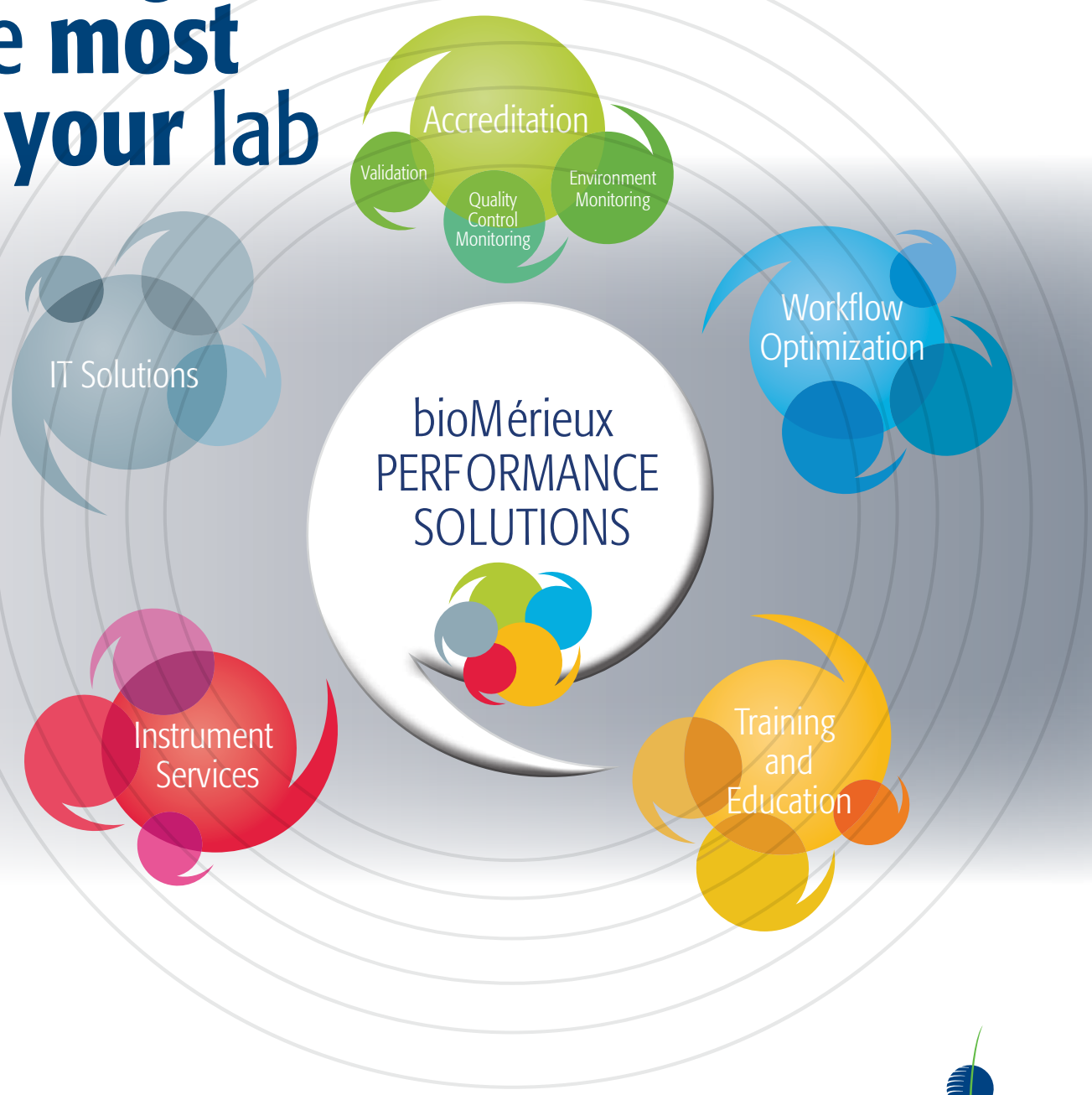
bioMérieux Connection
NEWSLETTER

November 2011

In this issue:

Making the **most** of **your** lab



BIOMÉRIEUX

LEAN Lab Implementation Improves Turnaround Times and Leads to Faster Results and More Confident Clinical Decision Making

Joseph Campos, Ph.D.
Director of the Microbiology and Molecular Diagnostics Laboratories
Children's National Medical Center

LEAN Lab Design is a service offered by bioMérieux in partnership with Guidon Performance Solutions. The service applies LEAN®/Six Sigma® principles to the microbiology lab. This service involves 3-5 days of observing the lab at its current state – the physical layout and the manner in which samples are processed. The deliverable is a roadmap outlining how the lab can improve processes to reduce waste and improve efficiency, while simultaneously increasing the quality of results and reducing errors.

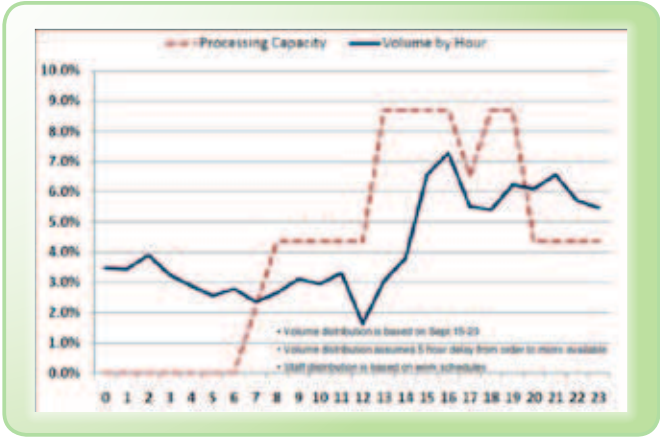
In 2009, The Children's National Medical Center (CNMC) partnered with bioMérieux-Guidon to apply the Lean/Six Sigma process to the hospital's microbiology lab. Two years later, the results on workflow, turnaround times (TATS), and patient outcomes have been dramatic.

What is the Value to the Patient?

According to data collected by bioMérieux, the vast majority (87%) of process time in the average U.S. hospital microbiology laboratory is not spent on "core value" activities. On average, 5% of process time is spent on backlog requests, 23% on extra work performed because of missing information, 27% waiting to complete the next "core value" step due to unavailable staffing or equipment, 4% spent on unnecessary motion (e.g., walking to the next task), 12.5% spent on review and quality assurance, 7% spent on call or log information, and nearly 10% spent on correcting quality issues.

The Intangible Value of the Microbiology Lab and How It Can Be Wasted

In the bioMérieux-Guidon Lean Lab process, inefficiencies are defined as waste - but not in the traditional sense. This waste includes over-producing, work-in-process, transport, excess motion, inactivity, errors and rework, and over-processing. "In our approach, waste actually refers not to the true value proposition offered by the microbiology laboratory: its expertise, time, and capital," said Anne Beal, Manager Workflow Optimization Team at bioMérieux. "It's not a tangible thing, but the relationship of the laboratory as a resource and the members of the laboratory staff. This is not the kind of waste that ends up in a garbage can, but it is in a very real sense a missed opportunity to improve the core value of the microbiology laboratory."



GRAPH 1: Hourly Volume and Specimen Process Staff Capacity Distribution

For example, Graph 1 demonstrates "waste" because laboratory staffing isn't aligned with laboratory workload. This analysis was part of the "Kaizen Approach" used in bioMérieux and Guidon's review of the microbiology laboratory at CNMC.

Post-LEAN Staffing: Minimizing the Extreme Peaks and Valleys

Prior to the LEAN laboratory assessment, the microbiology laboratory at CNMC employed 11 FTEs plus a supervisor - and it still does. But thanks to our increased efficiency, the productivity of our staff has dramatically improved. The LEAN Laboratory assessment demonstrated that the microbiology laboratory had marked peaks and valleys of activity, which we needed to level off.

Spreading the Workload and Improving Morale

Pre-LEAN, we were essentially a day-shift laboratory, from 7:30am to 4pm, with almost all of our staff working that shift. As a result, the day shift began each morning with a backlog of new specimens and positive blood cultures from the previous night that needed to be processed. One of the most effective changes made after our LEAN assessment was to convert our microbiology laboratory to a 24-hour operation, Monday through Friday. By staffing both an evening shift (3:30pm to midnight) and a night shift (11:30pm to 8am) with two technologists, the day shift (7:30am to 4pm) arrives each morning to find the workload from the evening and night shifts has already been completed.

And, since that 8.5 hour day shift window often wasn't sufficient to complete the work, the pre-LEAN laboratory required a great deal of overtime. Those overtime hours have been markedly reduced by distributing the workload over a 24-hour period.

With four FTEs working the evening and night shifts post-LEAN, the laboratory is constantly processing new specimens and examining new cultures. Positive cultures are now identified and worked up during the evening and night shift hours and those results are made available to physicians immediately. There are still mild peaks and valleys of activity, but we have eliminated a great deal of wasted inactivity.

The reallocation of our 11 FTEs was just one step in our LEAN process. By redistributing our staffing to make it possible to process our workload across all three shifts, we made it possible to move automated molecular testing from our day shift-only Molecular Diagnostics laboratory to the Microbiology laboratory. This testing is now performed STAT as specimens arrive rather than waiting to be tested in batch mode. The improved TAT for automated molecular testing has been impressive.

In the pre-LEAN laboratory, all culture plate reading occurred during the day shift only. If growth was insufficient to permit culture workup, the culture media were placed back into the incubator for another 24 hours. Now, our cultures are examined for the first time after 16 hours of incubation, regardless of the time of day. If growth is insufficient for culture workup, the culture media are re-incubated for four hours and checked again. Very often, 16 hours of incubation is enough time to obtain adequate growth to inoculate identification and antimicrobial susceptibility tests. In our pre-LEAN laboratory, inoculation of identification and susceptibility tests from uncomplicated cultures often occurred 24 - 48 hours after specimen receipt. Currently, it usually happens within 16 hours, and almost always in less than 24 hours.

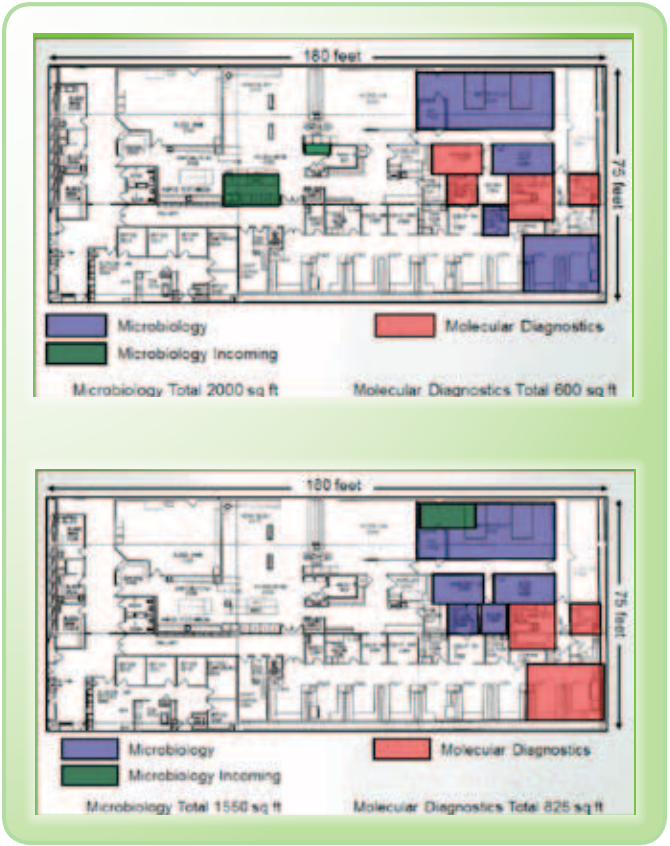
Redesign Focusing on Core Value Improvement

One of the other major changes resulting from the LEAN Laboratory assessment was better utilization of our laboratory floor space. Prior to the redesign, our Incoming area was a major laboratory thoroughfare, so you can imagine the chaos created by frequent walk-throughs in an area where our laboratory scientists needed to be very focused. Post-LEAN, our Incoming area is cellular in nature and is now much closer to our media storage cold room and our incubators, resulting in much less nonproductive walking.

The Law of Unintended Good Consequences

An unexpected benefit of distributing our workload over 24 hours derived from consolidation of our workstations. With fewer staff now working on our day shift, the microbiology laboratory actually needs less bench space since we eliminated two of our four culture plate reading areas. By converting our classic virology testing to molecular testing, we eliminated two tissue culture hoods and a tissue culture incubator, freeing up valuable floor space. Even more floor space was recovered by instituting twice weekly, instead of once weekly, culture media shipments, enabling us to move refrigerated supplies from no longer needed floor-standing refrigerators to now empty shelves in our cold room. Some of the "new" floor space was used to house bioMérieux's PREVI® Isola automated plate streaking system. Not only does this award-winning device free up well-trained lab scientists from the chore of manually streaking culture plates, PREVI Isola has demonstrated that it provides better colony isolation, leading to fewer subculture plates during workups and faster results from identification and antimicrobial susceptibility tests.

As shown in Graph 2, the Molecular Diagnostics laboratory occupied many noncontiguous spaces in the Department of Laboratory Medicine prior to the LEAN redesign. That is because such a laboratory could not even be imagined when the hospital was built in the early 1970s and thus it was squeezed into existing "nooks and crannies" available in the Department. Now, the Molecular Diagnostics laboratory is more consolidated and has an additional 225 square feet.



GRAPH 2: Before (top) and after (below) lab layout at CNMC

The Ultimate Measure: Turnaround Times

We compared the TATs from identical six month periods: November 2009 to April 2010 (Pre-LEAN) and November 2010 to April 2011 (Post-LEAN). We confirmed that testing performed during these periods was comparable in nature and volume, and came from patients with similar demographics.

We have seen a significant improvement in TATs for positive cultures from all specimen types, including blood, stool, urine and more. We've gained, on average, a complete day in our positive culture TATs post-LEAN (Table 1). This is most profound early in the work week. Since the LEAN staffing changes had to be limited to weekdays, we've seen no improvement in TAT for specimens collected on Saturdays, and a slight improvement for those collected on Sundays.

TABLE 1: Days of the Week: Pre- and Post-LEAN Positive Culture TATS

Specimen Collection Day	Pre-LEAN Average TAT	POST-LEAN Average TAT
Monday	4.1 days	3.2 days
Tuesday	3.8 days	2.7 days
Wednesday	3.7 days	2.9 days

We analyzed the TAT improvements for patients located in our critical care areas, the pediatric and cardiac intensive care units (PICU and CICU), our emergency department (ED), and in our neonatal intensive care unit (NICU). Table 2 illustrates the improved TATs for positive cultures from these patients.

TABLE 2: Critical Care TAT Improvements by Department

Critical Care Department	Pre-LEAN Average TAT	POST-LEAN Average TAT
CICU	3.5 days	2.7 days
ED	3.2 days	2.8 days
NICU	2.7 days	2.6 days
PICU	2.9 days	2.3 days

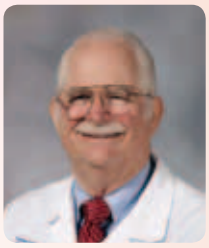
Ultimately, physicians want to make sure they can make the best possible decisions based on their clinical expertise and the symptoms and clues they see in their patients. Often, they have to act before they have all the data at their fingertips because their patient is in critical condition. These time-to-results improvements that we've seen across the board from our microbiology lab are vitally important because they confirm when our physicians have made the right empiric decisions and their patients are being treating correctly, or they tell our physicians to change course and treat their patients differently. In the first case, our improved TATs have given us greater confidence that our patients are being cared for appropriately. In the second case, these saved hours or days can mean the difference between recovery and serious morbidity/mortality in a difficult-to-diagnose patient. ■

In our sustained effort to advance scientific knowledge, bioMérieux sponsors many online presentations and seminars that are developed and presented by experts in the field. Many of these Continuing Education programs offer P.A.C.E. credits. Here, we highlight two recent webinars about D-dimer testing and Toxoplasmosis. View these webinars at **www.biomerieux-usa.com/2011webinars**.

WEBINAR 1: New CLSI guideline for D-dimer exclusion testing and its impact on your lab

CE Credit: 1 P.A.C.E. CEU available

Presenter:
Dorothy M. Adcock, MD
Esoterix Inc.
Laboratory Services



Presenter:
William A. Rock, Jr., MD
University of Mississippi
Medical Center

Webinar Topics:

- Review of the new Clinical Laboratory Standards Institute (CLSI) guideline, H59-A: Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease (VTE).
- The new guideline establishes minimum requirements for a D-dimer test when used for the exclusion of a VTE in the outpatient setting.
- Labs will now be responsible for understanding the differences among various D-dimer assays, and ensuring they use the appropriate D-dimer for exclusion of VTE and the importance of Negative Predictive Value (NPV).

This guideline validates what bioMérieux has been supporting for years through large patient management outcome studies, an FDA-clearance claim, and the importance of using a Gold Standard D-dimer for exclusion of VTE, such as VIDAS® D-dimer Exclusion™.

WEBINAR 2: Toxoplasmosis, Rubella, Cytomegalovirus infections during pregnancy: Risk to the Newborn

Presenter:
Jose G. Montoya, MD
Stanford University
Medical Center

Presenter:
Gary B. Munk, PhD
Hackensack University
Medical Center

Webinar Topics:

- Webinar attendees will learn about ToRC infections, the associated risks during pregnancy, and options for screening and diagnosis.
- Recognize the clinical characteristics of Toxoplasmosis, Rubella and CMV infections.
- Understand screening, diagnosing, preventing and determining the risk of these infections.
- Become aware of the different laboratory diagnostic methods: advantages and disadvantages.

On May 18, the U.S. Food and Drug Administration (FDA) cleared the new VIDAS® TOXO IgG Avidity (TXGA) assay as the first test in the U.S. to help determine if a toxoplasmosis infection was developed within the past four months. For pregnant women diagnosed with toxoplasmosis, the VIDAS TXGA can be used to exclude a recent infection to help ease a pregnant woman's anxiety, and eliminate the need for additional, unnecessary procedures.

bioMérieux, Inc. is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program.

WORKSAFE™ Blood Culture Collection Kits Help Mercy Medical Center Reduce Blood Culture Contamination

LEAN blood culture collection processes save money and resources for the hospital

John F. Boyle, Director of Laboratory
Respiratory and Ancillary Services
Mercy Medical Center
New York

Introduction

Blood culture contamination is an ongoing concern for every laboratory. Accepted methods to help reduce contamination are well documented and clearly stress the need for proper technique in disinfecting both the site of collection and the blood culture bottle septum [1,2]. Continuous direct observation of specimen collection, paired with education, seems to be the most effective approach to keeping contamination rates below the acceptable level of 3% [3,4].

Numerous studies have reported additional hospital costs of up to $5,000 every time a patient is put on antibiotic treatment as the result of a contaminated blood culture [3,4,5]. Even for hospitals that consistently demonstrate low blood culture contamination rates, there is the potential to lose hundreds of thousands of dollars each year in unnecessary treatment and misdirected personnel resources.

In 2010, Mercy Medical Center (MMC) reached its hospital goal of being under 3% for its blood culture contamination. However, despite this favorable result, we recognized that there was room for improvement and additional cost savings. The MMC laboratory adopted a "LEAN" blood culture collection approach to improve efficiency and reduce occurrences in errors. The three key elements of Lean are standard work, user-friendliness and unobstructed throughput. By providing each of these elements in our blood culture collection in the Emergency Room, we reduced our contamination from one in every ten positive blood culture sets, to one in every hundred positive blood culture sets.

Experiment Design and Methods

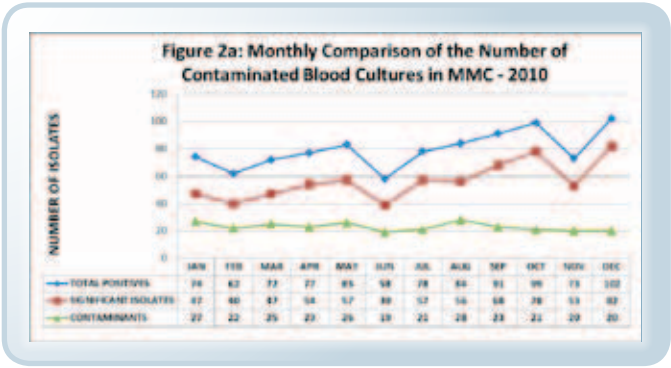
In December 2010, the MMC Emergency Room launched a pilot LEAN study to determine the impact of collection kits on contamination rates. The pilot was designed to: 1) determine which units had the highest blood culture contamination rates, 2) assess the impact of the new blood culture system and the introduction of a Blood Culture Collection Process/Protocol (BCCP) augmented by practitioner training on blood culture contamination rates, and 3) determine the value of purchasing a commercially prepared Blood Culture Collection Process.

The Emergency Room and ICU were each provided WORKSAFE™ blood culture collection kits. Each kit includes BacT/ALERT® 3D blood culture bottles, alcohol prep pads (2), PDI® Chlorascrub™ 3.15% Chlorohexidine gluconate swab stick, 2"x 2" gauze, tourniquet, bandage, biohazard bag, and collection instructions (Fig. 1). The standard operating procedure approved at MMC for blood collection was included in the kit.

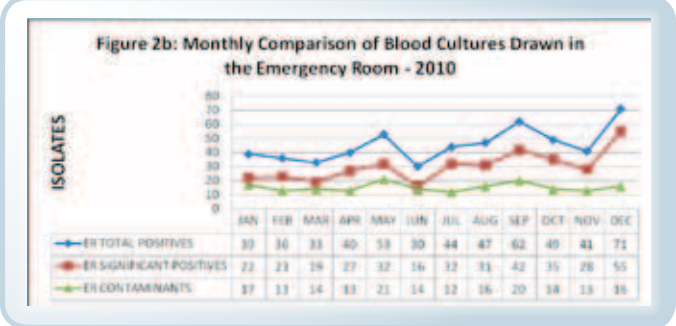
Figure 1: WORKSAFE™ Blood Culture Collection Kit

Results

In 2010, there were 9,765 sets of blood cultures (19,530 bottles) drawn at MMC, of which 9.76% were reported positive for bacteria. Of the reported positive cultures, 28.9% were determined to be blood culture contaminants, and largely identified as coagulase negative *Staphylococcus* (Fig. 2a). Further analysis showed that 56% of all blood cultures were drawn in the Emergency Room, and 67% of all contaminated blood cultures came from the Emergency Room (Fig. 2b).



The calculated cost of lost revenue would be between $900,000 to $1.3 million [3,4,5]. Although, it is an unreasonable expectation



to eliminate all contaminated cultures in a hospital and/or in the Emergency Room, it is reasonable to expect that when personnel are provided with the appropriate supplies, user-friendly process, and unobstructed throughput, they could significantly reduce the number of contaminated cultures.

> **"In the Emergency Room, we reduced our contamination from one in every ten positive blood culture sets, to one in every hundred positive blood culture sets."**

Conclusion

Prior to December 2010, the Emergency Room's monthly contamination rate for positive blood cultures demonstrated a mean of 34.86% for coagulase negative *Staphylococcus*. After the WORKSAFE™ blood culture kits were distributed, only 22.5% of the blood cultures were identified as contaminated, which represents a 12.36% reduction. Even more encouraging was the fact that only 1% of the blood cultures were identified as a contaminated culture.

We conclude that the use of prepared WORKSAFE blood culture kits is an effective tool in reducing blood culture contamination. In comparison to the first 11 months of 2010, the mean 12.36% reduction in contamination in December was significant and reflected trends seen in our ICU when direct monitoring of specimen collection with the blood culture kits resulted in lower rates of contamination. Interestingly, a parallel effect was the increased percentage of significant isolates (9.5%) seen in the Emergency Room during December, in comparison to 6.69% for the previous 11 months.

> **"An extremely conservative estimate of 3% reduction in contamination in one year will have the potential to avoid $30,000 in non-reimbursable treatment expenditures, and over $100,000 associated with extended lengths of stay in the hospital."**

The data in our pilot study strongly suggests that having prepared blood collection kits can have a significant reduction in contamination, and combined with continuous direct monitoring of the collection process will avoid the unnecessary action of antibiotic treatment on patients based on contaminated blood cultures. An extremely conservative estimate of 3% reduction in contamination in one year will have the potential to avoid $30,000 in non-reimbursable treatment expenditures, and over $100,000 associated with extended lengths of stay in the hospital [6,7,8]. ■

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WORKSAFE

MERCY MEDICAL CENTER

A Unique Lab Depends on VITEK® 2 for its Unique Patients

Laurie Page, BS, M(ASCP)
Microbiology Supervisor
Bako Pathology Services

Bako Pathology Services is a physician-founded and owned laboratory offering a wide array of anatomic pathology and clinical microbiology services focused on the specialized needs of podiatrists and their patients. Testing offered includes histopathology, bacterial and fungal cultures and epidermal nerve fiber density testing. Specimen types received are predominantly bone, soft tissue, skin, nail bed and nail clippings. We serve clients in many areas of the country and the U.S. Virgin Islands.

From left to right: Dr. Bradley Bakotic, Laurie Page, BS, M(ASCP), and Kris Viens, MT(ASCP)

The needs of the podiatric patient population are increasing, primarily due to the epidemic of diabetes in this country. According to the National Institutes of Health, 18.8 million Americans are currently diagnosed with diabetes, and an estimated 7 million additional cases remain undiagnosed.

"We rely on our VITEK® 2 and PREVI® Color Gram systems to help us turn around bacterial cultures in as little as 36 hours."

Among those aged 65 years and older, 10.9 million – nearly 30% of this demographic group – have diabetes, according to 2010 NIH statistics. A particularly alarming trend is the increased prevalence of diabetes in young patients. In 2010, 215,000 patients under the age of 20 were identified as either Type I or Type II diabetics. The NIH estimates that as many as 79 million Americans over the age of 19 are pre-diabetic.

Among the general population, 10 to 20% of adults between the ages of 40 and 60 suffer from abnormalities of the pedal nail unit. Common conditions include onychomycosis (fungal infection of the nail), microtrauma due to poorly fitting shoes, non-infectious dermatological diseases such as psoriasis or lichen planus, and neoplastic processes such as melanoma. Thickening and discoloration of the nail can be painful and unsightly.

Serious bacterial infection is a complication of diabetes. Approximately three-quarters of all diabetic patients suffer from mild to severe peripheral nerve damage, leading to impaired sensation in the feet. Patients often develop wounds on their lower extremities, which may go undetected for a period of time. Infections in this patient population can be difficult to treat and may eventually lead to amputation of the affected digit or limb. Therefore, time is critical. We rely on our VITEK® 2 and PREVI® Color Gram systems to help us turn around bacterial cultures in as little as 36 hours.

Yeast and fungal infections are a different matter. These pathogens can take as long as four weeks to grow. We read fungal cultures after 3, 7, 14, 21 and 28 days of incubation. We have processed over 21,000 fungal cultures this year to date, and of these, approximately 80% are positive.

The VITEK 2 can provide rapid identification of yeast isolates. *Candida albicans* is a common pathogen affecting our patients, but the VITEK 2 database allows us to identify many other species of *Candida* as well as *Geotrichum, Pichia, Trichosporon* and *Zygosaccharomyces* species. ■

Visit bioMérieux at

2011 ASHP
Mid-Year Meeting

December 4-8
New Orleans, LA
Booth # 3213

Exhibit Hours:
December 5-7:
11am to 3pm

Join us for an Educational Dinner Program
December 4
at Red Fish Grill

Presentations:
When and Why Pharmacists Should Ask their Microbiology Lab for MICs

Audrey Wanger, Ph.D.
Professor, Department of Pathology & Laboratory Medicine – University of Texas Medical School, Houston Director Microbiology – Memorial Hermann Laboratory System and LBJGH

and

Joseph Kuti, PharmD
Associate Director, Clinical and Economic Studies Center for Anti-Infective Research and Development Hartford Hospital

To register, visit **www.biomerieux-usa.com**, click News & Events, visit the Events page and scroll to December 4th program details. Register by November 25th, as seating is limited.

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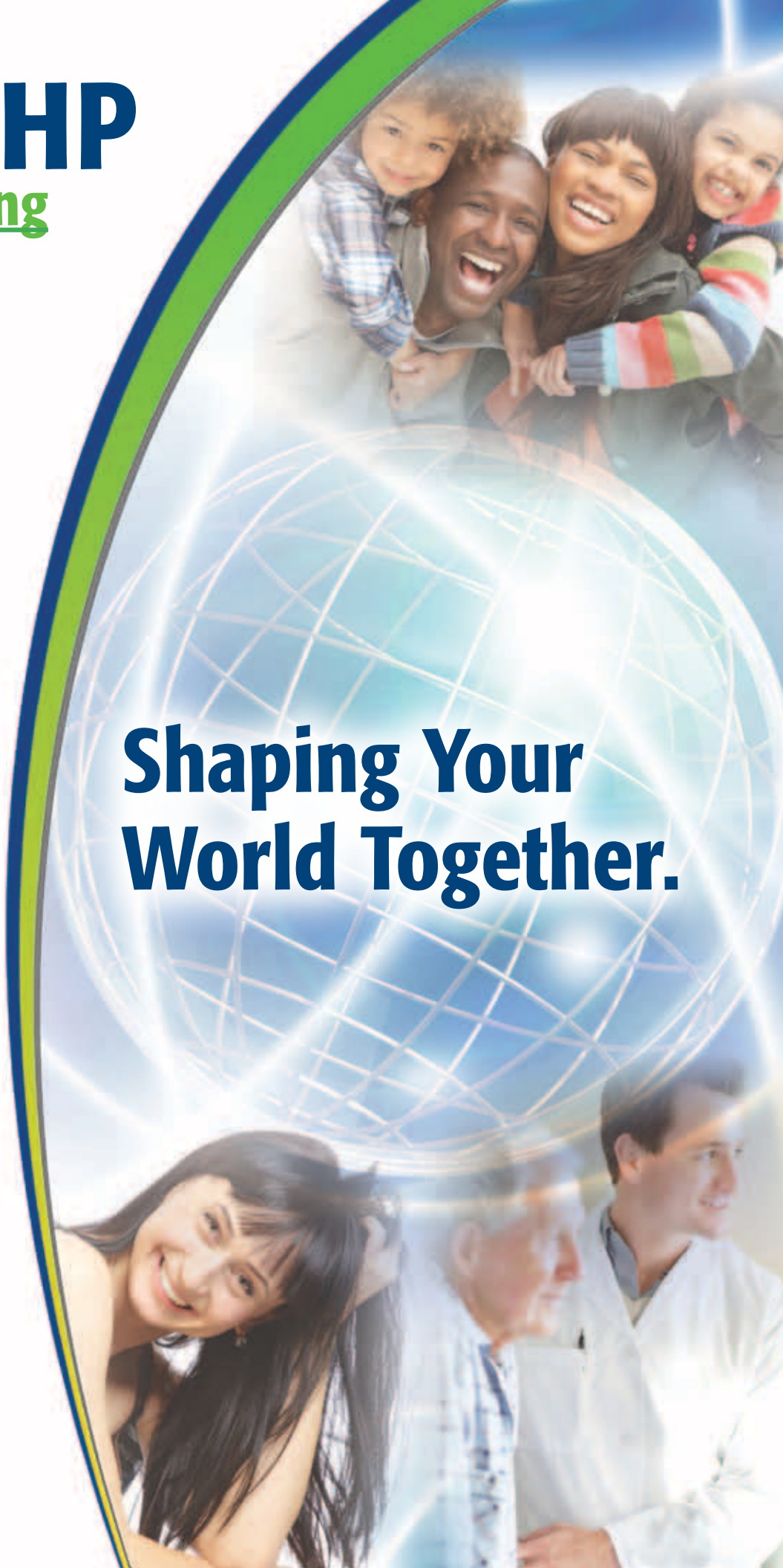

NucliSENS™ easyMAG

Update on FDA-cleared Molecular Assays Supported

bioMérieux's NucliSENS® easyMAG® has been widely adopted across the U.S. as an automated nucleic acid extraction platform in front of a variety of laboratory-developed tests. Laboratories performing these assays have appreciated the easyMAG's ability to extract high-quality nucleic acid from a variety of sample types and its exceptional level of flexibility and productivity.

In recent years, the easyMAG system has also been employed by diagnostic companies as a key IVD-labeled automated extraction method used in the development of their own molecular diagnostic assays. easyMAG is currently on label for use in front of the following companies' FDA-cleared assays:

Luminex®
- xTAG® Respiratory Viral Panel v1
- xTAG® Respiratory Viral Panel FAST

Gen-Probe/Prodesse®
- ProFlu+™ (Flu A/B and RSV)
- ProFAST+™ (Flu A subtyping)
- Pro hMPV+™
- ProGastro™ Cd (*C. difficile* toxin)
- ProParaFlu+™
- ProAdeno+™

Focus Diagnostics
- Simplexa™ Flu A/B & RSV

Eragen®
- MultiCode®-RTx HSV 1&2

Centers for Disease Control
- H1N1 Influenza Panel

(for use by qualified public health laboratories)

Customer Survey

As 2011 comes to a close, we would like your valuable feedback to help us prepare for the coming year. Please complete this survey and fax it to **919.479.3616** or visit **www.biomerieux-usa.com/connection** to submit online.

The first 100 survey respondents will receive a complimentary copy of the Camp Clinical Micro Supplement to *Journal of Clinical Microbiology* AND a Dog Tag USB Drive, preloaded with Continuing Education presentations on "LEAN Microbiology" and "Making the Case for Lab Automation"!

What print resources do you read most frequently? Rank your answers, with #1 being the best.

__ *CAP Today*
__ *Clinical Lab Products (CLP)*
__ *Medical Laboratory Observer (MLO)*
__ *Journal of Clinical Microbiology (JCM)*
__ *ADVANCE for Administrators of the Laboratory*
__ *ADVANCE for Medical Laboratory Professionals*
__ *IVD Technology*
__ Other_____

Where do you go for work-related news and information online? Rank your answers, with #1 being the best.

__ Trade magazine website or e-news (e.g., *CAP Today, MLO, CLP,* etc.)
__ ClinMicroNet
__ asm.org (Division C)
__ Social Media (e.g., blogs, Twitter, industry forums, etc.)
__ Other: _____

Do you use social media (i.e., Twitter, Facebook) more for work or entertainment?

☐ Work
☐ Entertainment
☐ Do not have social media accounts

Do you participate in industry forums or blogs? Please list the forums you visit most frequently.

☐ My favorite forums are_____
_____
_____
_____
☐ I don't participate in online forums or read blogs

Have you participated in bioMérieux-sponsored Webinars or Podcasts this year (2011)?

☐ Yes (please list)_____
_____
_____
_____
☐ No

Which tradeshows do you plan to attend in 2012?

☐ ECCMID (March/April in London)
☐ ASM (June in San Francisco)
☐ AACC (July in Los Angeles)
☐ Regional ASM Meetings
☐ Other_____

Did you visit the Odyssey truck this year during it's cross-country tour?

☐ Yes
☐ No

Which topics would you like to see in *Connection* newsletter next year? Rank your answers, with #1 being the best.

__ LEAN Lab design/Justifying costs to management
__ Training/Education/Staffing
__ Antibiotic Stewardship
__ Lab Automation/FMLA
__ MALDI-TOF Mass Spectrometry
__ Molecular diagnostics and automation
__ Controling Hospital-Acquired Infections (HAIs)
__ Healthcare reform and its impact on the lab
__ Software/Informatics/Connectivity
__ Other (please specitify)_____
_____
_____

We appreciate your feedback!

☐ Please have a bioMérieux sales representative contact me about lab automation products.
☐ Email me information on new products, special offers, surveys or educational events.
☐ Contact me to feature my lab in a future issue of *Connection* newsletter.

Name: _____

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ADDRESS SERVICE REQUESTED

EVENTS CALENDAR

National Regional Holiday

Date		Event & Location
NOVEMBER	3-5	**Southern California ASM**, La Jolla, CA
	9	**Odyssey™ Cities on Tour**, Tampa, FL
	17-19	**Association for Molecular Pathology (AMP) Booth #328**, Grapevine, TX
	24-25	**Thanksgiving Holiday**
DECEMBER	4-8	**American Society of Healthcare Pharmacists (ASHP) Booth #3213**, New Orleans, LA
	26-27	**Winter Holiday**
JANUARY 2012	2	**New Year's Holiday**
	14-18	**Mass Spectrometry in the Clinical Lab (MASCL) Annual Meeting Booth #24**, San Diego, CA
	16	**Martin Luther King, Jr. Day**

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