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INNOVATION IN MOTION THE TOUR IS BACK

bioMérieux's high-tech bus tour featuring a presentation theater and mobile laboratory will be hitting the road again shortly. This laboratory on wheels allows hands-on experience with bioMérieux's innovative microbiology systems and shows how integrated solutions can improve patient as well as financial outcomes.

> If you are a microbiologist, lab professional, pharmacist, pharmacy director or administrator do not miss this unique opportunity when it comes to your facility. Keep an eye out for the new tour schedule. Visit our web site at www.biomerieux-usa.com for more information.

DIAGNOSTIC MARKERS: EMPOWERING CLINICAL DECISIONS IN THE EMERGENCY DEPARTMENT

At the American College of Emergency Physicians (ACEP) 37th Annual Scientific Assembly, bioMérieux hosted a scientific symposium entitled Advancing ED Clinical Decisions with Diagnostic Markers. During this event, two leading researchers presented new findings and exciting clinical implications from their recent work.

The symposium was moderated by Dr. Jerald Solot, Clinical Associate Professor at the University of Pittsburgh Medical Center (UPMC).

This month, we highlight the talk by Dr. Philip Wells, a physician at The Ottawa Hospital and Professor and Chief of the Division of Hematology at the University of Ottawa.

The next issue of *Connection* will feature a summary of Dr. Beat Müller's presentation on the application of Procalcitonin as a guide for antibiotic use in suspected lower respiratory tract infections.

Dr. Wells has developed a clinical and research practice enabling him to perform internationally recognized research. He pioneered the concept of clinical prediction rules to assist in the diagnosis of patients with suspected deep vein thrombosis or pulmonary embolism. The resulting clinical algorithm, commonly called the Wells' Score, is now used in emergency rooms and thrombosis units throughout the world. [+] (continued on page 2)





from diagnosis, the seeds of better health

innovation In

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(continued from page 1)

His approach to Deep Vein Thrombosis has been validated in more than 7,000 patients and in dozens of publications. In 2003, an entire scientific session at the International Society of Thrombosis and Hemostasis was devoted to the Wells' Deep Vein Thrombosis Clinical Model.

Understanding the Importance of D-dimer Assays in the Diagnosis of PE and DVT.

Dr. Solot introduced Dr. Wells' discussion of D-dimer tests with some sobering statistics on Venous Thromboembolism (VTE) – a term which includes both Pulmonary Embolism (PE) and Deep Vein Thrombosis (DVT). There are two million reported cases of DVT in the U.S. every year, and a million more of PE; 200,000 of those patients will die. And that represents only an estimated 20% of the actual population with these conditions.

He also raised a provocative question for the audience of emergency physicians: If the spouse of the hospital's CEO comes into your ED at 2 am complaining of pain in the right calf, and he or she has a low risk for PE based on the Wells Pre-Test Probability Score and a negative D-dimer test, would you send the patient home?

It was agreed that this would be a difficult decision to make.

This real-world scenario highlighted how important it is for physicians to have confidence in the results of the D-dimer test they use. And as Dr. Solot stressed, that confidence can only come from using an appropriate test, one with a clinically proven negative predictive value. This makes it especially important for ED physicians to know which D-dimer test is being run in their hospital laboratory.

Diagnostic Methods For PE and DVT.

Dr. Wells discussed the use of ultrasound as a diagnostic tool for DVT. While these tests are highly sensitive and specific for proximal veins, they are less effective on veins in the calf, as well as time-consuming to perform. In addition, good evidence suggests that by the time patients present with symptoms and are diagnosed with DVT in their calf veins, 85% will already have DVT in the proximal veins, making ultrasound a low-yield test.

Concerns about possibly missing a clot in the calf led to a serial testing strategy in the ED: Perform an ultrasound; for negative results, repeat the test one week later. Dr. Wells pointed out that this is an effective and safe strategy, but not very convenient, as most patients who have a follow-up test are determined not to have DVT.

This situation led to the development of a new strategy to avoid repeat ultrasounds: Calculate a

pre-test probability score of the likelihood of PE or DVT, and then use a D-dimer test to rule out patients unlikely to have VTE.

Pre-Test Probability: The Wells Score

According to Dr. Wells, the concept of a pretest probability is that if a patient has a low likelihood of disease, a negative test will usually rule disease out – but a positive test is less likely to rule the disease in. In his work on the exclusion of DVT, he focuses on the low probability/negative test scenario.

The clinical model he uses is one that he created, the widely used Wells Score. It assigns points to a series of risk factors, physical findings and possible alternative diagnoses. From the total score, physicians can assign a patient to a DVT probability category – either low/medium/high or, using a newer classification, likely/unlikely.

Highlighting his research, Dr. Wells explained that they demonstrated the usefulness of this "selective repeat" strategy: patients with a normal ultrasound and a low probability score could be managed safely and effectively without a second ultrasound. Compared to the conventional methodology, additional ultrasounds were much less likely to be indicated, and



diagnostic yield was improved when they were. Just as important, three-month patient followup showed very similar results.

The Relationship Between D-dimer and VTE.

D-dimer is a protein fragment left over when fibrin mesh is broken down by plasmin. Dr. Wells explained that even as a clot forms, the body is trying to dissolve it with plasmin; it is constantly being broken down, just not fast enough to prevent serious conditions. Having an elevated level of D-dimer in the blood stream can be an indicator that a blood clot is present, but it can also result from other conditions: major surgery, malignancy, old age, or even pregnancy. However, a low level of D-dimer indicates that no clot is present.

Dr. Wells said that there are a number of different types of D-dimer assays available. In fact, there is no standardized analyte for D-dimer; results will vary from one test to the next, and results from one test cannot

be extrapolated to another. Putting D-dimer To The Test With DVT: A D-dimer Exclusion Strategy.

Dr. Wells tested a revised strategy that included a pre-test probability score and a D-dimer test to see if it could be used safely to rule out DVT. The results showed a considerable improvement in the diagnostic process: in low- and medium-probability patients with negative D-dimer assays, no ultrasound test was required. There were fewer ultrasounds performed, and three-month follow-up of patient outcomes demonstrated the safety of the method.

The studies did, however, show a real difference between the D-dimer

Negative Test Result

0/0

Negative Predictive Value (NPV) at a cut-off of 500 ng/ml¹. Proven in more than 50 published peer-reviewed studies with greater than 11,000 patients, including five prospective management trials.

assays that were used.



used to exclude a diagnosis of DVT with greater than 99% accuracy. However, for patients with moderate probability scores, these same tests only had a negative predictive value of 95%, while the most highly sensitive D-dimer assay provided an NPV of >99%. And as Dr. Wells mentioned, those few percentage points are the difference between an assay that can be used for exclusion, and one that cannot.

As a result, Dr. Wells now employs a diagnostic algorithm that starts with the pre-test probability score. "DVT unlikely" patients with a negative

Case Closed.

on a

highly

result

Disposition the Patient. FBDA CLEARED for Exclusion of PE and DVT when used in conjunction with a pre-test probability model at a cut-off of 500 ng/ml. sensitive D-dimer can be safely excluded; a positive D-dimer leads to an ultrasound.

"DVT likely" patients have an ultrasound first; and then a D-dimer assay if the ultrasound is negative.

D-dimer And PE: An Exclusion Strategy For A Serious Condition.

PE is the more serious of the two conditions that fall under the VTE

In low-probability patients, even D-dimer assays that were only moderately sensitive could be umbrella. In these cases, a clot breaks free and can travel through the venous system to the lung. So it is important to determine if an exclusion strategy for PE based on the use of a single D-dimer test is as safe and effective as for DVT.

Based on his research, Dr. Wells described a similar evolution in diagnostic tools for the two conditions.

CT scans have been predominantly used to diagnose PE, but these tests are not 100% sensitive and specific, commonly generate false positives, and have results that can vary depending on the age of the equipment being used.

As with DVT, Dr. Wells created a pre-test probability scoring model ranking patients as either low/ moderate/high or unlikely/likely. Studies have also shown that a Wells Score in the unlikely range, along with a negative D-dimer test, can be used to safely and effectively exclude a diagnosis of PE.

While there are other models for exclusion, none of them are as simple and straightforward as the algorithm he has used.

Dr. Wells pointed to a recently completed, as-yet unpublished study of almost 700 patients, which demonstrated equivalent safety between traditional CT scans and this newer diagnostic model.

Highly Sensitive Equals Highly Effective.

Safe and effective exclusion for PE and DVT in hospital emergency departments is possible with a single D-dimer test, but only if a pre-test probability model is used with an appropriate D-dimer assay.

With such a strategy in place, EDs can eliminate unnecessary testing and improve patient care. Patients can be diagnosed, treated, or released more quickly and with less reliance on multiple tests or complicated procedures.

In particular, Dr. Wells' research showed that while most D-dimer assays could safely exclude patients with low pre-test probability scores, welk issue. Look for a sammary of Dr. Beat Müller's ACEP presentation, Summary of Dr. Beat Müller's ACEP presentation, Summary of Dr. Beat Müller's ACEP

FLUCONAZOLE SUSCEPTIBILITY **TESTING OF CANDIDA:**

AUTOMATED TESTING HAS FINALLY COME OF AGE

In 2002 Drs. Rex and Pfaller published an article entitled "Has Antifungal Susceptibility Testing Come of Age?"1 Their conclusion was "yes" as standardization of methodology had seemingly made antifungal susceptibility testing more accessible to clinical



microbiology laboratories and their recommendation was to perform routine fluconazole susceptibility testing on all Candida species isolated from sterile sites. However, despite the availability of manual commercial methods, most

Garey KW, et al. Clin Infect Dis 2006;43:25-31.

Day 2

 $Day \ge 3$

Dav 1

clinical laboratories still have not made antifungal testing routine, even though physicians find antifungal susceptibility data useful and will alter therapy accordingly.^{2,3} Antifungal susceptibility testing can help predict the clinical response to antifungal therapy for a specific isolate as well as establish epidemiological trends. With the recent addition of fluconazole to the VITEK[®] 2 menu, susceptibility testing for this key antifungal agent is now accurate, rapid and fully automated with the potential to have results available within a few hours of Candida isolation. Given the increasing incidence and complexity of Candida infections as well as the availability of multiple therapeutic agents, it is now appropriate to consider routine fluconazole susceptibility testing of all Candida isolates from serious, systemic infections.

Used at a variety of doses, fluconazole has a reliable safety and efficacy profile. Fluconazole remains a first line treatment for most types of Candida infections.⁴ Although resistance to fluconazole has emerged, the vast majority (>90%) of clinical isolates remain susceptible^{5,6,7} and most infections due to Candida species can still be successfully treated with fluconazole, although some require higher doses.^{6,7}

The availability of fluconazole susceptibility data soon after the initial isolation of Candida from a serious infection will enable physicians to make informed decisions about the selection of antifungal therapy for their patients and to choose the appropriate dose of fluconazole. The right choice of therapy can have significant impact on patient outcome as demonstrated in two recent studies where delays of 12-24 hours in start of effective antifungal therapy resulted in a mortality rate 2-3 times higher than for those patients who received more timely therapy.8,9 (See Figure 1)

In a recent review, it was shown that infection with Candida species is common, serious, and costly.6 The prevalence of Candida infections is 6-23 infections per 100,000 persons annually in the United States and Candida species are the most common fungal pathogens in the intensive care unit (ICU), solid organ transplantation, and bone marrow transplant patient populations. During the last 30 years, the incidence of Candida-associated bloodstream infections (BSIs) has increased steadily and account for 8%-10% of all nosocomial BSIs in the USA. Systemic Candida infections are associated with an excess attributable mortality rate of 10%-49% and an excess length of hospital stay of 3-30 days. The excess cost attributable to candidemia in the United States is almost 1 billion dollars per year.6

Only a few species of Candida are consistently isolated from patients with clinical infections and the vast majority of isolates are susceptible to fluconazole.5 (See Figure 2) Approximately 95%-97% of all Candida-associated BSIs are caused by 5 species: Candida albicans, Candida glabrata, Candida parapsilosis, Candida tropicalis, and Candida krusei.67 C. albicans is the species most commonly isolated from patient material and is responsible for 50%-70% of episodes of Candida blood stream infections.6 In the USA, 95% of C. albicans isolated from clinical specimens are susceptible to fluconazole.⁵ C. glabrata is emerging as an important fungal pathogen, causing

15

10 5

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Culture day

approximately one-fifth of fungal BSI in North America. Susceptibility to fluconazole is variable⁵ but many infections can be successfully treated with high doses of fluconazole. C. parapsilosis is the third most common Candida species isolated from patients in North America and is the most common species found on the hands of health care workers. C. parapsilosis is associated with infections of intravenous catheters and other implanted devices and has the tendency to form biofilms. Most isolates are susceptible to fluconazole.5 Candida tropicalis is the fourth most frequent Candida associated BSI isolate recovered in North America, causing 7% of BSIs and appears to have increased virulence in patients with mucosal disruption. It is associated with BSI and invasive candidiasis in cancer patients. C. tropicalis has remained highly susceptible to fluconazole⁵, and prophylaxis with fluconazole in patients with neutropenia has proven to be protective against the development of C. tropicalis infections. In contrast, C. krusei causes only 2%-4% of all Candida-associated BSIs but is known to emerge in settings where fluconazole is used for prophylaxis. C. krusei is intrinsically resistant to fluconazole, but sensitive to the newer azoles and to the echinocandins.⁶

The guidelines from the Infectious Diseases Society of America (IDSA)⁴ recommend fluconazole for treatment of most serious *Candida* infections including

Fig. 2a. Species distribution worldwide of *Candida* infections 1997-2003



known candidemia and acute hematogenously disseminated candidiasis, empirical treatment of suspected disseminated candidiasis in febrile non-neutropenic patients, chronic disseminated candidiasis (hepatosplenic candidiasis), and urinary candidiasis. Fluconazole is widely used for prophylaxis of cancer patients undergoing chemotherapy and in some transplant patients, so fluconazole is not recommended as empiric therapy in these patients; rather use of the newer azoles, the echinocandins, or amphotericin B is suggested. Because fluconazole is well tolerated, effective against most clinically relevant *Candida* species, and inexpensive it has remained the drug of choice in many institutions for seriously ill patients with

candidiasis who have not received azole prophylaxis and who are not colonized with fluconazole-resistant strains of *Candida* species. Fluconazole is less costly than the newer agents¹⁰ (*See Table 1*) and its extensive use across a wide range of doses has led to a good understanding of the pharmacokinetics, pharmacodynamics and safety profile.

Table 1. Per day cost estimates for antifungaldrugs in US dollars (70 kg patient)

Fluconazole tablets	\$28
Fluconazole IV	\$148
Voriconazole IV	\$245
Amphotericin B	\$17
AmB lipid formulations	\$448-805
Caspofungin IV	\$301

Data from 2004 Drug Topics Redbook

There are good data to show that the MICs for fluconazole correlate very well with patient response. Over the last 20 years, fluconazole has been administered in a variety of settings and at a variety of doses. In a recent summary 7 of multiple trials involving 1295 patients, half of which had invasive candidiasis, the success rate was 85% for patients with susceptible isolates (MIC $\leq 8 \ \mu g/mL$), 67% for patients with isolates in which the MIC was 16 or 32

Fig. 2b. Distribution of fluconazole resistance (by disk diffusion) in *Candida* species worldwide 1997-2003



 μ g/mL (SDD), and 42% for patients with resistant isolates (MIC \leq 64 μ g/ mL); clearly demonstrating a strong correlation between susceptibility test results and clinical

outcome.

Antifungal susceptibility testing is often performed only by reference laboratories or laboratories that serve the larger hospitals. Sending out the isolate for testing delays reporting to the physician by several days to weeks, severely limiting the utility of the results. Even when the tests are performed locally, results are often not available to physicians for several days after isolation of the pathogen, limiting the usefulness of the information in clinical decision making. Thus antifungal susceptibility testing is seldom considered a routine test. [+]

(continued from page 5)

Recent addition of the fluconazole test to the VITEK® 2 menu has the potential to change this paradigm and will allow any laboratory with a VITEK® 2 or VITEK® 2 Compact to perform fluconazole susceptibility testing for Candida isolates with confidence. Analogous to the VITEK[®] 2 antimicrobial susceptibility testing cards, the fluconazole susceptibility test can be set up at the same time as the Yeast Identification card (YST) with minimal impact on work flow and results can be available within a mean of 13 hours.14,15

It is becoming increasingly clear that it is critical to decrease time to initiation of appropriate antifungal therapy to minimize mortality.^{8,9} It is also apparent that physicians are interested in obtaining susceptibility results and will use them to modify therapy.^{2,3} Availability of fluconazole susceptibility test results within a few hours to a day of isolation can guide therapeutic decisions and benefit patients. A susceptible result will allow physicians to transition patients empirically treated with amphotericin B, voriconazole, or the echinocandins to fluconazole, decreasing cost and/or exposure to toxicity. For patients initially treated with fluconazole, a susceptible result will confirm the initial choice of therapy and provide confidence in transitioning the patient to oral therapy and hospital discharge as appropriate.

¹⁻¹⁵ Please visit our web site at www.biomerieux-usa.com to view an expanded version of this article, including a complete listing of references, and to learn more about susceptibility testing of Candida species.

FIRST STOP: FORT STEWART, GA

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Flemington

The VITEK[®] 2 Compact in action. Part 1 of 3.

bioMérieux's VITEK® 2 Compact automates bacterial identification and antibiotic susceptibility testing (ID/AST) in small to mid-sized microbiology labs. These space-saving systems are designed to provide everything labs need for testing, in an easy-to-set-up and easy-to-operate format.

We recently spoke with some users of the system to get their perspective on the VITEK[®] 2 Compact in real-world settings. In future

issues, we'll head to Tell City, Indiana to meet Zack Blair, who set up the microbiology lab at Perry County Hospital, and to Tiffin, Ohio, where Janet Lane is the Microbiology Supervisor at Mercy Hospital of Tiffin.

This month we'll hear from Joe Laynor, Microbiology Supervisor at Winn Army Community Hospital in Fort Stewart, Georgia.

In the Army now.

Winn Army Community Hospital in Fort Stewart, Georgia is an army community hospital, with about 100 beds and a moderate sized lab. There are four technologists who work in the micro section, and we run a 1-shift micro lab. We've employed the VITEK® system for the last 12 years that I've been here – we had the Legacy for quite some time until we purchased the VITEK® 2 Compact. We've been using it for almost a year now.

The patient population we deal with can really vary. I think the unique thing is, because it's an army post, the soldiers here deploy all the time. They may come in originally from anywhere in the county, and they come back from all over the world. So we're not looking at an endemic



Joe Laynor and the microbiology team at Winn Army Community Hospital along with their Technical Consultant Madea Gordon.

population from just this area; we're looking at specimens from all over the world. For both the identification of an organism and the sensitivities it can certainly vary.

A good example of that is some of our MRSA rates have increased as soldiers come back from Iraq. We attribute this to being in that kind of environment and close quarters, where communityacquired MRSA can spread a lot more. It's sometimes challenging to track a trend when that trend may not be our local trend – it may be coming from another community or another country.

But we also have a retirement community here, so we see a lot of elderly patients, and we have family members of the soldiers, so we do see a diverse population.

Part of our focus in care now is listening more to what the

patients want. That's true for all hospitals, and an army hospital's no different; as a matter of fact we're trying to follow along the same lines as civilian hospitals. We're taking anything they have to say into consideration, and we're getting them actively involved in their own care, and they're getting the family members involved, too.

Living up to a Legacy.

Our Legacy system was over ten years old, so we started considering a change. Even though l've been very happy with the Legacy system – and actually, I've been around VITEK® probably the last 25 years – we certainly looked at other possibilities: what they offered and how it would meet our needs, which would work best. And we just felt a lot more comfortable with VITEK®, both with the results that we get and the way the system works.

bioMerieux's people were very important in helping us reach that comfort level. We worked with our Client Consultant Madea Gordon a lot in this process, and she was fantastic – very personable, and always here, making the trip way out here to visit with us and look over our requirements and our needs.

Some of the other companies we talked with weren't as responsive, which always leaves a bad taste in your mouth, and that helped make the decision. "We just felt a lot more comfortable with VITEK, both with the results that we get and the way the system works."

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Because I look at it this way: if they're not as interested in trying to sell us a piece of equipment, how are they going to be in maintaining it, servicing it, and responding whenever you have questions?

As far as set-up, Madea came here and actually worked with the techs in the in-house training, focusing on how to set it up, how to read the results and everything else to make interpretations. And, while you don't want to be calling or emailing constantly, we have done some of that, and tech support has been fantastic in helping us out, resolving issues.

A really nice little system.

The Compact 2 we really do like. It's a nice little system.

The Advanced Expert System has been a plus. The AES gives you a lot more explanations, if you look into your lab reports it goes into some depth about what it is that you're seeing and what's going on. It highlights any questionable areas. That's always a plus; especially for the techs who aren't as experienced. And it helps me when I'm getting the phone call at odd hours when they're looking at something and they need an explanation. It's easier to talk them through some of that than it was with the Legacy.

VITEK°2 —compact

There are certainly other things that are a plus. The fact that it's got *Strep. pneumonia* on there, that's a nice thing. And I like that overall there are fewer steps – now you've got the loader that actually loads the cards for you, and seals the cards, that's a nice step. Having less hands-on really makes a big difference.

Some other things are made a little easier – for instance, you can use the same suspension for gram positives and gram negatives; that eliminates confusion there from a possible mix-up. Having colorcoded pipettes, that helps, too. I think any time you can eliminate some procedures and steps, you also eliminate some errors.

We're very happy with the compact size of the instrument. We have limited counter space and it fits in nicely. We've got everything set up the way we like. It's been a really nice system.



NEW PRODUCT NOTIFICATION VITEK[®] 2 GRAM POSITIVE SUSCEPTIBILITY CARD

There is a new VITEK[®] 2 Gram positive Susceptibility Test card. This card is the AST-GP66 with Product #22175. The GP66 card incorporates two important new tests:

- The VRSA Screen Test that predicts the presence of a possible high-level vancomycin-resistant Staphylococcus aureus (VA MIC >16 μg/mL).
- The Cefoxitin Screen Test which has been shown to be an excellent predictor of oxacillin-resistance in Staphylococcus aureus.

We encourage customers who are using the AST-GP61 and the AST-GP63 card to move to the new GP66 card to take advantage of these tests.

Remember, VITEK[®] 2 customers must have Software Version 4.03 installed and VITEK[®] 2 COMPACT customers must have PC Software Version 2.01 (is being mailed in the first quarter of 2007) to run the GP66 card.

Here is the configuration of the new card:

AST-GP66	PRODUCT #22175
DRUGS	
Ampicillin	Nitrofurantoin
Penicillin	Oxacillin
Ciprofloxacin	Quinupristin/Dalfopristin (Synercid)
Clindamycin	Rifampin
Erythromycin	Streptomycin HL
Gentamicin	Cefoxitin Screen
Gentamicin HL	Tetracycline
Levofloxacin	Trimethoprim/Sulfa
Linezolid	Vancomycin
Moxifloxacin	VRSA Screen Test



2007 SHOWS AND CONFERENCES

Lab Info Tech Summit (LITS) Las Vegas, NV • Mar. 5-7

Society for Healthcare Epidemiology of America (SHEA) Baltimore, MD • Apr. 14-17

Clinical Virology Symposium Clearwater Beach, FL • Apr. 27-28

National Patient Safety Foundation (NPSF) Washington, DC • May 2-4

American Society of Microbiology (ASM) Toronto, Canada • May 21-25 – Booth #709 Save the Date: Tuesday, May 22, 2007 Annual Customer Appreciation Event

Association for Professionals in Infection Control (APIC) San Jose, CA • June 24-28

American Society of Health-System Pharmacists (ASHP) San Francisco, CA • June 25-27 – Booth #229

American Association for Clinical Chemistry (AACC) San Diego, CA • July 15-19

Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) Chicago, IL • Sept. 17-20

Infectious Disease Society of America (IDSA) San Diego, CA • Oct. 4-7

American College of Emergency Physicians (ACEP) Seattle, WA • Oct. 8-11

Association of Molecular Pathology (AMP) Los Angeles, CA • Nov. 7-10

American Society of Health-System Pharmacists (ASHP) Las Vegas, NV • Dec. 2-6 – Booth #3217

bioMérieux connection

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Please share your comments and suggestions with us through your local account manager or by emailing us at the address above. As always, we thank you for being a bioMérieux customer.

AST-GP66