

# bioMérieux *Connection*

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**Booth  
#429**

## NucliSENS® easyMAG™ receives Frost & Sullivan Technology Innovation Award

bioMérieux is proud to be recognized as the recipient of Frost & Sullivan's 2006 Technology Innovation Award in the field of In-Vitro Diagnostics for development of the innovative NucliSENS® easyMAG™ platform. NucliSENS easyMAG, described in the award as a breakthrough in the field of molecular diagnostics, represents a next generation sample preparation platform for automated total nucleic acid isolation (DNA and RNA) from clinical samples.

Frost & Sullivan's Technology Innovation Award is bestowed upon a company (or individual) that has carried out new research, which has resulted in innovation(s) that have or are expected to bring significant contributions to the industry in terms of adoption, change, and



competitive posture. This award recognizes the quality and depth of a company's research and development program as well as the vision and risk-taking that enabled it to undertake such an endeavor.

Visit [www.biomerieux-usa.com/easymag](http://www.biomerieux-usa.com/easymag) for more information on NucliSENS, easyMAG or BOOM® technology or contact your local bioMérieux account manager.

## bioMérieux brimming with knowledge at ASM 2006

Please join bioMérieux at the 106<sup>th</sup> American Society for Microbiology General Meeting May 20-24, 2006 at booth #429 Orange County Convention Center, Orlando, Florida. This year's show will feature the Satellite Symposium and reception with keynote speaker John M. Barry, author of "The Great Influenza". bioMérieux's Knowledge Forums will present expert speakers on topics that have an immediate impact on the microbiology laboratory. And don't forget our Customer Appreciation Night at the Hard Rock Café featuring music by Rockin' Dopsie, Jr. and the Zydeco Twisters. To learn more, flip to page eight.

## VITEK® 2 NH Card is here!

The new VITEK® 2 NH Identification Card is available now. The Product Number is 21346.

This card identifies 28 species of bacteria. In addition to *Haemophilus* sp. and *Neisseria* sp., it will identify one or more species of organisms belonging to the following genera:

.....

VITEK 2 NH Card, continued on page 7

# Introducing bioMérieux's Advisory Committee

# VRSA



To stay connected with the microbiology community, bioMérieux held the first meeting of its newly formed Advisory Committee for Clinical Microbiology in May of 2005. Consisting of individuals with diverse specialties, including microbiologists, physicians, and pharmacists, the Committee was formed to provide bioMérieux with perspectives and insights on a range of issues affecting today's microbiology laboratories and healthcare as a whole. Through active collaboration with the Advisory Committee, bioMérieux has gained valuable information about diagnostic products that are needed and wanted in clinical microbiology laboratories, pharmacies and hospitals.

## **Some of the topics covered in 2005 included:**

- VRSA: Screening Test vs. MIC
- Laboratory Management and Staffing: Discussions on common struggles facing today's labs
- Emerging Resistance: Identifying the new "VRSA" and other challenges in AST testing
- Molecular Testing: Can it become a useful tool in today's labs?
- Natural Disasters and Bioterrorism: How to be better prepared

An example of how the Advisory Committee was able to make a positive impact was in the favorable feedback received for a screening test for VRSA. As a result, the Committee's discussions have helped to push this project forward in its development process.

Additionally, multiple recommendations for an increased molecular test menu, including syndrome-specific panels, have justified on-going efforts in this area. Expressed interest in niche areas may result in the formation of other Advisory Committees to focus on possibilities outside the realm of traditional microbiology.

With the formation of this Advisory Committee, bioMérieux hopes to establish a pipeline through which we can directly reach out to the microbiology laboratory and all areas of the hospital, in order to better understand concerns that impact day-to-day operations. This committee will be an on-going focus for bioMérieux and topics for this year's meetings are currently under review.

It is the intention of bioMérieux to remain the market leader in automated microbiology testing. In order to do so, we will need to continue to provide solutions that help healthcare institutions improve clinical and financial outcomes, control the spread of antibiotic resistance and reduce the incidence of hospital-acquired infections. We also need to better anticipate emerging issues so that we can lessen the reaction time needed to respond. Partnership with the Advisory Committee is a means to help us reach these goals, and better assist you, our customer, to provide quality patient care.

# How my laboratory impacts patient care by rapidly reporting antibiotic susceptibility test results

**by Dr. Vincent J. LaBombardi**  
**Chief of Microbiology**  
**St. Vincent's Hospital - Manhattan**  
**New York, New York**



Many of us can remember the days when we could take an isolate, set up a Kirby-Bauer, read the zone size the next day, call it S, I or R — and not give it a second thought. Those days are gone.

The current-day microbiology laboratory no longer performs susceptibility tests; instead, it performs resistance detection tests. The minimum inhibitory concentration (MIC) result generated on a single antibiotic may not be able to be interpreted on its own merit. We now must rely on an isolate's phenotypic expression of its resistance mechanisms to be able to predict what the *in vivo* response will be to a particular agent. For example: if an isolate is producing an Extended Spectrum Beta-Lactamase (ESBL), it should be considered resistant to all of the penicillins and third-generation cephalosporins regardless of the MIC value. There are now many different resistance mechanisms that have been described that will affect susceptibility results. It is becoming difficult to keep track of all of these emerging resistance mechanisms. Unfortunately, what you do not know can harm your patient! This is why the use of an "expert" system is essential when generating susceptibility test results.

At St. Vincent's Hospital in Manhattan, we have been using the Advanced Expert™ System (AES) contained in the VITEK® 2 since June of 2000. We are no different than many of the hospitals in New York City, in that we have resistant bugs. However, to maximize the usefulness of the VITEK 2, we needed to get the information to our health care providers in a timely fashion. In the AES, you can set the frequency of occurrence for a particular resistance mechanism, such that you either hold the result for review or automatically accept the expert interpretation. These results can now be sent across the LIS interface and be available to the medical staff. After customizing the expert system, with the assistance of our bioMérieux technical specialist, and after an extensive validation, we felt comfortable auto-posting results as they cleared the AES. That is, once it has been determined

that the susceptibility profile is consistent with the organism identification, even if changes in therapeutic interpretations have been made, the results go across the interface and are available in the LIS. These results are then verified by the technologist the next day. Inconsistent results, for example, in a mixed culture, will be held up by the AES pending technologist review. It is also possible to affix a canned message to the report, explaining to the medical staff what resistant mechanism(s) has been detected in the isolate and what it may mean clinically. In our experience, very few of these AES-cleared results have had to be retracted. The bottom line is that we can release clinically significant results all through the day and evening and make them available in time frames that can affect patient care.

"I like the fact that AES reviews every result. Rules-based expert systems only address isolates that break one of the written rules. My technologists get a green, yellow or red light with each isolate and this guides them on accepting or rejecting the susceptibility test result on every organism they encounter."

The use of an expert system is imperative to good clinical practice in the face of emerging resistance. The AES associated with the VITEK 2 has performed well and has become a vital tool for the clinical microbiologist.







## In development: new VITEK® 2 Card for identification of anaerobic bacteria and *Corynebacterium* species

bioMérieux is making very good progress in developing a VITEK® 2 Identification Card that speciates anaerobic bacteria and *Corynebacterium* species. This card will be called the ANC Card.

This new card will identify 66 species of anaerobic and coryneform using VITEK® 2 and VITEK® 2 Compact systems.

As with other VITEK 2 Identification Cards, the ANC Card is incubated and read on-line. Results are available in six hours.

Early studies performed in bioMérieux laboratories and in a hospital clinical microbiology laboratory showed very promising results. The card gave a high level of correct identifications with a small percentage requiring supplemental testing to discriminate between multiple choices.

The identification of these two groups of organisms is often problematic for microbiology laboratories. The development of this exciting new product brings added value to VITEK 2 and VITEK 2 Compact and reflects bioMérieux's ongoing commitment to the development of new products through vigorous research and development activities.

We expect all developmental work on this card to be completed and available for customer use in the 4th quarter of 2007. We will keep you informed of progress and evaluations of the ANC Card in the *bioMérieux Connection* newsletter.

## Coming soon: Innovation in Motion 2006



Coming soon to a location near you, the 2006 Innovation in Motion bus tour launches this spring. Check our website, [www.biomerieux-usa.com](http://www.biomerieux-usa.com), for the 2006 schedule and register to participate when we visit your city. The 2006 Innovation in Motion tour will feature the new NucliSENS® easyMAG™, VITEK® 2 and VITEK 2 Compact ID/AST systems, the BacT/ALERT® 3D microbial detection system, OBSERVA® data management software, the VIDAS® immunoassay system and STELLARA™ Intelligent Patient Management System, powered by TheraDoc® Expert System Platform®.

**Look for the bus coming soon!**

# STELLARA™ demonstrates significant cost savings and reduction of adverse drug events at Franciscan Health System

## Study confirms clinical decision support software improves patient safety

bioMérieux, Inc. recently announced the one-year anniversary for STELLARA™ Clinical Intervention and Patient Monitoring software, powered by TheraDoc® Expert System™ Platform. STELLARA was showcased at last year's Health Information and Management Systems Society (HIMSS) conference. A six-month study completed at Franciscan Health System (FHS) in Tacoma, Washington demonstrates impressive results achieved after only one year of implementing STELLARA software.

From July 2004 to June 2005, FHS pharmacy management monitored the number of medication orders and the staff's productivity for six months prior to the implementation of STELLARA as compared to the first six months post-implementation. The study revealed remarkable results.

"We have experienced tremendous success with STELLARA as our intelligent interface software over the past year, which led to an increase in clinical interventions by our pharmacists," said J. Kelly Martin, PharmD, director of pharmaceutical services at FHS. "We are seeing concrete results in the forms of cost savings and improved patient care. In 2005, cost

savings from interventions increased by 23 percent and our pharmacists prevented 222 adverse drug events (ADEs) (a 23 percent increase from 2004) after implementation of STELLARA. Interventions made by pharmacists increased from 17,906 to 27,667 – a 55 percent increase."

Implementation of STELLARA proved to significantly decrease adverse drug events and healthcare costs while improving pharmacist productivity. In addition, FHS pharmacists efficiently managed a 41 percent increase in medication orders without forfeiting quality or adding staff.

The STELLARA system provides knowledge-enriched, infectious disease-specific recommendations to clinicians for medication treatment management. With the recent availability of the final level of functionality, Étage 4, bioMérieux completed its suite of Intelligent Patient Therapy Software Systems enabling the clinician to capture a more comprehensive view of the patient, avoiding potential medication errors and reducing the chances of costly adverse drug events.

bioMérieux's web-based application operates on most mobile computing and PDA systems, offering mobility and real-time alerts for the clinician. Moreover, the system provides documented return on investment for the hospital.





# Lab Partnerships Are Critical

by Douglas Hill, DO, FACP, FACEP



Emergency physicians are faced with making critical life or death decisions every day in the emergency department (ED). One of the most valuable lessons I have learned on the job is the importance of a strong partnership with the laboratory. Emergency physicians rely on results produced by the lab to make potentially life-saving decisions, and it is critical that the lab use the most appropriate diagnostic technology.

Venous thromboembolism (VTE) is a disease commonly misdiagnosed or missed altogether. Deep vein thrombosis (DVT) and pulmonary embolism (PE) represent two points on the continuum of VTE and because PE has a high rate of mortality, a speedy diagnosis is critical. PE will be missed at least 400,000 times each year, resulting in 100,000 deaths!

Fortunately, 75% of patients who present to the ED with suspected VTE do not actually have the condition. For this reason, it is medically prudent to first rule out a diagnosis in patients with low to medium risk factors. The ideal screening test would offer the following characteristics: a negative predictive value (NPV) of 98% or greater, rapid results, demonstrated validity and a cost-efficient platform. Emergency physicians are most concerned with turnaround time; they view anything less than one hour as being ideal.

Patients enter the ED presenting with any number of symptoms, and it's imperative that emergency physicians are equipped with the necessary resources to make an accurate and fast diagnosis. New diagnostic technology is introduced to the health

care industry every day, and emergency physicians must stay informed about what test methodologies employed in their own labs and the approved clinical utility and limitations of these assays.

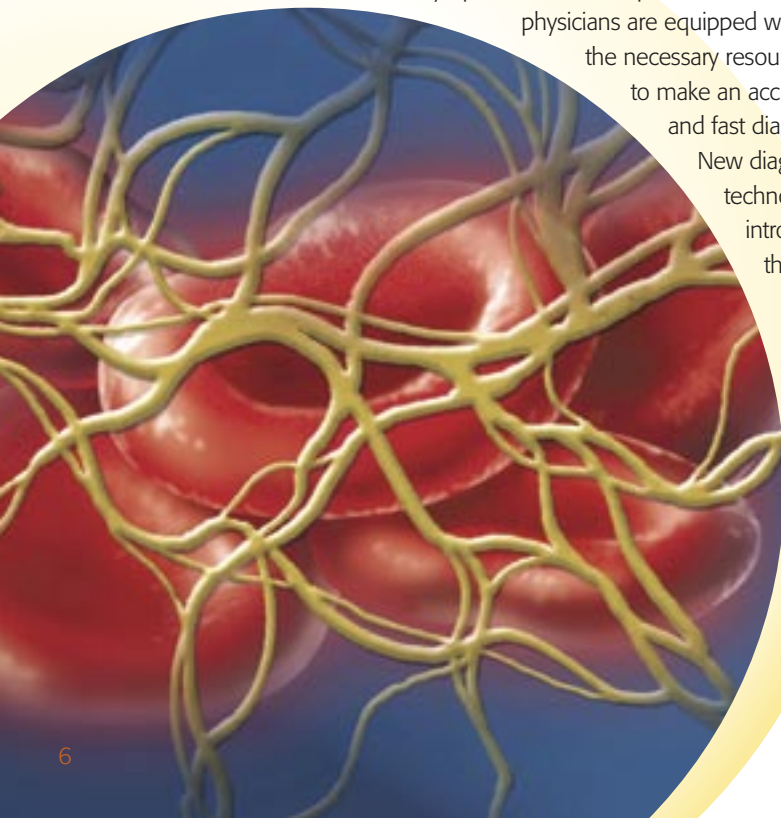
The only D-Dimer test found to be helpful as a negative predictor is the second-generation ELISA assay. In our ED, we request use of the VIDAS® D-Dimer Exclusion™, a rapid, automated ELISA test. It is highly sensitive, packaged for individual testing, has less than a one-hour turnaround and provides accurate, objective and quantitative results. It is the only methodology that has a specific indication from the FDA to rule out both DVT and PE when used in conjunction with a clinical pretest probability (PTP) assessment. The VIDAS D-Dimer Exclusion, is also the most validated D-dimer assay for the exclusion of patients with a low to moderate risk of DVT and PE. The combination of an FDA cleared use for exclusion of VTE and volumes of clinical literature support are paramount to assuring physicians that they can confidently and safely exclude patients from the diagnosis of VTE.

An ELISA D-dimer value less than 500ng/mL is considered negative. The VIDAS D-Dimer Exclusion's negative predictive value is documented to be 99+%. Evidence-based critical care and emergency medicine algorithms support this methodology as an end-point in certain patients. The American College of Emergency Physicians' recently published "Critical Issues in the Evaluation and Management of Adult Patients Presenting with Suspected Pulmonary Embolism" recommends that a negative quantitative ELISA D-Dimer assay as a single test is sufficient to exclude PE in patients with a low PTP of PE. The policy also states that a nondiagnostic VQ Scan and a negative quantitative ELISA will likewise exclude a clinically significant PE in a patient with low to moderate PTP of PE.

Automated ELISA D-Dimer exclusion testing is quickly becoming a widely accepted method for ruling out VTE in the ED. A negative D-Dimer test result can prevent patients from undergoing invasive and painful testing procedures and reduce the need for costly confirmatory tests in a significant number of patients. When physicians and laboratories work together to offer the appropriate laboratory test for challenging, and sometimes lethal, disease states such as a VTE, positive outcomes are shared by the laboratory, physicians and, more importantly, patients who trust in our decisions.



**mini VIDAS® immunoanalyzer**



# QC changes for VITEK® 2 and VITEK® 2 Compact customers

Quality Control changes are being implemented with the VITEK® 2 and VITEK® 2 Compact GN Identification Card.

## The changes are as follows:

- 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.
- The expected results for *Klebsiella oxytoca* ATCC 700324 with CMT and SUCT have been changed to +/-.
- Expected results for *Acinetobacter baumannii* ATCC BAA-747 with AGLTp, IMLTa, ILATa and IHISa are being modified to +/-.
- A reminder from the February newsletter: The expected result for *Proteus vulgaris* ATCC 6380 with dMAL has also been changed to +/-.

If you are using the GN test kit 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 are not seen in currently installed versions of VITEK 2 and VITEK 2 Compact software. The changes will be reflected in the next software updates. For now, please store this information with your Quality Control Records for documentation.

## VITEK 2 NH Card, continued from page 1

*Actinobacillus, Campylobacter, Capnocytophaga, Cardiobacterium, Eikenella, Gardnerella, Kingella, Moraxella, Oligella and Sutonella.*

The excellent performance of this card is demonstrated in a 2005 ASM poster (C-196). You can read an abstract of this poster in the September 2006 issue of the *bioMérieux Connection*.

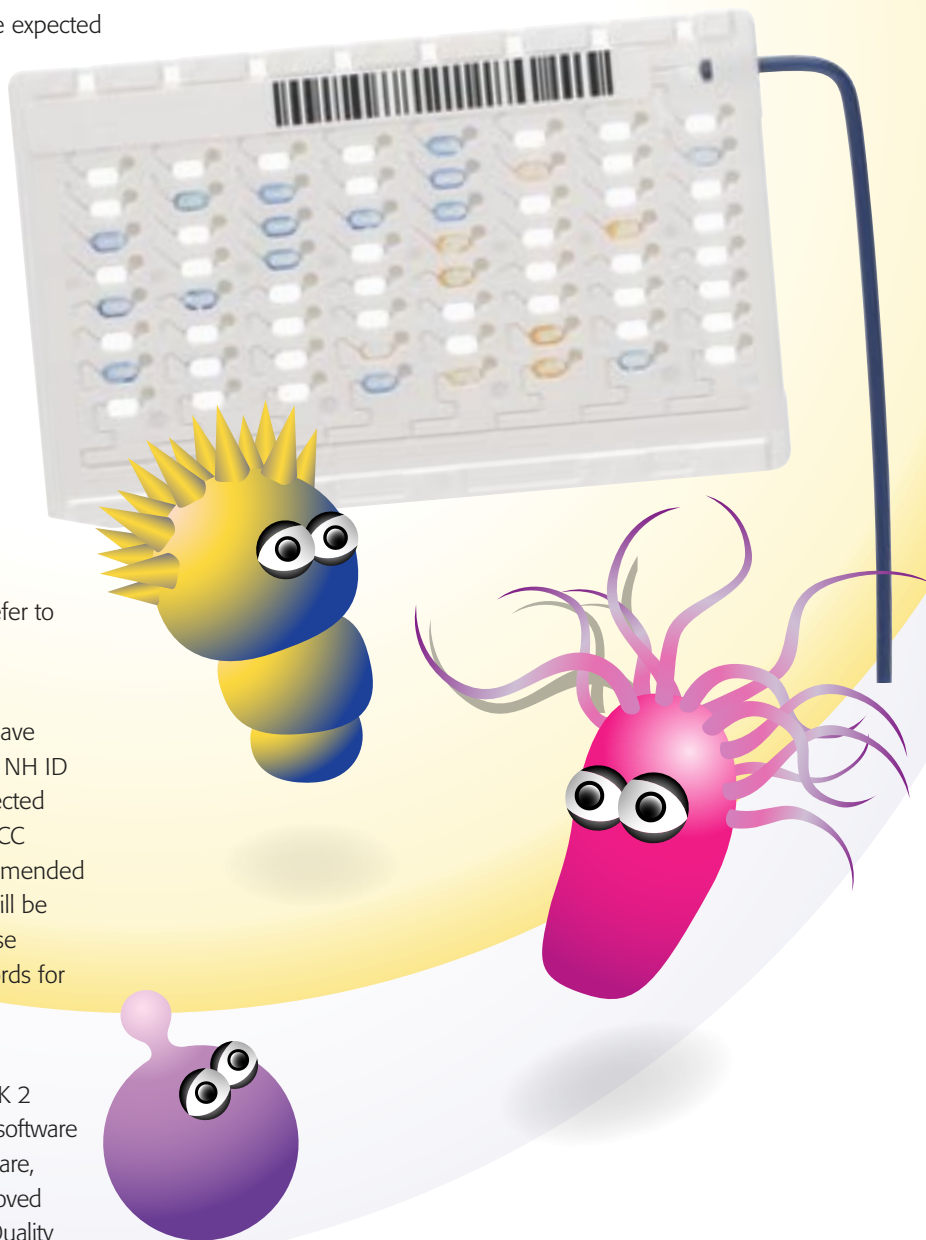
For more information on the VITEK 2 NH ID Card, refer to your February 2006 *bioMérieux Connection*.

## VITEK 2:

Laboratories with VITEK 2 instruments will need to have software version 4.02 installed to utilize the VITEK 2 NH ID Card. Note that the following QC change is not reflected in this version of software: *Gardnerella vaginalis* ATCC BAA-1154 has been removed from the list of recommended organisms to test for Quality Control. This change will be reflected in a future software update. For now, please store this information with your Quality Control Records for documentation of this change.

## VITEK 2 Compact:

The VITEK 2 NH ID Card will be available for the VITEK 2 Compact in the fall of 2006 when VITEK 2 Compact software version 2.01 is installed. Again, note that, in this software, *Gardnerella vaginalis* ATCC BAA-1154 has been removed from the list of recommended organisms to test for Quality Control and that this deletion is not reflected in your current 1.02 software, but will be included in a future software update. Please store this information with your Quality Control Records for documentation of this change.





# ASM 2006 General Meeting

innovation @ work

Connecting Solutions to Outcomes

**You're invited to attend bioMérieux's full line-up of symposiums, forums and fun at this year's ASM.**

**bioMérieux booth #429**

**American Society for Microbiology  
106<sup>th</sup> General Meeting  
Orange County Convention Center  
Orlando, Florida**

## Customer Appreciation Night

Monday, May 22 from 7-11 p.m.

Hard Rock Café

6050 Universal Blvd.

Universal Studios – CityWalk

Featuring Rockin' Dopsie, Jr. and the Zydeco Twisters

Round trip transportation will be provided to the Hard Rock Café starting at 6:30 p.m. with return service throughout the evening from the following hotels:

- The Peabody & Rosen Center
- Doubletree Castle Hotel
- Renaissance Orlando Resort at SeaWorld
- Sheraton World Resort
- Hilton Grand Vacations

*Don't get left out. Be sure to pick up your party invitation at the bioMérieux Booth #429 before Monday night.  
**It's your ticket to party.***



## Satellite Symposium

Saturday, May 20, 2006

Registration from 4-5 p.m.

Presentations from 5-7 p.m.

Peabody Hotel (Opposite Convention Center)

Orlando Ballroom, Rooms 2 and 3

Reception from 7-10 p.m. on the Peabody Poolside Deck

Featuring Keynote Speaker **John M. Barry** "Nature Against Man: The 1918 Influenza Pandemic and What it can Teach Us" and "Best Practices" by **Dr. Ellen Jo Baron**, Director, Stanford University Medical School, Director Clinical Microbiology/Virology Laboratory. Visit [www.biomerieux-usa.com/asm2006](http://www.biomerieux-usa.com/asm2006) for complete details.

*bioMérieux is giving away a free copy of "The Great Influenza" to the first 300 registered attendees to arrive at the Satellite Symposium.*

## Knowledge Forums

These forums will take place during the convention inside booth #429 throughout the day. Each year, bioMérieux Knowledge Forums present expert speakers on topics that have an immediate impact on the microbiology laboratory.

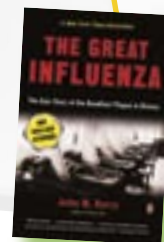
### Key topics include:

Business Process Management for Microbiologists  
CLSI Updates  
Fungal Update  
KPC Resistant Mechanisms  
New Markers for Sepsis  
Nucleic Acid Extraction  
RSV and hMPV Blood Culture Updates and more

### Delivered by industry notables such as:

Dr. Paul Bourbeau	Dr. Christine Ginocchio
Dr. Janet Hindler	Dr. Vincent LaBombardi
Dr. Davise Larone	Dr. Ken Thomson
and others	

Please check our ASM 2006 web site for Knowledge Forum scheduling updates. You can also register for the symposium, reception and forums at [www.biomerieux-usa.com/asm2006](http://www.biomerieux-usa.com/asm2006).



# bioMérieux *Connection*

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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.