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®, is used to determine the Minimum Inhibitory Concentration (MIC) of antibiotics, antifungal agents and antimycobacterial agents. Etest is very complementary to bioMérieux’s VITEK® range for antibiotic susceptibility testing.

Today, VITEK® 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 (PREVİ™ Isola), urine analysis (UF-1000i) and Gram staining (PREVİ™ 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.
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.

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

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

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)

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!
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.

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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 enable clinical laboratories to quickly adopt advanced molecular testing involving much less validation and ongoing quality control measures than their home-brew counterparts.

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. They also provide more information than the typical laboratory developed test.

Prodesse’s ProFlu+™ 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™ RVP assay involves post-multiplex PCR detection using xMAP technology on the Luminex 100 instrument. It tests for a broad panel of respiratory viruses that includes Influenza A (including H1 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.

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

Even with the NucliSENS® easyMAG™ 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 reaction-ready 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
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+™ and Luminex’s xTAG™ 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-of-the-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® easyMAG™
- 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

To view the webinar, please visit www.biomerieux-usa.com/education.
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 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

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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.

Dr. Patel says that the key to their optimal microbiology operation is around-the-clock service and the use of automation whenever possible. "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® 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.
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: ________________________________

General
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? □Yes □No
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? __________
2. 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 10^3; and NPV of 95% at 10^4 colonies per mL? □Yes □No
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® 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® 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® 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.
Come aboard the Odyssey to gain industry insights in a relaxed environment with refreshments and our friendly staff in your city.

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
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® 2 card with new Tigecycline and new Vancomycin
Product Coming Soon!