### bioMérieux CONNECTION JUNE 2008 · VOL 5 NO 3



# Message from bioMérieux

Welcome to the June 2008 issue of *bioMérieux Connection*. We are pleased to announce bioMérieux has acquired AB BIODISK, based in Solna, Sweden, on June 18, 2008.

AB BIODISK's leading product line, Etest<sup>®</sup>, is used to determine the Minimum Inhibitory Concentration (MIC) of antibiotics, antifungal agents and antimycobacterial agents. Etest is very complementary to bioMérieux's VITEK<sup>®</sup> range for antibiotic susceptibility testing.

Today, VITEK<sup>®</sup> 2 Technology can cover the majority of antimicrobial susceptibility testing needs in routine laboratories; Etest is an invaluable tool for handling non-routine exceptions. Etest is commonly used for testing fastidious, slow-growing organisms and for the detection of certain resistance mechanisms. Etest can be used as a complimentary test method when additional information is needed for particular bacteria or antibiotics.

bioMérieux is very enthusiastic about adding Etest to bioMérieux's extensive line of microbiology solutions, including the soon to be launched automated solutions for plate streaking (PREVI<sup>™</sup> Isola), urine analysis (UF-1000i) and Gram staining (PREVI<sup>™</sup> Color Gram).

bioMérieux expects Etest to complement the VITEK Technology range, and to expand its offering of quality information and high medical-value results for your institution's needs.

BIOMÉRIEUX



from diagnosis, the seeds of better health

### Introducing 360°/365™

As many of you know already, we have a great team of people behind our products. They work 24/7 to make sure your team is fully trained, equipment is operational and supplies are delivered on time. You may, however, not be aware of all the services offered by this support group, so we are pleased to introduce 360°/365: New Dimensions in Support. From technical and engineering support to order processing, educational training and research, the service professionals at the heart of 360°/365 are available 24/7 to make certain your laboratory services team delivers accurate and timely results in support of clinical decision making.

Our support team loves to hear new best practice tips from customers, as evidenced by the WorkSmart tips inside this issue. Please make sure to share your best practices with your service representative; he or she will be happy to add your tips to a future issue.

Additionally, we often hear from our customers that our support professionals have gone the extra mile to deliver outstanding service. How has your laboratory benefited from our support staff? We'd love to hear your stories! In this and future issues, we will share some of your experiences.

We at bioMérieux are focused on your success. We thank you for your confidence in our products and services, and look forward to our continued partnership with you to improve patient outcomes now and in the future.

Fronk U. Crout

Frank V. Crout, Ph.D. Executive Director, Customer Support Operations

# BIDMÉRIEUX $360^{\prime}/365^{\circ}$ NEW DIMENSIONS IN SUPPORT

bioMérieux 360°/365 is a comprehensive suite of customer services that offer personalized support for bioMérieux solutions. 360°/365 encompasses a wide and customizable array of tools, talent and technology focused on meeting customers' specific service and support needs. bioMérieux's 360°/365 team is committed to delivering top-rated support that both respond to and anticipate customer needs.

# **360°/365 Includes the Following Support Components:**

### **Order Fulfillment**

- Personal phone support available with our call center staff
- Customer focused service
   environment
- Coming Soon: 24/7 Web ordering for reagents and disposables, including real-time order tracking and access to online order history

### **Application Support**

- 24/7 call center
- Quality verification
- Workflow analysis
- Test results guidance

#### **Engineering Support**

- 24/7 call center
- Multi-level support, call center and field representation
- Instrument repair, emergency and preventative maintenance
- Installation and upgrades
- Laboratory Information System (LIS) support

### **Coming Soon – Online Ordering!**

Timely ordering of supplies is a vital component of your

laboratory operations. As part of bioMérieux's 360°/365: New Dimensions in Support, we are pleased to introduce web ordering. To better serve you, our valued customer, bioMérieux is diligently working to provide you the ability to order via the worldwide web any time, anywhere,

at your convenience. We're putting you in the driver's seat.

This order fulfillment option is coming soon – look for details in our next newsletter!

### **Service Contracts**

 Cost-effective solutions that deliver preventive maintenance and corrective actions

#### **Education and Training**

- PACE accreditation
- Training videos
- · Key operator hands-on training
- Training on-site
- Key opinion leader webinars
- Web training

### **Consultation and Research**

- Bacterial and yeast culture submittal service
- Collaborative clinical microbiology research initiatives (BORIS)







# NucliSENS<sup>®</sup> easyMAG<sup>™</sup>

Validated with Both FDA-Cleared



June 2008 🖏 Printed on recycled paper.

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bioMérieux Connection



Respiratory Viral Assays

System Supports Automated Nucleic Acid Extraction For Use with Prodesse ProFlu+<sup>™</sup> and Luminex xTAG<sup>™</sup> RVP Assays

Since its market introduction approximately three years ago, bioMérieux's NucliSENS easyMAG has been broadly adopted as an automated nucleic acid extraction platform in front of a variety of home-brew molecular tests. Laboratories developing their own nucleic acid-based assays have appreciated the system's ability to extract high-quality nucleic acid (particularly that stemming from infectious disease targets) across a variety of sample types while delivering an exceptional level of productivity.

Now, the NucliSENS easyMAG is claimed for use as a validated nucleic acid extraction method in front of both recently FDA-cleared respiratory virus assays. Earlier this year, both Prodesse and Luminex received clearance of 510(k) applications for the ProFlu+ and xTAG RVP assays respectively. Key clinical trial sites used to generate performance data for both assays used easyMAG for extracting viral nucleic acids from nasopharyngeal samples.

### Gold Standard Nucleic Acid Extraction Chemistry

The foundation of the NucliSENS easyMAG is bioMérieux's own BOOM chemistry which is based upon the lysing and nuclease-inactivating properties of the chaotropic salt, guanidium thiocyanate, combined with the nucleic acid-binding qualities of silica. As a broadly accepted gold standard for nucleic acid isolation and purification, bioMérieux has licensed this proprietary technology to several different companies.

For development of the easyMAG system, bioMérieux set its sites on developing a premium paramagnetic particle variation of BOOM chemistry. The result was magnetic silica highly optimized for binding both RNA and DNA from a variety of clinical sample types. The system's reputation to perform high-quality extraction of viral nucleic acids from respiratory samples was quickly established and now has been confirmed given its use in the extensive studies connected with these FDA-cleared assays.

Continued on page 4. [+]



Barcoded & Monitored On-Board Reagents

Continued from page 3. [-]

### The First FDA-Cleared Molecular Tests for Respiratory Viruses

Until recently, laboratories wanting to offer nucleic acid-based testing for respiratory viruses were faced with development of their own assays which required rigorous clinical and analytical validation. Now, these new assays offer complete instructions for use and for a broad panel of respiratory viruses that includes Influenza A (including HI and H3 subtyping), RSV A, RSV B, Influenza B, Parainfluenza 1, 2, and 3, Human Metapneumovirus, Adenovirus and Rhinovirus. The company estimates that the entire test process takes approximately 6.5 hours.

These **new assays** offer complete instructions for use and **enable clinical laboratories to quickly adopt advanced molecular testing** involving much less validation and ongoing quality control measures than their home-brew counterparts.

> enable clinical laboratories to quickly adopt advanced molecular testing involving much less validation and ongoing quality control measures than their home-brew counterparts. They also provide more information than the typical laboratory developed test.

> Prodesse's ProFlu+<sup>™</sup> is a multiplex real-time RT-PCR assay designed to amplify and detect Influenza A, Influenza B and Respiratory Syncytial Virus A/B. It offers the advantages of a closed-tube amplification test and the company estimates the test time to result to be approximately three hours (including nucleic acid extraction).

Luminex's xTAG<sup>™</sup> RVP assay involves post-multiplex PCR detection using xMAP technology on the Luminex 100 instrument. It tests

### Flexibility and Superior Ease of Use in an Automated Nucleic Acid Extraction System

Even with the NucliSENS® easyMAG<sup>™</sup> supporting these new respiratory assays, the overall flexibility of the instrument will be maintained. This includes the ability to process different sample types/volumes and selection of variable elution volumes within the same run. A full run on the easyMAG is 24 samples and if less than that number of respiratory samples is processed, the instrument easily accommodates a further mixture of samples for nucleic acid extraction in front of other molecular applications, if needed. A run of 24 samples is completed in approximately one hour and the eluted nucleic acid is immediately ready for downstream use.

The overall design and operation of the easyMAG is unique among automated nucleic acid extraction devices. The distinctive processing method is based upon a stationary sample concept where the entire BOOM extraction procedure is performed in a single sample well. This includes sample lysis, binding of nucleic acid, all washing steps and the final elution of reactionready nucleic acid. In addition to reducing the potential for sample loss, this concept also resulted in a cascade of other key instrument features. This included a smart disposable design that requires the use of only one disposable tip per sample which greatly minimizes plastic waste along with reducing



# The Door Opens Wider for Molecular Infectious Disease Testing

the risk of cross contamination. The system utilizes a patented magnetic particle handling method that employs lateral magnet arrays that surround the sample wells for extremely efficient mixing of the magnetic silica used throughout the nucleic acid extraction procedure. On-board extraction reagents that are continuously monitored by the system round out the set of features that provides the user with a simple workflow requiring minimal hands on time.

### easyMAG<sup>™</sup> System Device Master File at the FDA

To support the 510(k) applications for the respiratory viral assays, bioMérieux provided documentation to the FDA in order to establish a device master file (DMF) at the regulatory agency. Thus, the complete system is on file and available for other companies to reference as an automated nucleic acid extraction method that can be included as part of other molecular diagnostic assays in the future.

Find out more about these exciting new molecular assays:

For Prodesse's ProFlu+: www.prodesse.com/USA/product/usIVD.html

For Luminex's xTAG RVP: www.luminexcorp.com/rvp Until recently, laboratories wanting to offer nucleic acid-based testing for respiratory viruses were faced with development of their own assays which required rigorous clinical and analytical validation. With the FDA's clearance of Prodesse's ProFlu+<sup>™</sup> and Luminex's

xTAG<sup>™</sup> RVP assays, testing once thought of as esoteric can now be adopted as routine testing by a wider range of clinical labs. In addition, a state-ofthe-art automated nucleic acid extraction solution is validated for use with both tests, further enhancing the accessibility of molecular testing for these important infectious disease agents.

bioMérieux presented a webinar on July 17 to review two recently FDA-cleared assays for nucleic acid extraction, amplification and detection of respiratory viruses. Belinda Yen-Lieberman, PhD and Christine C. Ginocchio, PhD discussed the following topics:

- Improved patient care and other benefits of molecular testing for respiratory viruses
- Efficient automation of viral nucleic acid extraction using NucliSENS<sup>®</sup> easyMAG<sup>™</sup>
- Implementation and performance of the Prodesse Pro-Flu+ assay
- Implementation and performance of the Luminex xTAG Respiratory Viral Panel

### **Presenter Information:**

### Belinda Yen-Lieberman, Ph.D.

Professor of Pathology, Lerner College of Medicine Director of Clinical Virology, Serology and Cellular Immunology The Cleveland Clinic

#### Christine C. Ginocchio, Ph.D.

Director Microbiology, Virology and Molecular Diagnostics North Shore-LIJ Health System Laboratories As technology continues to accelerate, people expect the same amount of speed in every facet of their lives. When it comes to health care, people expect and demand to get vital information and results fast. Much of this information comes out of the laboratory, where efficiency is a crucial component of meeting and exceeding patients' needs. When a laboratory runs a seamless and efficient operation, it positively affects hospital administration, physicians, pharmacists and most importantly – the patients. That is clearly the case in the microbiology laboratory at Kaleida Health, the largest health care provider in Western New York.

# Near-Perfect Workflow: How Kaleida Health's Microbiology Lab Gets Results to the Clinician Faster

Kaleida Health reads plates every two hours after 22-24 hours incubation to provide continuously updated ID/AST information to clinicians 24/7.

Kaleida Health serves the area's eight counties with state-of-the-art technology and comprehensive health care services provided by expert, compassionate health care professionals. More than one million sick or injured patients are seen annually at Buffalo General Hospital, DeGraff Memorial Hospital, Millard Fillmore Gates Circle Hospital, Millard Fillmore Suburban Hospital, Women and Children's Hospital of Buffalo and numerous community health care centers. The Department of Pathology and Laboratory Medicine provides all diagnostic services for Kaleida owned and affiliated institutions.

Embracing its primary focus, Kaleida always places its patients first. With a dynamic, semi-automated laboratory, Kaleida's staff is well trained, knowledgeable and dedicated. The staff includes Microbiology Technical Director

Dr. Pravin H. Patel and Microbiology Laboratory Supervisor Diane Dryja, who both say that the reason their lab runs as efficiently as it does is because they have a good system in place and a continuous workflow that can meet the high standards they have set for themselves.

Recognizing the ongoing needs of physicians, Kaleida provides results in real-time. The design of their workflow centers on the patient and, as a result, they provide physicians with greater information to make smarter, customized healthcare decisions and help prevent deaths, adverse events and additional costs. Their 24-hour, three-shift service keeps the microbiology laboratory open all day, every day and helps to deliver results more quickly. Additionally, a courier service runs every two hours to keep a continuous workflow in place. Kaleida's microbiology lab provides rapid results, which gives physicians early, and accurate information to optimize diagnosis and treatment, thus reducing costs associated with the use of inappropriate medication and unneeded additional testing. This also results in patients spending less time in the hospital or clinic waiting room.

"In our off-site lab, we see 600 to 800 specimens each day. Our 24-hour, three-shift service makes delivering results in real-time possible," said Dryja. "All physicians, especially infectious disease practitioners, want a lab flow that yields results. This allows physicians to make decisions concerning therapy and review pharmaceutical options quicker, hopefully before the patient's infection escalates or worsens."

Communication is instrumental for the Kaleida microbiology laboratory. An efficient operation means communicating internally to build and develop relationships with hospital staff, physicians, pharmacists and administration. At Kaleida, the microbiology lab

participates in bimonthly

Continued on page 8. [+]

"Physicians tell us they appreciate that we are always here, day and night. They know...there is always someone in the lab that can help answer questions, provide more information or are available to contact regarding an issue." Dr. Patel says that the key to their optimal microbiology operation is around-the-clock service and the use of automation whenever possible



The VITEK® 2 provides rapid and accurate organism identification and antibiotic susceptibility test results. It is a fully automated ID/AST that allows Kaleida to provide physicians with the earliest possible microbiology results. **Continued from page 7.** [-] meetings with pharmacy, infectious diseases and infection control. Departments meet to determine the need for new infectious disease testing, antimicrobial testing and formulary

recommendations for each Kaleida Health hospital. Semiannually and annually, antibiograms are reviewed at the meeting. Antibiotic usage and cost analysis is also discussed. Additionally, community-based relationships and information systems technology create seamless result delivery systems and is a determining factor in developing an efficient laboratory.

"Physicians tell us they appreciate that we are always here, day and night," said Dr. Patel. "They know we are only a phone call away and that there is always someone in the lab that can help answer questions, provide more information or are available to contact regarding an issue."

Kaleida laboratories offer reliable, fast and accurate results to aid in the proper selection of antibiotic therapy. Providing rapid antibiotic susceptibility test results allows physicians to quickly decide if an antibiotic is appropriate or if a change in therapy is required. This results in better patient care and improved antibiotic stewardship. If results indicate that a patient requires isolation, rapid reporting of results ensures that this will happen earlier and will protect other patients against a hospital-acquired infection. Timely results not only improve the quality of care given to patients, it also reduces the need for frequent physician office appointments, costly emergency room visits and unnecessary hospitalizations.

Kaleida has a detailed list of microbiology laboratory equipment, including bioMérieux's VITEK<sup>®</sup> 2. The VITEK 2 provides rapid and accurate organism identification and antibiotic susceptibility test results. It is a fully automated ID/AST that allows Kaleida to provide physicians with the earliest possible microbiology results.

When discussing tips to share with other labs, Dr. Patel says that the key to their optimal microbiology operation is around-the-clock service and the use of automation whenever possible. What is essential is designing a workflow that is completely focused on optimizing microbiology's impact on patient care.

"Our service and commitment to excellence is possible because of our dedicated, knowledgeable staff who love microbiology," said Dryja. "They know what to do, when to do it and they are happy while doing it.

This makes all the difference."

For additional information about Kaleida Health and its microbiology laboratory, please visit www.kaleidahealth.org.

"Our service and commitment to excellence is possible because of our dedicated, knowledgeable staff who love microbiology."

# **Questions on Microbiology Automation**

*Please complete the survey below and fax to 919.620.2615 or complete the survey online at www.biomerieux-usa.com/connections* 

Name:	Title:
Institution:	
Address:	
City:	State: Zip:
Phone:	Email:

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- 1. Who performs the microbiology specimen set up in your laboratory? (Please check all that apply) □ Certified CLS/MT/MLT trained in microbiology □ Lab Assistant □ 2nd Shift Generalist
- 2. What type of fixation method do you use for gram stains? □ Heat □ Ethanol □ Methanol
- 3. What benefits would be the most important when considering pre-analytical automation? □ Standardization □ Labor savings □ Improved specimen quality
- 4. Have you considered the purchase of pre-analytical automation within the past two years?
- 5. If yes, what type of equipment were you considering? Please check all that apply.
  □ Gram stainer □ Platestreaker □ Urine Screening □ Other \_\_\_\_\_
- 6. Did you make that purchase? □Yes □No
  If no, is the purchase still in your budget for purchase within the next two years?
  □Yes □No

### Surveillance Testing

- 1. Is your institution planning on performing surveillance on newly admitted patients? Yes / No
- 2. If yes, please check all that apply: □ VRE □ MRSA □ ESBL □ Other
- 3. If you are planning on performing surveillance what method will you be using? 

  Culture 
  Molecular
- 4. Even though bioMérieux is not your primary supplier of pre-plated media, would you consider buying chromogenic agar media for MRSA and VRE from bioMérieux? □Yes □No

### Urine Screening to Rule Out Culture

- 1. What department performs Urinalysis? \_\_\_\_\_\_\_ Volume per day? \_\_\_\_\_\_
- Please describe any automated equipment you have for Reading urine dipstick\_\_\_\_\_\_
   Performing urine microscopic\_\_\_\_\_\_
- 3. Would you consider performing urine screening for the presence of bacteria and yeast to rule out need for culture, assuming proven performance? □Yes □No
- 4. Would the following claims be sufficient for ruling out need for culture: NPV of 95% at 10<sup>3</sup>; and NPV of 95% at 10<sup>4</sup> colonies per mL? □Yes □No



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# How do you WORKSMART?

We want to hear your tips and best practices! Here are a few our own ID/AST Application Specialists have contributed:



### Go Green! Save Paper Using the VITEK<sup>®</sup> 2

Some customers have the "Automatic Lab Report" feature enabled on the VITEK® 2 AIX. With this feature enabled, a report prints every time a card analysis is completed and an additional lab report prints every time an exam is removed from a qualifier.

To save paper, disable the "Automatic Lab Report" feature by doing the following: From the Main menu select: VT2 > Setup > Configuration > Processing Tab > Automatic Lab Report

After disabling the "Automatic Lab Report" print feature, in order to print your daily lab reports you will now need to:

- 1. Resolve all qualifiers in the VITEK<sup>®</sup> 2 Directory
- 2. Select "Park" and highlight the desired exams
- 3. Select "Print"
- 4. Smile knowing you have just saved a tree!

### Set Up a Guide for Streaking Purity Plates

When inoculum tubes are not labeled, some VITEK<sup>®</sup> 2 AIX customers use the New Cassette Report as a guide for streaking their purity plates.

From the Main Menu select: VT2 > Setup > Configuration > Processing Tab > Automatically Print New Cassette

PC customers can enjoy the same benefits by doing the following: For a "Virtual Cassette" – from the Setup Tests Post Entry Screen

- 1. Save the virtual cassette
- 2. Click on the Print Icon
- 3. Select the Cassette Report For a "Load and Go Cassette"– Use the previously completed Cassette Worksheet



### Scan Job Aid Card Barcodes for Faster QC Set Up

Some customers cut the Smart Carrier Job Aid Card apart to separate the barcodes and either paste them on index cards or attach them to a key ring for easier scanning.

One computer savvy customer has even gone a step further he scanned the Job Aid Card barcodes into his Lab computer. He was then able to generate barcode labels from the Laboratory Information System (LIS) and attach them to the Quality Control (QC) plates. As a result, all the technicians need to do when setting up QC is scan the QC barcode label on the plate.

[▶] Do you have a great WorkSmart tip? Submit it online at www.biomerieux-usa.com/worksmart.



Are you over-worked, short on time and do you have a limited travel budget? We understand your challenges.

# bioMérieux Odyssey

### 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.

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

If you're a Quality Assurance Professional, Microbiology Lab Professional, Infection Control Professional, Phlebotomist, Clinician and/or part of Healthcare Administration, this tour is for you.

## bioMérieux's Odyssey is Navigating to a Stop Near You!

Jackson, MS • July 3 Houston, TX • July 7-8 San Antonio, TX • July 10-11 Irving, TX • July 14-15 Ft. Worth, TX • July 16 Oklahoma City, OK • July 18 Long Beach, CA • July 23-24 Los Angeles, CA • July 25 San Jose, CA • July 28 Oakland, CA • July 30 Sacramento, CA • July 31 Eugene, OR • August 4-5 Seattle, WA • August 7-8 Salt Lake City, UT • August 11 Denver, CO • August 13 Des Moines, IA • August 15

Minneapolis, MN • August 18-19 Waukesha, WI • August 21 Hammond, IN • August 22 Melrose Park, IL • August 25 South Chicago, IL • August 26 Ann Arbor, MI • August 28 Detroit, MI • August 29 Cleveland, OH • September 2-3 Rochester, NY • September 5 Syracuse, NY • September 8-9 Albany, NY • September 10 Springfield, MA • September 11 Worcester, MA • September 12 Boston, MA • September 15 Woburn, MA • September 16 Hartford, CT • September 18-19

### Visit the Odyssey to learn more about:

· Emerging pathogens and source tracking through strain typing

SPOTLIGHT

- Latest developments in blood culture and ID/AST, as well as 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.

Danbury, CT • September 22-23 Brooklyn, NY • September 25 Long Island, NY • September 26 Ridgewood, NJ • September 29 Neptune, NJ • September 30 Baltimore, MD • October 2-3 Alexandria, VA • October 6-7 Richmond, VA • October 9-10 Lexington, KY • October 13-14 Hazelwood, MO • October 16

St.Louis, MO • October 17 Kansas City, MO • October 23 Overland Park, KS • October 24 Indianapolis, IN • October 27-28 Cincinnati, OH • October 30-31 Columbus, OH • November 3-4 Cleveland, OH • November 6-7 Philadelphia, OH • November 10-11 Pittsburgh, PA • November 13 Warrendale, PA • November 14

### Visit www.biomerieux-usa.com/odyssey to see the latest updates to the Odyssey schedule. Interested in hosting the Odyssey at your site? Call 919-620-2823.

### **COMING SOON!**

#### VITEK® AST-GP67 card

D-test on a VITEK<sup>®</sup> 2 card with new Tigecycline and new Vancomycin **Product Coming Soon!** 



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# 2008 shows and conferences

Annual Meeting of the American Association of Clinical Chemistry (AACC) Booth # 1743 July 29-31 • Washington, DC

Micro in the Mountains (CACMLE) August 13-15

South West Association Clinical Microbiology (SWACM) September 10-13 • St. Louis, MI

Inter. Mountain State September 17-20 Lab Supply Company (LABSCO) September 29-October 1 • Louisville, KY

Healthcare Industry Distributors Association (HIDA) October 16-18 • Chicago, IL

American College of Chest Physicians (CHEST) October 25-28 • Philadelphia, PA

Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) – 47th Annual October 25-28 • Washington, DC American College of Emergency Physicians October 27-30 • Chicago, IL

Association for Molecular Pathology October 30-November 2 • Grapevine, TX

# **bioMérieux** connection

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