Message from bioMérieux

Welcome to the April 2008 issue of the bioMérieux Connection newsletter. In this issue, we are highlighting the upcoming 108th American Society for Microbiology (ASM) annual meeting in June.

In past issues of the Connection Newsletter, we discussed the skilled-labor issue in U.S.-based labs. While this issue is still valid, we are also seeing some level of lab consolidation to improve efficiency and cost effectiveness. Consolidation and the demand for improved efficiency will drive automation. Microbiology labs historically have not had the same level of automation as Chemistry or other labs, which is why our current focus zeroes in on bringing full automation to the microbiology lab.

bioMérieux’s theme for ASM 2008 is Full Microbiology Lab Automation: Delivering the Future. The more automated microbiology laboratories can become, the better. Today’s microbiologist is expected to do more work, faster, to increase profitability. We are committed to delivering automated solutions at the pre-analytical, analytical and informatics stages to streamline processes while delivering accurate results. As you will see in this issue, we will be launching many new solutions at ASM that support this effort. A fully automated microbiology lab will better serve the patient, as well as be cost effective for your institution.

Join us at ASM 2008 to learn more about taking your microbiology lab to full automation. We look forward to seeing you at our annual customer appreciation event – held this year at Fenway Park, the home of the Boston Red Sox. We also plan to refocus our 30th Annual Microbiology User Group event. Hosted by key industry leaders, this year’s event will focus on ID/AST, blood culture and new, pre-analytical solutions. ASM is an important show for our community, and we look forward to seeing you there.

Sincerely,

Herb Steward

Executive Vice President
and General Manager,
bioMérieux North America
The American Society for Microbiology (ASM) is holding the 108th General Meeting in Boston, MA, from June 1-5, 2008. bioMérieux is excited to offer a variety of educational events that will teach you how to provide better patient care while improving the clinical value of your lab. In addition to our traditional ASM events, we have partnered with clinical laboratories throughout the U.S. to deliver poster presentations of our research on highly drug-resistant organisms.

Experience The Fully Automated Lab
We are excited to share with you the ultimate integrated experience at the ASM 108th General Meeting. We will show you the benefits of our integrated solutions by bringing the microbiology lab to you. Visit us at booth #731 and experience the Automated Microbiology Lab, where you will learn how to enhance, automate and make the most of your lab.

In-Booth Knowledge Forums
Please visit bioMérieux booth #731 June 2nd and June 3rd between 11:15am and 1:45pm to listen to your peers discuss the following topics:

- Hudson Garrett, PDI – Chlorhexadine and Safe Blood Culture Collection
- Christine Ginochio, Ph.D, North Shore LIJ Health System, – Molecular Automation
- John Glassen, Bioscience Consultant, LabTech – Automated Streaking
- Janet Hindler, MCLS, MT(ASCP), F(AMM), UCLA Medical Center – CLSI Updates: Antibiograms
- Davise Larone, Ph.D, D(ABMM), F(AMM), Cornell University – Galactomann & Beta-Glucan (Non-Culture Based Diagnostic Tests for Fungi)
- Margie Morgan, Ph.D, Chief Microbiologist, Cedar-Sinai Medical Center – Managing Blood Stream Infections

More details to come! Be sure to visit www.biomerieux-usa.com/asm2008 often for updates.
bioMérieux User Group (BUG CLUB)

To register for this bioMérieux customer only event, visit www.biomerieux-usa.com/asm2008 and use access code BUGASM

WHEN: Tuesday, June 2nd

WHERE: Westin Waterfront, Grand Ballroom

WHAT: bioMérieux is going back to the basics at our 30th Annual Microbiology User Group. An evening hosted by key industry notables will provide you the opportunity to learn about antibiotic overuse, rapid results and the trends in lab automation.

5:00-6:00 p.m. – Registration, Cocktail and Dinner
6:00-6:05 p.m. – Welcome, Herb Steward, Executive Vice President and General Manager, bioMérieux North America
6:05-6:30 p.m. – Microbiology Update, Doug Flammang, VITEK®/VITEK 2® Project Leader, bioMérieux
6:30-8:00 p.m. – Industry Panel

Blane Schilling, Aspen Consulting – Moderator
George Drusano, Ordway Research – The Lab’s Role in Getting Relevant Results Interpretable Data to the Clinical
Susan Foster, APUA – Economic Impact of the Overuse of Antibiotics, The Trends in Lab Automation

Additional Posters at ASM

bioMérieux and Washington University School of Medicine (St. Louis, MO) will also be presenting two posters at ASM. Look for “Daptomycin and Telavancin MIC Tests for Gram-Positive Organisms with the VITEK 2 Systems” and “Ceftobiprole, Clindamycin, Doripenem, Faropenem, and Televancin MIC Tests for Streptococcus pneumoniae with the VITEK 2 Systems.”

Prepare Your Lab for Battle

Reducing the emergence and spread of drug-resistant organisms continues to pose a major challenge to clinical laboratories today. To help combat these emerging disease threats, bioMérieux established the BORIS (bioMérieux Organism Resistance Initiative Surveillance) network to collect and study drug-resistant organisms from participating U.S. clinical laboratories. In collaboration with our network laboratories, we will present two posters of original research from BORIS at this year’s ASM General Meeting in Boston.

Both presentations will 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 (MBL). The posters will include our research of the multi-drug resistant organisms Acinetobacter baumannii (AB) and Pseudomonas aeruginosa (PA).

For more information about these presentations, visit www.biomerieux-usa.com/connection.

bioMérieux Appreciates YOU!

Each year bioMérieux kicks off ASM with a special Customer Appreciation Party. Join us this year for an exciting evening at Fenway Park, Monday, June 2 at 7:30 p.m. Start the night off with an ice-cold beverage in an authentic Boston Red Sox stadium cup! Next, you may want to go check out the Green Monster or visit one of the many buffet stations placed around the Executive Suite.

Now that your arms have had a workout, then you can take a tour of the stadium and locker rooms or go and snack on some delicious desserts!

When you want to move back to the Suite you can dance the night away with one of Boston’s favorite bands!

If that isn’t enough…you will leave with an authentic bioMérieux/Boston Red Sox ticket stub to remember the evening…

Please visit www.biomerieux-usa.com/asm2008 to register to attend this bioMérieux customer only event.
bioMérieux Launches PREVI™ Color Gram Automated Gram Stainer

bioMérieux and Wescor signed an agreement making bioMérieux the exclusive distributor of PREVI Color Gram for Wescor. With this OEM (original equipment manufacturer) agreement, bioMérieux brings automation to a new level in the pre-analytic process with the unique slide staining technology, PREVI™ Color Gram.

The PREVI Color Gram will provide the following benefits:
• Produce slides that are dry and ready to read
• Reduce reagent usage
• Create a cleaner environment

The PREVI Color Gram complements a complete range of fully automated solutions for the microbiology bench, with recent innovations such as the PREVI™ Isola for PPM streaking and Sysmex UF-1000i for urinary screening.

About Centrifugation, Gram and Mycobacteria Staining
Properly Gram-stained preparations can quickly give you considerable information that can be applied immediately to patient care. The Gram stain is particularly useful in the presumptive diagnosis of bacterial meningitis, bacterial pneumonia, bacteriuria, gonorrhea, and infections of the brain, lung, abdomen, and wounds.

The Cytopro Cytocentrifuge rotor uses centrifugal force and three unique patented chamber designs to sediment cells onto the slide. With the standard volume (single or dual) chambers, suspension fluid is simultaneously absorbed into the Cytopad® absorption pad as cells contact the microscope slide. The recently introduced high volume Cytopro Magnum™ chamber is easy to use and also retains the excess fluid from a suspended sample.

Gram staining is a critical and mandatory test performed in the microbiology laboratory. It is a preliminary step used to differentiate Gram-positive and Gram-negative bacteria. A cumbersome and long procedure, traditional Gram staining requires technical expertise, numerous manual steps and therefore lacks reliability and reproducibility. Wescor’s automated spray technology saves time and enables standardization and accuracy of results. The addition of the Cytopro* rotor to the slide stained results in a cytocentrifugation with eight-slide capacity. The innovative technique also improves laboratory workflow and generates significant savings for laboratories of all sizes.

bioMérieux Launches PREVI™ Isola Automated Pre-Pour Media (PPM) Streaker

LabTech Systems, an Australian health care equipment and services company, and bioMérieux signed an exclusive worldwide license agreement for LabTech Systems’ automated pre-poured media (PPM) streaker, PREVI™ Isola.

The fully automated pre-poured media (PPM) streaker is an innovative, patented robotic system for the automation of routine agar plate processing undertaken in microbiology laboratories. This pre-analytical phase still remains manual and time-consuming in most laboratories worldwide. In the current trend of laboratory concentration, there is strong demand for automation that can standardize processes and provide traceability, timesaving and optimized workflow, as well as improved safety.

The PREVI Isola will offer:
• Greater number of isolated colonies
• Customer configured set-up and sort
• Easy management of bi-plates
• Accommodation of up to five different types of media at one time

LabTech Systems’ patented robotic instrument, which provides a solution at this early stage of the microbiology process, has major synergies with bioMérieux’s pre-poured media range. It also enhances bioMérieux’s current portfolio of automated solutions including BacT/ALERT® for blood culture, VITEK® 2 for identification and antibiotic susceptibility testing and DiversiLab® for microbial typing.
bioMérieux to Distribute Sysmex’s UF-1000i Fully Automated Urinalysis System

Sysmex Corporation and bioMérieux signed an agreement making bioMérieux Sysmex’s global partner for distributing its UF-1000i urinalysis system in microbiology laboratories.

Current urinary screening methods, mainly based on microscope cell numeration, are still very manual, time-consuming and a source of errors. Sysmex developed the fluorescence flow cytometry UF-1000i urinalysis system, a highly standardized and automated solution.

**Smart Technology**

UF-1000i is a fully automated, urinary screening system that bases its objective analysis on both physical and chemical particle properties. It uses:

- Advanced flow cytometry technology with hydrodynamic focusing
- Specific fluorescent dyes for bacteria and sediment
- Three high-definition, reproducible measurement signals: size, structure and fluorescence

**High-Quality, Standardized Results**

- Accurate detection and enumeration of urine particles (two separate analysis channels for bacteria and sediment)
- Reduced cross-contamination with anti-carryover function and sequential analysis mode
- New second channel for improved bacteria detection
- Barcode reader identification of samples and reagents
- Daily Quality Control performed for all the main parameters (high and low positive controls)

**Easy to Interpret**

- Easy-to-read, color-coded scattergrams and clear-cut numeric values for a concise overview
- User-definable flagging of all the parameters for rapid result assessment
- Rule-based flagging of UTI information to facilitate reporting positive results

**Time-Saving**

- Simply Load & Go
- Minimum hands-on time – Maximum workflow efficiency
- Results in approximately one minute
- Continuous loading function for immediate processing of samples or series testing with up to 50 positions
- Bi-directional connection to LIS

The UF-1000i urinalysis system complements a complete range of fully automated solutions for the microbiology bench, with recent innovations such as the PREVI™ Color Gram and the PREVI™ Isola for PPM streaking.
Are you over-worked, short on time and have a limited travel budget? 

We understand your challenges.

We know that you need more than 24 hours in a day, and although we can’t move time, we can bring our mobile lab to you!

What: The bioMérieux Odyssey is embarking on a quest across the U.S. with more than 40 stops in cities and towns near you. Odyssey’s mission is to provide industry professionals with innovative training and education on advanced diagnostics solutions that improve public health.

Who: Microbiology Lab Professionals, Infection Control Professionals, Phlebotomists, Clinicians, and Healthcare Administration

Why: Hands-on training and education is essential for today’s busy lab professional. The bioMérieux Odyssey offers you and your colleagues dynamic options and empowers you to make valued decisions. Visit the Odyssey to learn more about:

- Emerging pathogens and source tracking through strain typing
- Latest developments in blood culture and ID/AST, and ways to rapidly deliver relevant data to clinicians
- Hands on instrument training and educational PACE credits
- The next generation consolidated microbiology lab with advanced automation
- Quality assurance solutions
- New reagent tests and a biomarker for sepsis
- Your role with antibiotic stewardship
- What local experts and key opinion leaders are discovering in your area

Come aboard the Odyssey to gain industry insights in a relaxed environment with refreshments and our friendly staff in your city.

When: bioMérieux’s Odyssey 2008 Kickoff Schedule
Durham, NC • May 27
Columbia, SC • May 29-30
Orlando, FL • June 2-3
Ft. Lauderdale, FL • June 5
Hollywood, FL • June 6
Miami, FL • June 9-10
Tampa, FL • June 12-13
Augusta, GA • June 16
Atlanta, GA • June 17
Greenville, NC • June 19
Chapel Hill, NC • June 20
Durham, NC • June 23
Birmingham, AL • July 2
Jackson, MS • July 3
The Woodlands, TX • July 7-8
San Antonio, TX • July 10
Austin, TX • July 11
Irving, TX • July 14-15
Ft. Worth, TX • July 16
Oklahoma City, OK • July 18
Los Angeles, CA • July 23-25
San Jose, CA • July 28

Visit www.biomerieux-usa.com/odyssey to see the latest updates to the Odyssey schedule.
PNA FISH™ receives Frost & Sullivan’s Rapid In Vitro Diagnostic Technology Innovation of the Year Award

PNA FISH™ received Frost & Sullivan’s 2008 Technology Innovation of the Year Award in the field of rapid in vitro molecular diagnostic technology. The award recognizes how hospitals depend on AdvanDx’s easy-to-use, molecular-based PNA FISH diagnostics to quickly identify bloodstream pathogens in hours instead of days. The rapid PNA FISH results enable laboratories to report critical information to physicians and pharmacists earlier to help optimize therapy and reduce mortality rates for patients afflicted with bloodstream infections.1

Research Methodology and Selection Process Criteria
To choose The Technology Innovation of the Year Award recipient, Frost & Sullivan’s analyst team conducted a selection process that included primary interviews and extensive primary and secondary research via a bottom-up approach. The analyst team considered AdvanDx’s pace of research and technology innovation and its significance and relevance to the overall industry. The ultimate Award recipient was selected after a thorough evaluation of this research.

The recipient of the Award has excelled based on the following criteria:
• Significance of technology in the industry
• Potential of technology/products to become an industry standard
• Competitive advantage of technology when compared to competing technologies
• Ease of adoption of technology
• Breadth of intellectual property related to the innovation (e.g., patents, coverage in scientific publications, papers and in peer reviewed articles).

For more information, visit www.frost.com. ■


New! bioMérieux Technical Library
To access the technical library, please visit www.biomerieux-usa.com and follow these three simple steps to register.

• Read and accept the Conditions of Use

• Enter your Customer Number (If you don’t know your customer number, you may enter your system/site number or your account’s 10-digit telephone number), Institution/Facility Name, City, and State.

• Set up your Login: Create your password (must contain at least six characters, two of which must be numerical digits), Confirm your password, enter your last name, enter your first name, enter your e-mail address, and select your browsing language.

You will receive an e-mail confirmation of your registration within 30 minutes of submitting your application.

Please allow up to one business day for your account to be activated. You will receive an e-mail confirming your account activation. ■
Last year, bioMérieux launched WorkSafe™, an education campaign to provide labs and infection control personnel with resources and educational materials to support best practices in blood culture collection. WorkSafe is designed to easily integrate into any facility to improve specimen collection, transport, storage, and disposal.

Automation in the field of blood culture is proven to play a significant role in early detection of positive blood cultures through continuous test monitoring. However, blood culture contamination is a continuous problem. bioMérieux spent the past year taking WorkSafe directly to customers for product training and safety education on BacT/ALERT® 3D, our automated microbial detection system.

bioMérieux’s WorkSafe initiative is designed to provide the tools needed for proper blood culture collection to increase safety and combat rising infection rates, antibiotic resistance and sepsis in hospitals. The campaign includes four phases: collection, testing, culture and care. bioMérieux launched the initiative by providing laboratory professionals with WorkSafe resource kits that included a blood culture collection training video, competency checklist and certification that highlights all four phases of the program.

WorkSafe will teach lab technicians and nursing personnel best practices in all stages of blood culture, from collection to care. The campaign supports the use of plastic blood culture bottles, instead of glass, to decrease the risk of breakage, which can lead to blood and body fluid exposures, and contact with dangerous materials. There are many safety benefits to using plastic instead of glass. For example, the lightweight bottles can be sent through pneumatic tube systems without special holders, without fear of breakage.

Many labs already work with plastic to meet Occupational Safety and Health Administration (OSHA) standards and to comply with its Bloodborne Pathogens Standard. Glass puncture wounds are among the most
common injuries in the medical field, and glass that is contaminated with blood or other potentially infectious materials poses an extreme danger. In most cases, plastic can be easily substituted for glass, therefore, “OSHA makes it clear: using glass in the laboratory when an equivalent plastic alternative is available must be justified in writing.”

In addition to being break-resistant, plastic weighs one-half to one-third less than glass, offering additional advantages to the lab. Lightweight plastic bottles are easier to carry and put less weight on the phlebotomy tray. Additionally, disposal of biohazardous waste is charged by the pound, making lightweight plastic more cost-effective than glass.

**Blood Culture Collection Kit**
The WorkSafe collection phase, which launched May 2007, features the bioMérieux Blood Culture Collection Kit, which equips hospital workers with one simple kit to follow best practices for blood culture-collection. Each latex-free kit includes BacT/ALERT® Bottles, Smiths Medical Saf-T Holder®, Blood Culture Device, 2” x 2” gauze, alcohol prep pads, bandage, biohazard bag, PDI® Chlorascrub™, 3.15% Chlorhexidine Gluconate Swabstick, folded instruction sheet and tourniquet.

The Blood Culture Collection Kit is a WorkSafe best practice for blood collection. The kit is designed to provide a safer and easier process for blood culture collection that can help minimize collection contamination, minimizing the risk of false positives.

Marshalltown Medical Lab in Iowa implemented the WorkSafe initiative and started using the Blood Culture Collection Kit last fall. Already, the kit is proving to be effective and efficient.

The kit eliminates the need for nurses or phlebotomists to manually pull loose pieces together for blood culture collection.

“I have used the WorkSafe initiative to train nursing staff and phlebotomy/lab staff. I used the Blood Culture Collection video to train our nursing staff, and the sample bottles to train our lab staff. Our contamination rate has dropped from above three percent to roughly one percent,” said Sharon Finch, chief technologist at Marshalltown Medical Lab.

Prior to the Blood Culture Collection Kit, the lab in Marshalltown used SPS tubes to transfer blood samples to the BacT/ALERT 3D, creating the opportunity for contamination. The kit eliminates the need for tubes and saves time for the technician. The reduction in contamination is important to the hospital because of rising costs associated with longer hospital stays.

**Industry Recognition**
bioMérieux is the proud recipient of a 2008 Clinical Creative Communication Award from the Diagnostic Marketing Association for the Blood Culture Collection Kit. The kit was recognized for the education and training it provides and won in the category of Professional Relations.

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WorkSafe™ Survey Results

Customers logged on to www.biomerieux-usa.com/worksafe and took a survey to determine what issues they were experiencing with blood culture contamination. Shown below are key findings from the 121 BacT/ALERT® customers who responded to the survey.

Seventy-two percent were from an urban setting, with 71 percent from not-for-profit facilities, and 66 percent were from hospitals of 250 beds or less. Less than half were CAP-accredited, and only 45 percent had participated in the Institute for Healthcare Improvements (IHI)’s $5 Million Lives Campaign.

Phlebotomists drew 79 percent of the blood cultures, and nurses only drew 15 percent. Less than half of the respondents have a pediatric facility.

It was rewarding to learn that 90 percent of the respondents collected blood from two different sites and used a two-bottle set for each draw.

Coagulase-negative Staphylococcus was the main contaminant.

When surveyed, the majority of the respondents wanted video/DVD training, understandable literature and online training.

The bioMérieux WorkSafe initiative is on target to help facilities reduce blood culture contamination. A second survey will be distributed to these survey respondents to determine contamination rates before and after WorkSafe implementation.


FDA Clears bioMérieux’s VIDAS® NT-proBNP Assay

bioMérieux received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market VIDAS® NT-proBNP, a test that aids in the diagnosis of suspected congestive heart failure.

Heart failure is a major healthcare issue, whose frequency is expected to continue to rise in the coming years due to the worldwide aging population and increased survival rate from acute coronary events. It is the leading cause of hospitalization in people over 65 years of age, affecting up to 17 million people worldwide.

In the U.S., five million people suffer from heart failure, and 550,000 new cases are diagnosed each year1.

VIDAS NT-proBNP (N-terminal fragment of B-type natriuretic peptide) is a quantitative marker of heart stress with the potential to detect all stages of heart failure, even the early stages, which can be difficult to detect. The test provides objective diagnostic information that helps clinicians distinguish heart failure from other disease states with similar clinical symptoms, such as lung diseases or pulmonary embolism. VIDAS NT-proBNP is a proven marker for heart failure and will provide clinicians with a powerful tool for the management of life-threatening cardiac pathologies.

NT-proBNP can also be used to assess the prognosis of patients with established heart failure or acute coronary syndrome. Its measurement is cost-effective and leads to important healthcare cost-savings as shown by analysis from a study at Harvard Medical School’s Brigham and Women’s Hospital in Boston2 and a pivotal randomized multi-center study in Canada3. The latter study reported a reduction in direct medical costs of 15 percent (USD $949 per patient) when NT-proBNP testing was part of routine assessment of emergency department patients with dyspnea (shortness of breath).  

bioMérieux Receives FDA Clearance for VIDAS® C. difficile Toxin A&B Assay

bioMérieux is broadening its infectious disease testing panel following clearance from the U.S. Food & Drug Administration (FDA) for C. difficile Toxin A&B (CDAB), used with the automated VIDAS® system.

The VIDAS C. difficile Toxin A&B assay offers rapid detection of the C. difficile bacterium, which is the most common cause of antibiotic-associated diarrhea in hospitals.

In recent years, the incidence of C. difficile has increased and evolving strains can result in pseudomembranous colitis, sepsis and even death.

The VIDAS C. difficile Toxin A&B test provides results in 75 minutes, enabling physicians to administer proper treatment and prevent unnecessary patient isolation and outbreaks.

bioMérieux’s VIDAS C. difficile Toxin A&B Assay is the only automated test on the market today, making bioMérieux the first company to offer a complete solution for managing C. difficile infections, including identification with the API® 20A strip, antibiogram with the ATB™ Anaerobic strip, and bacterial genotyping with the DiversiLab® system.

bioMérieux receives FDA clearance for VIDAS® Troponin I Ultra Assay

bioMérieux received FDA clearance for Troponin I Ultra Assay, a new emergency panel assay for the VIDAS system. Due to its high sensitivity, VIDAS Troponin I Ultra can aid in the diagnosis of myocardial infarction accurately, even at a very early stage.

The VIDAS Troponin I Ultra enables physicians to diagnose and therefore initiate treatment without delay in patients presenting to emergency departments with symptoms of acute coronary syndrome. Furthermore, the VIDAS Troponin I Ultra is one of the first to comply with the National Institute of Standards and Technology (NIST)’s new Standard Reference Materials (SRM) 2921 (human cardiac troponin complex), which will facilitate the interpretation of results for biologists and medical practitioners.

The VIDAS Troponin I Ultra assay offers the following benefits:
- Easy to use: just load and go
- Cost effective single test format
- Tests run individually or batched
- Gold standard ELISA methodology
- Highly reliable: Mean Time Between Failure (MTBF) > two years

NEW VIDAS® ASSAYS
bioMérieux Adds ANC Identification Test Card for the VITEK® 2

bioMérieux recently announced a new addition to the VITEK® 2 test card portfolio. The ANC card will provide an accurate, rapid and automated method for the identification of anaerobes and corynebacteria. There is no other simple automated method available to speciate these organisms that are often time-consuming and difficult to identify.

The VITEK® 2 ANC card can identify 63 species of anaerobes and corynebacteria. The test card is instrument-read and results are available within six hours. Laboratories will need to operate the new test card using AIX 5.01 or PC 3.01 software. The ANC card will be available for VITEK® 2 and VITEK® 2 Compact users in April 2008.

In the current healthcare environment, it is increasingly important for the rapid and accurate diagnosis of infectious diseases. The VITEK 2 is an automated system designed to provide rapid and accurate identification and susceptibility results for most clinically encountered strains. Anaerobic bacteria represent a significant organism group for both the medical and industrial lab and are often difficult to cultivate and identify accurately.

bioMérieux developed this card to enhance the investment customers have in VITEK 2 technology and improve the identification process for a group of organisms that are typically difficult to identify. The result will be improved productivity in the lab and enhanced utilization of the VITEK 2 system.