

# bioMérieux *Connection*

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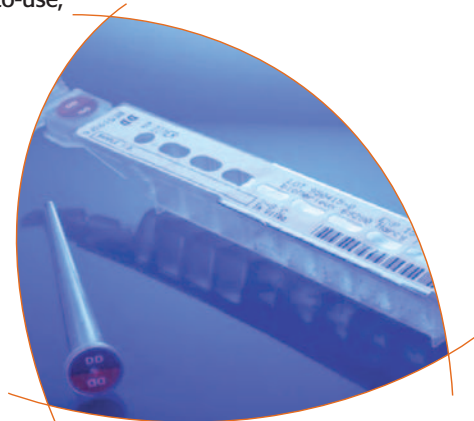
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## Exclusion of DVT and PE – a first! Only from bioMérieux

VIDAS® D-Dimer Exclusion™ is the first and only D-dimer assay to be cleared in the U.S. for exclusion of a diagnosis of both deep vein thrombosis (DVT) and pulmonary embolism (PE) when used in conjunction with a pretest probability assessment, and no other testing, in low-to-moderate probability outpatients. bioMérieux just received this extended clearance from the U.S. Food and Drug Administration (FDA), which adds PE to the existing DVT exclusion intended-use statement. DVT and PE are conditions that affect up to 3 million patients and kill up to 200,000 patients in the US annually, more than breast cancer and HIV combined.\*

The new name, **VIDAS D-Dimer Exclusion**, reflects the intended use of this "gold standard" assay and reminds laboratories and emergency departments that they

can use this product with the confidence of the claim. And remember, VIDAS D-Dimer Exclusion is the same great assay you have been used to, only with a more descriptive new name and expanded intended use. You still have the easy-to-use, single-dose format, automated ELISA results in under one hour, a well-validated, published cutoff, and CVs under 4%, with sensitivities and negative predictive values (NPVs) of >99%.\*



.....  
**Exclusion of  
DVT and PE  
continued on  
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## Attention API® Voice Response System users

**APIweb™** is replacing the **API®** Voice Response System. If you have used the **API** Voice Response System in the past, be sure to order your free Internet or CD version of **APIweb** now. Because of technological obsolescence, it is not possible to maintain the **API** Voice Response System beyond September 30, 2004. After September 30, the options for obtaining an interpretation of an **API** strip result are paper code books, **APIweb** Internet version or **APIweb** CD version. Customer service will be available to assist with technical questions and troubleshooting but will not be available to look up **API** codes. To ensure a smooth transition for your laboratory, please order your free Internet or CD version of **APIweb** as soon as possible.

**See details about  
APIweb on page 7**





## Integrated Solutions: The Combination to Unlock Your Potential

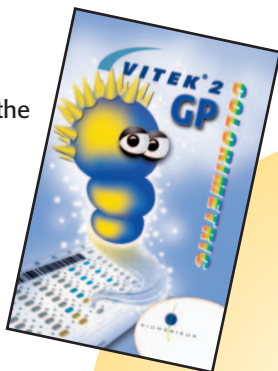
bioMérieux's exhibit booth theme at the 104th General Meeting of the American Society for Microbiology (ASM) was "Integrated Solutions: The Combination to Unlock Your Potential." Attendees were introduced to the key elements that make up our Integrated Solutions package – which effectively links microbiology, clinicians and the pharmacy to the data and results generated throughout key areas of the hospital for improved patient care and hospital-wide cost savings.

### STELLARA™

bioMérieux introduced STELLARA™, an integral part of our Integrated Solutions package. This multi-tiered, clinical decision support system brings BacT/ALERT® and VITEK® results together with patient antibiotic profiles for the pharmacist and clinician in real time. STELLARA gets actionable results to the right person at the right time.

### New VITEK® 2 Colorimetric Identification Cards

bioMérieux also previewed the new VITEK® 2 Colorimetric Identification cards, which give VITEK 2 the most extensive identification data base of any rapid bacterial identification system, an important benefit of bioMérieux's Integrated Solutions. Several ASM poster sessions documented the performance of these new cards. VITEK Colorimetric ID cards will be rolled out to customers between October 2004 and January 2005.



### New VITEK® 2 Compact

bioMérieux unveiled the new VITEK® 2 Compact ID/AST system. VITEK 2 Compact is an extension of the VITEK 2 family and is designed for low- to mid-volume laboratories. It is more automated than a VITEK 1, has Windows® software, uses the same disposables as VITEK 2, includes *Streptococcus pneumoniae* and *Stenotrophomonas maltophilia* testing and features the Advanced Expert™ System (AES). It will be available in the U.S. in mid-2005.



### New Observa™ Data Management for BacT/ALERT® 3D

Ease of use and flexibility are the hallmarks of the new Observa™ data-management system. Observa simplifies complex data management and provides a complete suite of tools that brings ease of use, convenience and flexibility to a new level for the laboratory.

### VIDAS® Data Station

Also premiering was the VIDAS® Data Station, our new PC-based CPU workstation with Windows® interface and a space-saving flat-screen monitor. Designed for the VIDAS 30 immunoassay system, VIDAS Data Station provides "load and go" workflow, unit-dose technology, quality results and reliability.

### Molecular Diagnostics

The new NucliSens® EasyQ Analyzer was on display, as were the FDA-cleared NucliSens CMV pp67 kits and the FDA-approved NucliSens HIV-QT. Also on hand was the highly popular NucliSens Basic Kit, which is an open format with amplification components for home-brew/laboratory-developed tests. NucliSens Analyte Specific Reagents (ASRs) for enterovirus were also exhibited.

### For Sepsis and DIC – the MDA® A2 Flag™

Laboratories and clinicians can now have an early warning of sepsis and disseminated intravascular coagulation (DIC) with bioMérieux's MDA® A2 Flag™ technology, which was shown at ASM for the first time. The MDA A2 Flag, in conjunction with a patient's APTT test, is an indicator that an abnormal waveform pattern has been identified which may be associated with a developing or clinically evident coagulopathy, such as is seen in sepsis or DIC.

### bioMérieux Knowledge Forums

For five years, bioMérieux has sponsored Knowledge Forums in our booth, with expert speakers on topics that have an immediate impact on the microbiology laboratory. This year the speakers and topics were:

Vincent LaBombardi, Ph.D., St. Vincent Hospital & Medical Center, New York, NY: "Resistance in Gram Positive Bacteria"



Margie Morgan, Ph.D.,  
Cedars-Sinai Medical Center,  
Los Angeles, CA: "Community  
Acquired Resistance"

Mike Broyles, Pharm.D.,  
Randolph County Medical Center,  
Pocahontas, AR: "Data Flow –  
PDA Use to Reduce Antibiotic Use"

Mike Dunn, Ph.D., Washington  
University School of Medicine,  
St. Louis, MO: "Strain Typing"

Janet Hindler, UCLA Medical  
Center, Los Angeles, CA:  
"NCCLS Updates"

Joseph Ketcherside, Jr., Ph.D.,  
TheraDoc, Salt Lake City, UT:  
"TheraDoc – Linking of  
Information"

Joan Barenfanger, Ph.D.,  
Pathology Associates of Central  
Illinois, Springfield, IL: "Rapid Viral  
Screening to Reduce Antibiotic Use"

Dennis Ernst, MT(ASCP), Center  
for Phlebotomy Education,  
Ramsey, IN: "Plastic Bottles –  
Lab Safety"

M. Sawcheuk, Joint Commission  
on Accreditation of Healthcare  
Organizations (JCAHO):  
"Infection Control Standards"

\*The appearance of a JCAHO speaker is in  
no way an express or implied endorsement  
of any bioMérieux products or services.  
JCAHO does not make any such  
endorsements and appeared solely for the  
purpose of disseminating information about  
its infection control standards.

### bioMérieux Satellite Symposium

For 26 years bioMérieux has been  
sponsoring knowledge symposiums  
that keep microbiologists abreast  
of the latest advances and  
challenges in infectious disease  
diagnostics.

This year our keynote  
speaker, Daniel  
Burrus, CEO of  
Burrus Research  
Associates Inc.,  
spoke on "The Future  
of Healthcare." Burrus  
is one of the world's leading  
technology forecasters and  
strategists and is the author of six  
books. He has established a  
worldwide reputation for  
predicting the future of  
technological change and its  
impact on the business world.

Joseph John, MD, Ralph Johnson  
Medical Center, Charleston, SC,  
provided a very interesting  
"Update on Resistance."

Also, Harald Rinde, MBA, MD,  
BioBridge Strategies, San Diego,  
CA, gave everyone very interesting  
insights into the "Global Burden  
of Infectious Diseases."



### bioMérieux Customer Appreciation Night

We would like to thank  
everyone who attended our  
Customer Appreciation party at  
New Orleans' popular House of  
Blues, with music by the Rockin'  
Dopsie band.

### VITEK® 2 User's Meeting

Thank you to all who attended  
the Second Annual VITEK® 2  
User's Meeting, where our  
customers heard the latest on the  
VITEK 2 system. This year's topics  
and speakers were:

Paul Schreckenberger, Ph.D.,  
University of Illinois, Chicago, IL:  
"VITEK 2 GN Colorimetric  
Identification"

Robyn Atkinson, Ph.D.,  
Washington University School of  
Medicine, St. Louis, MO:  
"Comparison of Gram Positive  
Identification Systems – VITEK 2  
Colorimetric ID, VITEK and  
MicroScan (Dade Behring)"

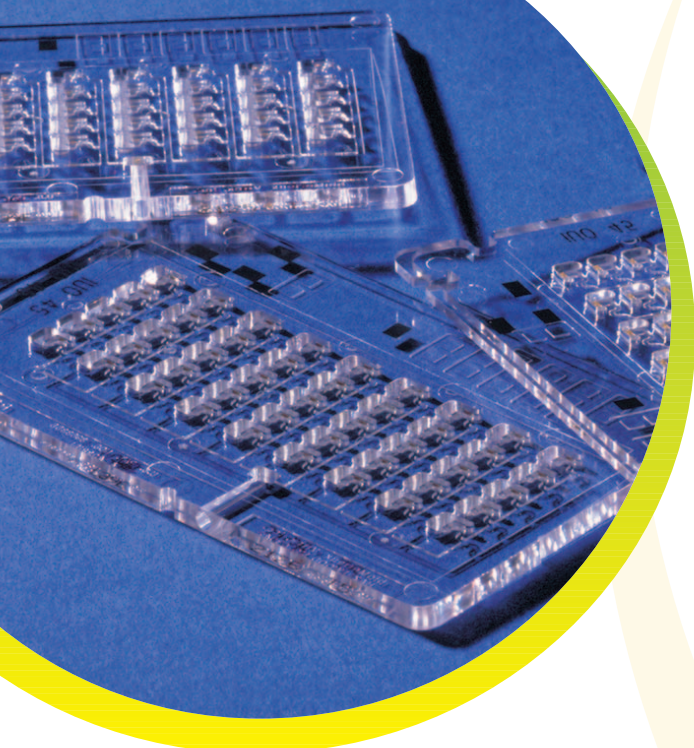
Doug Flammang, VITEK/VITEK 2  
Program Director, bioMérieux Inc.,  
St. Louis, MO: "VITEK 2 – Today  
and the Future"



## One hour free C.M.E. credit for meningitis education

Learn more about diagnosing meningitis and get one hour of free  
continuing medical education credit instantly. Simply log on to  
[www.medsite.com](http://www.medsite.com) where you will find Medsite® Educational Group's  
"Interactive Grand Rounds™." Look in the "Pediatrics" section  
and select "Management of Enteroviral Meningitis in  
8-year-old Boy."





## New VITEK® 1 susceptibility test cards

Two new VITEK® 1 Gram negative susceptibility cards are now available. Both cards have gatifloxacin in place of levofloxacin. The new panel configurations are as follows:

### Now available:

#### GNS-144 V4629 Gram neg

Ampicillin
Ampicillin/Sulbactam
Aztreonam
Cefazolin
Cefepime
Cefotaxime
Ceftazidime
Ceftriaxone
ESBL Confirmatory Test
Gatifloxacin
Gentamicin
Imipenem
Nitrofurantoin
Piperacillin/Tazobactam
Tobramycin
Trimethoprim/Sulfamethoxazole

### Now available:

#### GNS-145 V4630 Gram neg

Amikacin
Ampicillin
Ampicillin/Sulbactam
Aztreonam
Cefazolin
Cefepime
Ceftriaxone
Ciprofloxacin
ESBL Confirmatory Test
Gatifloxacin
Gentamicin
Imipenem
Nitrofurantoin
Piperacillin/Tazobactam
Tobramycin
Trimethoprim/Sulfamethoxazole

## Correction for VITEK® 1 GPS-111 Gram positive card

Our last issue listed an incorrect antibiotic on the VITEK® 1 GPS-111 (V4483) susceptibility test card: moxifloxacin. It should have listed levofloxacin. The correct card configuration follows:

#### GPS-111 V4483 Gram pos

Beta-lactamase
Cefazolin
Clindamycin
Erythromycin
Gatifloxacin
Gentamicin
Gentamicin 500
Levofloxacin
Linezolid
Nitrofurantoin
Oxacillin
Penicillin
Quinupristin/Dalfopristin (Synercid®)
Rifampin
Streptomycin 2000
Tetracycline
Trimethoprim/Sulfa
Vancomycin

### Coming August 1:

Also, in response to requests from numerous laboratories, bioMérieux has configured two new VITEK® 1 cards, one Gram negative and one Gram positive. They will be available August 1, 2004.

#### GNS-209 V4635 Gram neg

Amikacin
Amoxicillin/Clavulanic Acid
Ampicillin
Cefazolin
Cefepime
Ceftriaxone
Cefuroxime
Ciprofloxacin
ESBL Confirmatory Test
Gentamicin
Imipenem
Levofloxacin
Nitrofurantoin
Piperacillin/Tazobactam
Tobramycin
Trimethoprim/Sulfamethaxazole

#### GPS-112 V4636 Gram pos

Amoxicillin/Clavulanic Acid
Ampicillin
Beta-lactamase
Cefazolin
Ciprofloxacin
Clindamycin
Erythromycin
Gentamicin
Gentamicin High Level Synergy
Linezolid
Nitrofurantoin
Oxacillin
Penicillin
Streptomycin High Level Synergy
Tetracycline
Trimethoprim/Sulfamethaxazole
Vancomycin

For other available VITEK 1 cards, refer to *bioMérieux Connection* May 2004 issue, or to the 2004 *Clinical Products Price List*, both of which you may find on our website at [www.biomerieux-usa.com](http://www.biomerieux-usa.com).



# New VITEK® 2 susceptibility test cards

Three new VITEK® 2 susceptibility test cards are now available for ordering. Two are Gram positive and one is Gram negative.

## Gram positive cards

### AST-GP61 (Product Number 22076)

The AST-GP61 card is for antimicrobial susceptibility testing of *staphylococci*, *enterococci* and Group B *Streptococcus*. The new AST-GP61 card configuration is similar to the AST-GP55 card. The difference is the addition of linezolid, quinupristin-dalfopristin (Synercid®), gatifloxacin and moxifloxacin, and the elimination of ciprofloxacin, norfloxacin, and ofloxacin.

### AST-GP62 (Product Number 22077)

The AST-GP62 card is the new *Streptococcus pneumoniae* card. It contains all the antibiotics that were on the AST-GP56 card as well as levofloxacin, moxifloxacin, and linezolid.

bioMérieux hopes that this notice gives all our customers the necessary time to make laboratory information system (LIS) changes and to notify clinicians of the expanded antibiotic reporting the new cards offer.

AST-GP55 and the AST-GP56 will be discontinued after December 31, 2004.

## Gram negative card

### AST-GN11

The AST-GN11 card (Product Number 22082) is very similar to the AST-GN04 and the AST-GN09 cards. The primary difference is that the new AST-GN11 card substitutes gatifloxacin for levofloxacin.

### AST-GP61 22076 Gram pos

Ampicillin
Ampicillin/Sulbactam
Cefazolin
Chloramphenicol
Clindamycin
Erythromycin
Gatifloxacin
Gentamicin
Gentamicin High Level Synergy
Levofloxacin
Linezolid
Moxifloxacin
Nitrofurantoin
Oxacillin
Penicillin
Quinupristin/Dalfopristin (Synercid®)
Rifampin
Streptomycin High Level Synergy
Tetracycline
Vancomycin

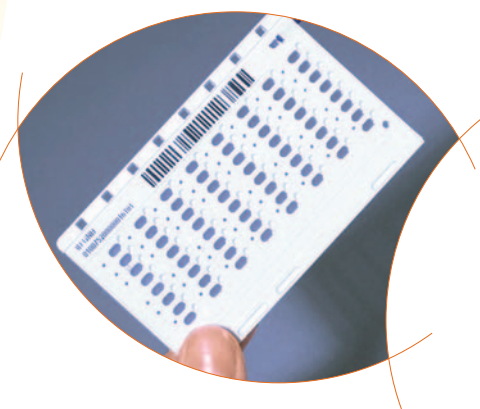
### AST-GP62 22077 Gram pos *Streptococcus pneumoniae*

Cefotaxime
Ceftriaxone
Chloramphenicol
Erythromycin
Levofloxacin
Linezolid
Moxifloxacin
Ofloxacin
Penicillin
Tetracycline
Trimethoprim/Sulfamethoxazole
Vancomycin

### AST-GN11 22082 Gram neg

Amikacin
Ampicillin
Ampicillin/Sulbactam
Aztreonam
Cefazolin
Cefepime
Cefotetan
Ceftazidime
Ceftriaxone
Cefuroxime
Ciprofloxacin
Gatifloxacin
Gentamicin
Imipenem
Meropenem
Nitrofurantoin
Piperacillin/Tazobactam
Ticarcillin/Clavulanic Acid
Tobramycin
Trimethoprim/Sulfamethoxazole

For other available VITEK 2 cards, refer to the 2004 *Clinical Products Price List*, which you may find on our website at [www.biomérieux-usa.com](http://www.biomérieux-usa.com).



## Confirmatory ESBL Test for VITEK® 2

bioMérieux has received FDA 510(k) clearance for our confirmatory ESBL test for VITEK® 2. This six-well test includes cefotaxime, ceftazidime and cefepime — with and without clavulanic acid. It can be used for *K. pneumoniae*, *K. oxytoca*, and *E. coli*.

When compared to the reference method, the VITEK 2 ESBL

confirmatory test shows 97.7% agreement.\*

Look for new VITEK 2 card configurations with this test in an upcoming edition of *bioMérieux Connection*. Cards with the VITEK 2 ESBL confirmatory test will be available later this year.

\*Data on file at bioMérieux.

## No more blue ice!

bioMérieux is pleased to inform you that it is no longer necessary to ship VITEK® 1 or VITEK® 2 test cards with blue ice. Shipping and in-house stability studies have indicated that the products are stable without the additional cooling effects of the blue ice. bioMérieux will continue to ship VITEK 1 and VITEK 2 cards overnight to reach all U.S. customers within 24 hours.



## VITEK® 1 card code changes

bioMérieux is changing the card codes on some VITEK® 1 cards. We have found that some cards have codes (Figure 1) that, in rare instances, contribute to the instrument reading the card as a different type than the one tested. For example, a GPS-107 card might be confused with a GPS-105 card.

You will receive a notice with each shipment of VITEK 1 cards instructing you to enter the package insert barcodes into the Flex Panel Entry Program. In addition to this notice, each box will have a label that alerts you to the new card code. This is necessary for your VITEK 1 system to recognize the new card code. It will be a one-time procedure and will have no impact on your LIS, DataTrac™ or bioLIAISON®. We hope the added security this change brings offsets any inconvenience it may cause.

The following cards are being assigned new card codes:

GPS-105	GNS-141
GPS-106	GNS-142
GPS-107	GNS-143
GNS-113	GNS-144
GNS-115	GNS-145
GNS-121	GNS-203
GNS-124	GNS-204
GNS-128	GNS-206
GNS-129	

**Instructions for using Flex Panel Entry:** From the Main Menu select VITEK=>Setup=> Flex Panels or refer to your VITEK manuals.

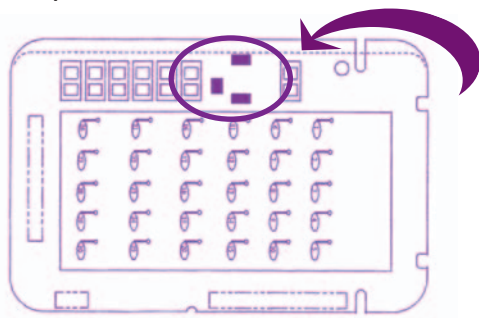


Figure 1: VITEK 1 Card Code

## VIDAS® VZG study results are now available

bioMérieux performed an external study last year to verify the performance of the VIDAS® VZG (Varicella Zoster IgG) assay (Product Number 30217). The results have been presented and are now available.

**Title:** In Vitro Diagnostic Kit Performance Verification as a Quality Control Metric

**Authors:** M. Dobec, Medica, Zurich, Switzerland; G. Munk, Hackensack University Medical Center, Hackensack, NJ; and D. Witt, bioMérieux, Durham, NC

**Presented:** 20th Annual Clinical Virology Symposium, April 25-28, 2004, Clearwater, FL

**Overall results:** VIDAS VZG performed very well in both immunocompetent and immunocompromised patient samples. Results are consistent with those described in the current package labeling. Using multiple and varied tests to define true immune status is essential to resolving perceived discrepant results.

Your patience during this process is very much appreciated. You can have confidence in the VIDAS VZG test results obtained in your laboratory, as this assay has a sensitivity of 99.5% and a specificity of 98.1% compared to industry-accepted reference methods.

The poster presentation is available for your review at [www.biomerieux-usa.com](http://www.biomerieux-usa.com) in the Technical Library in the VIDAS section.



## Introducing the new VIDAS® QCV strip

bioMérieux is pleased to introduce a new Quality Control test strip for VIDAS® instruments. Quality Control VIDAS QCV, Product Number 30706, is now available for you to use to perform an operational test of the VIDAS and miniVIDAS® instrument pipette mechanisms. Abnormal operation of these mechanisms may affect results of biological tests.

VIDAS QCV is also intended for checking that the optical system is capable of measuring high fluorescence levels. This new strip can distinguish the location of a dysfunction. VIDAS QCV strips also are used whenever bioMérieux Field Service Engineers perform any type of maintenance on your VIDAS instrument, including any preventive maintenance. The strips are easy to use and results are available in only 20 minutes.

This new VIDAS QCV (Product Number 30706) replaces VIDAS QCT (Product Number 30500). Please update your ordering records.

## Would you like more D-Dimer education?

For more in-depth information about advanced D-dimer assays, check out an article by bioMérieux's Susan L. Taylor, MS, MT(ASCP), MBA. "Stop the Clots: Diagnosing Venous Thromboembolism" appears in the *Advance for Medical Laboratory Professionals* March 2004 issue, or you can read it online at [www.advanceformlp.com](http://www.advanceformlp.com). In the "Search Articles" browser box, type in "D-Dimer."

## Exciting new tool for API® users

bioMérieux is pleased to announce the availability of **APIweb™**, an electronic code book that makes **API®** even easier to use. **APIweb** allows you to access the interpretation of **API** strip results instantly. Profile numbers can be accessed on **APIweb** either through the Internet or, for those without Internet access, by CD-ROM.

Every 2.5 seconds, an **API** strip is inoculated somewhere in the world. The **API** product line revolutionized microbiology testing a generation ago by miniaturizing and standardizing conventional biochemical tests. **API** strips are still found today in almost every clinical, veterinary and industrial microbiology laboratory in America.

**APIweb** means the end of searching for profiles in bulky paper codebooks or calling the Voice Response System. **APIweb** contains the databases for all your **API** strips. Updates to databases on the Internet version will be made periodically at no charge.

bioMérieux is happy to provide **APIweb** to our clinical customers FREE OF CHARGE! When ordering your **API** products, let our Customer Service representatives know which version of **APIweb** you would prefer: the Internet version (Product Number 40011) or the CD-ROM version (Product Number 40012). We are confident this tool will be a valuable addition to your laboratory.

## Free wall poster of the coagulation cascade

It's complex. It's fascinating. It's the *coagulation cascade*!

From initial vascular injury to the final cross-linked fibrin clot, this colorful wall poster details the physiological hemostasis mechanism, including intrinsic and extrinsic pathways. The 2' x 3' poster also lists the molecular properties of proteins in blood coagulation and fibrinolysis. To order your poster, email us at: [bioMerieux.connection@na.bioMerieux.com](mailto:bioMerieux.connection@na.bioMerieux.com) and ask for the CoaguChart.





# IMPORTANT NOTICE

## for BacT/ALERT® users performing platelet quality control testing

The performance of BacT/ALERT® BPA and BacT/ALERT BPN bottles using “delayed vial entry” has not been established. Therefore, in the interest of patient safety and compliance with the intended use of the BacT/ALERT BPA and BacT/ALERT BPN media package inserts, bioMérieux would like to reiterate the following as it relates to inoculation and transport of inoculated BacT/ALERT BPA and BPN bottles.

The package inserts, which were prepared from data collected, submitted and cleared by the FDA for quality control testing of leukocyte reduced apheresis and leukocyte reduced single units of whole blood platelet concentrates, specifically state:

*"BacT/ALERT BPA [BPN] bottles are used with the BacT/ALERT Microbial Detection systems for quality control testing of leukocyte reduced apheresis platelet (LRAP) units, and leukocyte reduced single units of whole blood platelet concentrates (WBPC)."*

The package inserts also state:

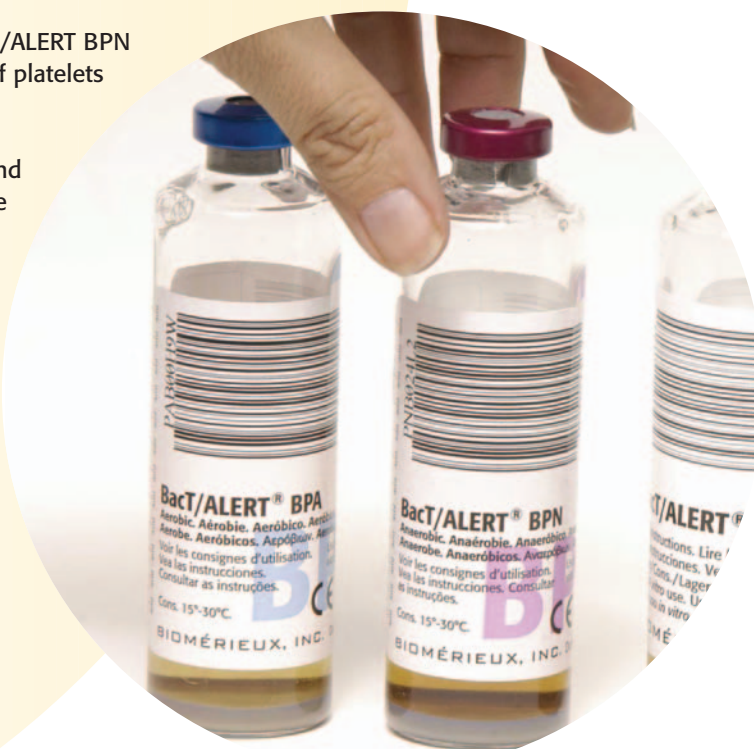
*"After collection, promptly transport the inoculated bottle to testing laboratory and test immediately."*

In data collected from platelet studies and submitted to the FDA, “promptly” refers to the time it takes for the laboratory staff to inoculate the bottle and transport it to a Bact/ALERT instrument located on site.

False negative test results may occur because of growth of bacteria between the time bottles are inoculated and subsequent loading of the bottles into the instrument if the growth is not sufficient to trigger the “threshold” algorithm **and** the organisms have entered the stationary phase in their growth cycle.

A false negative result also can occur when the BacT/ALERT BPN Anaerobic Culture Media for quality control testing of platelets has been excluded. BacT/ALERT BPN is the primary mechanism for the detection of strict anaerobic microorganisms, such as *Propionibacterium acnes* and *Peptostreptococcus spp.* This media may also provide quicker detection of some aerobic organisms and may facilitate subculture of *Streptococcus pneumoniae* where the organism growth in the aerobic bottle has auto-lysed. As a reminder, the package inserts state:

*"For best overall recovery when culturing platelet specimens it is **strongly** recommended that more than one type of culture bottle be utilized (e.g. one aerobic and one anaerobic)."*





# Platelet quality control – frequently asked questions

## Why is platelet quality control testing important?

Platelets are stored at room temperature and are therefore prone to contamination. Any bacteria present in the sample will grow (or at least remain viable). Bacteria are most commonly introduced during collection, or they may be present in the donor bloodstream. As with blood cultures, proper site preparation is the first line of defense against contamination and is very important.

However, unlike blood cultures, a contaminated sample can have dire consequences for the recipient of the contaminated unit. It is estimated that one in every 2000 platelet units is contaminated, and in the U.S. alone approximately 40-300 deaths occur each year from contaminated platelets. Platelet contamination is the most common cause of death due to transfusion-associated infection in the United States, and platelets are now considered the greatest threat for transfusion-transmitted disease.\*



## What are the differences between BacT/ALERT® SA & SN and BacT/ALERT BPA & BPN?

The BacT/ALERT BPA and BPN Culture Media are the ONLY bottles that are FDA-cleared and labeled for the platelet testing application. The Standard Clinical Culture Media bottles (BacT/ALERT SA and SN) were originally designed for recovery of microorganisms from blood. In addition to the quality control performed by bioMérieux on the SA and SN bottles, the BPA and BPN bottles are held in quarantine for an extended period of time and subjected to significantly enhanced quality control processing before release for sale.

## What are the consequences of using BacT/ALERT SA & SN rather than BPA & BPN?

Customers who choose to use the Standard Clinical Culture Media (BacT/ALERT SA and SN) for culturing platelet specimens are using those bottles "off-label" (i.e., outside the intended use as stated in the package inserts). BacT/ALERT SA and SN bottles are sold by bioMérieux only for the intended use stated on the package inserts, and bioMérieux assumes no responsibility or liability for any "off-label" use. "Off-label" users of BacT/ALERT SA and SN bottles for quality control testing of leukocyte-reduced apheresis and whole blood platelets may face additional risks when FDA-cleared and validated bottles and procedures have been made available. Associated regulatory risks of "off-label" use can be avoided through implementation of the BPA and BPN bottles.

Customer Support for quality control testing of leukocyte-reduced platelets is provided to customers who are using the BPA and BPN Culture Media for their testing. It is important to note that bioMérieux, as an FDA-regulated facility, is not permitted to offer technical support for "off-label" use of our products.

## Product and Accessory Ordering Information

### Product Numbers for BacT/ALERT Media Bottles

279018	BacT/ALERT BPA	100/case
279019	BacT/ALERT BPN	100/case

### Product Numbers for Platelet Sampling Devices

Charter Medical		
03-220-TM	Transfer set with 100 mL bag and needle assembly	48/case
03-220-AC	Transfer set with 100 mL bag and adapter cap	24/case
03-220-UNC	Transfer set with 10 mL syringe and needle assembly	24/case
03-220-BC	Transfer set with 10 mL syringe and adapter cap	24/case
Gambro BCT		
70050	Blood component sampling set	30/case

## Improving quality is the aim of a growing number of initiatives

What is the laboratory's role in improving performance? Initial therapies, initial procedures and admittance are based upon a clinician's judgment or upon care pathways currently in place. Laboratory data allow these decisions to be validated or adjusted based on data and more appropriate or less costly alternatives put in place. Turnaround time for results is critical. This means far more than posting the results to the laboratory information system (LIS). Getting the right data to the right person at the right time has been proven to reduce costs and improve outcomes. Improved outcomes can mean more reimbursement in the future as well as an enhanced reputation.

In the last newsletter, we discussed the challenge and opportunity resulting from medical errors. The challenge is how to modify the products and processes to take advantage of the opportunity. The opportunity is realized as a result of the axiom, "When quality goes up, costs go down!" Improving quality has the obvious benefit of improved patient outcomes, but these improved outcomes translate into economic benefits through reduced length of stay and more cost-effective and appropriate therapies as well as avoidance of other procedures and treatments.

The intent to improve patient safety is evident in the number of initiatives being proposed. Efforts to control health-care costs have moved from cutting full-time equivalents (FTEs) and operational costs to redesigning the processes, which offers far greater potential savings. These new products and processes also are being driven by the concept of evidence-based medicine (EBM). New diagnostic and treatment

algorithms are being created using a best-practice approach supported by data on patient outcomes.

Unlike past efforts, some new proposals are linked to a difference in reimbursements. Numerous third-party payers, in partnership with health-care institutions, are piloting projects designed to reward improved patient outcomes. Listed below are just a few of the pilots and programs currently in action or discussion.

- The Center for Medicare Services (CMS) and Premier Group Purchasing Organization will be measuring quality performance for five disease states:
  - Heart disease
  - Heart failure
  - Pneumonia
  - Coronary artery bypass grafts
  - Hip and knee replacements
- 279 Hospitals (Premier and non-Premier Affiliates) have enrolled:
  - Hospitals ranking in the top 20% of quality for those clinical areas will be financially rewarded
  - The quality thresholds will be set in year one
  - Hospitals ranked in the top 10% will receive a 2% increase in Medicare reimbursement
  - Hospitals in the next 10% will receive a 1% increase in Medicare reimbursement
- By year three, hospitals that do not achieve quality thresholds established in year one will have reimbursement cuts:
  - A 1% reduction in reimbursement for hospitals with performance below the 9th decile
  - A 2% reduction in reimbursement for hospitals with performance below the 10th decile



- Aetna Insurance of Dallas will be:
  - Recognizing hospitals that show "improvement"
  - Encouraging employers to create market incentives
  - Rewarding hospitals for implementing ongoing error-reduction practices - particularly LeapFrog™ Safety Standards
- Michigan Health and Safety Coalition will be:
  - Posting, for the second year in a row, the status of seven major medical conditions
  - Making the results available for intensive care units online at [www.mihealthandsafety.org](http://www.mihealthandsafety.org)
- New Jersey Intensive Care Unit (ICU) Project, under their Quality Institute, created:
  - An initiative to address serious adverse events that occur in approximately 17% of all ICU patients nationwide or the 1.7 errors committed on each ICU patient daily. Goals include improving quality by:
    - Reducing deaths
    - Reducing infections
    - Reducing average length of stay in the ICU for participating hospitals

These pilot projects and programs will offer benchmarks and comparisons among institutions for the targeted syndromes. Further comparisons will be made as a result of various web-based reporting schemes. One example comes from Pennsylvania Patient Safety Reporting System (PA-PSRS). Under Act 13, all Pennsylvania-licensed hospitals, birthing centers and ambulatory surgical facilities must submit reports of those events to the PA-PSRS. More than 400 facilities are subject to Act 13 requirements. The PA-PSRS program will receive and tabulate those reports and analyze the data to identify trends and suggest improvements to enhance patient safety. As consumers and payers examine these ratings, a hospital's image and brand can potentially change.

## Exclusion of DVT and PE continued from page 1

### The importance of sensitivity

The measurement of D-dimer levels can be used as a non-invasive tool to exclude outpatients with suspected DVT and PE, thereby avoiding further invasive and more costly examinations. However, the sensitivity of a D-Dimer test is of key importance because even a slight decrease in sensitivity can have serious consequences for the patient, who may subsequently not receive appropriate treatment. bioMérieux's VIDAS D-Dimer Exclusion has been validated by extensive published studies involving more than 10,000 patients worldwide. The results of these studies have contributed to the evolution of diagnostic practices within hospitals, and the test performance, in terms of sensitivity and negative predictive value, has positioned VIDAS D-Dimer Exclusion as the reference test for the exclusion of venous thromboembolism.

### Most-referenced quantitative D-dimer assay

Moreover, VIDAS D-Dimer Exclusion is the most-referenced quantitative D-dimer assay on the market and is supported by multiple prospective management studies. In these studies, physicians adapt their decision to stop further investigations on the basis of a clinical pretest probability score and a D-dimer result lower than the clinical decision cut-off (< 500 ng/ml). The most recent prospective management study, led by Dr A. Perrier and colleagues and published in *The American Journal of Medicine* (2004; 116:291-29), included 965 patients with suspected pulmonary embolism. The level of sensitivity obtained with VIDAS D-Dimer Exclusion in this study was 100%.

### The importance of management studies

Management studies have yielded data that have enabled bioMérieux to obtain FDA clearance for this D-dimer, in conjunction with a PTP model, for the exclusion of DVT and PE in outpatients. VIDAS D-Dimer Exclusion is the only test on the market that is validated and cleared by the FDA for outpatients with a low or medium pretest probability score to safely exclude a diagnosis of DVT or PE.

\*See package insert.

\*\*Perrier A, et al. Non-invasive diagnosis of venous thromboembolism in outpatients. *Lancet*. 1999; 353: 190-195.

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