioMérieux was the first to introduce plastic bottles for blood cultures and to date, bioMérieux remains the only supplier of plastic blood culture bottles. Plastic blood culture bottles don't break, crack



or shatter like glass, even in pneumatic transport systems. So whether you're collecting, transporting, testing or disposing of hazardous blood culture samples, a safer alternative and a safer working environment is at your fingertips.

Other Advantages for Using Plastic

Compared to glass, the BacT/ALERT plastic bottle weighs 30 percent less than the competitors' glass bottles. Besides being plastic, other advantages can be found in cost of freight, weight of transport of product from store room to shelf, weight on the phlebotomy tray, the ability to be transported via pneumatic tube systems, cost of disposal of biohazard waste, and many more.

The BacT/ALERT bottle has a well-established reputation in the laboratory community for ease of use, high-performance detection of positive results, and one of the industry's lowest false-positive rates. And with safety being the primary advantage to labs and hospitals, BacT/ALERT is the latest innovation in blood culture testing from bioMérieux, exhibiting our commitment to deliver products and services that stay one step ahead of the needs of our clients. Which only begs the question, what's next?

> ICAAC 2006 in San Francisco, CA Moscone Convention Center September 27-29 • Booth *1516 • www.icaac.org



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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.