

TREK TIMES

THE VERSATREK® SYSTEM GOES “CARIBBEAN” AND GETS GREAT RESULTS!

By Les Stutzman, Director of Global Marketing, TREK Diagnostic Systems

Our newest VersaTREK distributor, Bio-Nuclear Inc. of Puerto Rico, recently sold and placed their first VersaTREK instrument. A VersaTREK 240 model was placed in Metropolitan Hospital, which is located near San Juan, Puerto Rico.

Metropolitan Hospital is a 200-bed facility, making it a relatively large hospital in Puerto Rico, where the largest of their 45 hospital system is approximately 400 beds.

While Puerto Rico is for all intents and purposes a “separate country”, VersaTREK and Sensititre® placements go through a distributor, rather than direct, as is the case for the rest of the United States. However, Puerto Rican citizens very much consider themselves part of the United States. As a commonwealth, they are entitled to the same benefits as any other U.S. citizen.

We were fortunate enough that Metropolitan Hospital shared their first set of data results using the VersaTREK system with us.

Prior to utilizing the VersaTREK instrument in

their lab, Lizaida Cruz, Microbiology Supervisor, and her staff performed a small but complete validation study using an established set of controlled seeded cultures in addition to a select number of parallel blood culture comparison studies between VersaTREK and their prior blood culture system, the Bactec 9240 from BD. The evaluation performed had to prove the following two points before Ms. Cruz would be satisfactorily assured that moving to the VersaTREK instrument wouldn't compromise accuracy or performance in her selection of automated blood culture instrumentation.

- Would the REDOX® media support the growth of organisms (including yeast, anaerobes, aerobes, and fastidious organisms) commonly seen in their patient population?
- Would the instrument detect, in a timely fashion, the majority of the pathogenic organisms from blood cultures which contain these organisms?

The answer to those two questions was a resounding and unqualified YES!

The VersaTREK Automated Microbial Detection System was able to detect 18 out of 32 organisms faster than Bactec in the seeded study. In fact, Ms. Cruz noted that VersaTREK was able to detect organisms from 1 to as many as 11 hours faster than Bactec!

In the parallel study there was 100% agreement between

the two systems with the VersaTREK system detecting the positive bottle faster than BACTEC by more than 5 hours!

We look forward to a long and continued relationship with both Bio-Nuclear and Metropolitan Hospital.

Organism	VTI TTD	BACTEC TTD
<i>S. aureus</i>	12.2	17.55
<i>S. epidermidis</i>	20.2	28.49
<i>P. aeruginosa</i>	15.3	17.55
<i>S. pneumoniae</i>	13.7	17.55
<i>C. albicans</i>	15.2	18.18
<i>N. meningitidis</i>	17.4	22.35
<i>B. broncheseptica</i>	17.43	17.55
<i>S. aureus (MRSA)</i>	16	18.36
<i>E. coli (ESBL)</i>	12.9	13.23
<i>Salmonella sp.</i>	11.5	18.18
<i>A. baumannii</i>	11.4	13.07
<i>S. haemolyticus</i>	13	13.74
<i>E. faecalis (VRE)</i>	9.6	10.56
<i>E. faecium</i>	11.6	14.78
<i>B. cepacia</i>	16.9	18.36
<i>S. pyogenes</i>	13.9	17.55
<i>H. paraphrophilus</i>	25.9	36.18
<i>C. krusei</i>	12.1	13.27

WHY THE SENSITITRE® SYSTEM IS THEIR FIRST CHOICE!

"Sensititre truly sets the global standards for dry microbroth dilution method for susceptibility testing in the veterinary diagnostic industry. Laboratories all over the world choose to implement the Sensititre system due to the selection of antimicrobial agents, customization options and ability to automate and provide excellent results."

Dr. William Fales
University of Missouri, College of Veterinary Medicine

"The Sensititre ARIS® 2X system provides the laboratory with an automated platform for large volume susceptibility testing. Using a microtiter plate format with traditional doubling-dilutions of antimicrobials, the laboratory can efficiently generate accurate MIC's for aerobic, gram-positive and gram-negative bacteria, including fastidious organisms. The extensive number of available antimicrobials and reference based MIC methodology employed by the Sensititre system, has allowed my laboratory to consolidate most of our susceptibility testing to this system and eliminated the need to maintain costly supplemental testing methods."

Dr. Kirk Doing
Affiliated Laboratory Inc., Eastern Maine Healthcare
Bangor, Maine

VERSATREK® PLATELET BACTERIAL DETECTION

By DeAna Dziak, Product Manager, TREK Diagnostic Systems

"The VersaTREK Microbial Detection System offers a highly unique and sensitive comprehensive detection system used for the recovery of bacteria in blood and sterile body fluids that can also be used for the detection of bacteria in platelet components."

The most common transfusion-associated infectious risk in the United States today is bacterial contamination of platelet components¹. The presence of bacteria in platelet products can be detrimental to the patient in which those tainted platelets were infused. While there exists numerous strategies to detect the presence of bacteria in platelet products, the difficulty arises in that the bacteria in the products are difficult to detect because of the small quantity in which they are generally present in the testing inoculum. In order to recover the organisms the strategy used must be highly sensitive.

In December 2002, a new CAP standard was issued to laboratories that asked the question, "Does the laboratory have a system to detect the presence of bacteria in Platelet components" (TRM. 44955)?² In March 2004, the American Association of Blood Banks (AABB) required a combination of strategies both to limit the

initial inoculation of bacteria into the blood component and to detect the subsequent growth of bacteria during room temperature platelet storage¹.

The VersaTREK Microbial Detection System offers a highly unique and sensitive comprehensive detection system used for the recovery of bacteria in blood and sterile body fluids that can also be used for the detection of bacteria in platelet components¹.

In 2004, Walter Reed Army Medical Center designed a protocol in accordance with AABB Association Bulletin #03-12 to validate the ability of VersaTREK to detect platelet contamination in apheresis. Validation of the system went very well and their data suggested that VersaTREK is extremely sensitive to low numbers of organisms and meets the intent of the AABB guidelines to reduce the transfusion of bacterially contaminated platelets².

If you would like additional information or have any questions regarding this procedure please visit TREK's website (www.trekds.com) and/or contact us at 800-871-8909 ext. 104.

¹Validation of the VersaTREK Blood Culture Detection System for Detection of Bacterial Contamination of Platelets, R. Gonzalez et al. Presented at AABB, October 2004.

²Platelet Bacterial Contamination & Detection-2004 AABB Annual Meeting & EXPO, R. Yomtovian, MD, University Hospitals of Cleveland and Case Western Reserve University

THE VERSATREK® SYSTEM GETS ANOTHER ONE!

By DeAna Dziak, Product Manager, TREK Diagnostic Systems

Many thanks to Verna Morton and her staff at Cox Health Center in Springfield, Missouri for notifying TREK Diagnostic Systems of another unusual fastidious organism their VersaTREK Microbial Detection System found in two blood culture bottles in only 1 day! The organism found this time was *Anaerobiospirillum succiniciproducens*, a motile Gram-negative spiral bacillus with bipolar tufts of flagella.

This fastidious organism is rarely a causative agent of bacteremia in humans, however when encountered it is generally from those that are immunocompromised. This organism actually resides in feline and canine feces and was first discovered in 1976 by Davis et. al.¹

The patient in this case was brought to the emergency room after complaining of abdominal pain and GI bleeding, in addition to abdominal distention. Two sets of blood cultures were drawn. The REDOX 1® bottle of the latter drawn set signaled at 24.4 hours and the REDOX 2® bottle of the same set signaled at 28.2 hours. Initially the tech thought this might be *Campylobacter*. However the morphology was more spiral rather than “sea-gull” shaped and the bacteria stained well with safranin (something generally not seen with *Campylobacter*). The blood cultures were subbed onto blood and chocolate agars and incubated aerobically, anaerobically and in a microaerophilic environment. After three days the agar plates did not yield any

growth. The blood culture bottles were sent to the Mayo Clinic where molecular testing was performed along with electron microscopy showing the bipolar tufts of flagella which confirmed that this was an *Anaerobiospirillum succiniciproducens*.

Unfortunately the patient in this case succumbed to the infection. Some documented cases have demonstrated full recovery when treated with cefuroxime, tetracycline, and chloramphenicol.

With its unique and superior comprehensive detection system, simple “universal” two-bottle media format, enhanced ergonomics and user-friendly system - VersaTREK remains the system of choice for your laboratory!

¹ Davis, et. al. 1976, Int. Syst. Bacteriol. 26:498-504, *Anaerobiospirillum*, a new genus of spiral-shaped bacteria.



SENSITITRE® MIC PLATES FOR MYCOBACTERIA TESTING*

By Jenny Lorbach, Global Sensititre Product Manager

Sensititre MIC plates for *Mycobacteria* testing are now available! The plates are individually packaged, stored at room temperature, contain an extended shelf life (up to 24 months) and can be ordered in a single box of 10 plates at any time!

The plates contain antimicrobics. Therefore, the

technologist just needs to add the appropriate broth during set up procedures.

Each *Mycobacteria* format was designed based on scientific feedback from a group of global *Mycobacteria* experts. One format is available for rapid growing *Mycobacteria*, *Nocardia* species and other aerobic Actinomycetes (Part No.

RGMYCO) and the second format is for slow growing non-tuberculosis *Mycobacteria* (Part No. MAISLOW).

Contact our Customer Service Department at 1-800-871-8909 to place your order today!

Part No. RGMYCO		Part No. MAISLOW	
Amikacin	Gatifloxacin	Amikacin	Minocycline
Amoxicillin/Clavulanic Acid	Imipenem	Ansamycin	Moxifloxacin
Cefoxitin	Linezolid	Clarithromycin	Rifampin
Ceftriaxone	Minocycline	Ciprofloxacin	Streptomycin
Ciprofloxacin	Tobramycin	Ethambutol	Trimethoprim/
Clarithromycin	Trimethoprim/ Sulfamethoxazole	Gatifloxacin	Sulfamethoxazole
		Linezolid	

* For Research Use Only. Not for use in diagnostic procedures.

*“There is no need to worry about “Calcium additions” with **Daptomycin** on the Sensititre MIC plate; we have taken care of that “extra step” for you!”*

SENSITITRE® MIC PLATES NOW CONTAIN DAPTOMYCIN!

By Jenny Lorbach, Global Sensititre Product Manager

Many automated microbiology systems have antimicrobial limitations and laboratories must find alternative methods to fill these “susceptibility gaps”. Sensititre MIC plates are a perfect solution to test organisms when a primary test system has these limitations. Our newest MIC plates will compliment your existing methods with the latest antimicrobial selections! In addition, the plates are an *excellent, cost effective* way to report true MIC results.

Our newest addition, Gram-positive MIC plate,

(**Part No. GPN3F**) now contains **Daptomycin** for *in vitro* diagnostic use. There is no need to worry about “Calcium additions” with **Daptomycin** on the Sensititre MIC plate; we have taken care of that “extra step” for you!

Sensititre non-fermenter MIC plate (**Part No. NF**) allows for routine reporting for a wide selection of 23 antimicrobial agents in an easy-to-use MIC format. Laboratories can use a single plate for *Acinetobacter*, *Stenotrophomonas* and *Pseudomonas* isolates.

The *Streptococcus* plate (**Part No. STP3F**) is available to test *Streptococcus pneumoniae*. The new *Streptococcus* format includes Gemifloxacin, Gatifloxacin and Moxifloxacin. We will be adding Telithromycin soon!

All Sensititre MIC plates discussed can be read manually, or if you are currently an automated Sensititre customer, these plates can be read on your ARIS® 2X or AutoReader platforms.

Part No. GPN3F

Ampicillin
Ceftriaxone
Ciprofloxacin
Clindamycin
Daptomycin
Erythromycin
Gatifloxacin
Gentamicin
Levofloxacin
Linezolid
Oxacillin
Penicillin
Quinupristin/Dalfopristin
Rifampin
Streptomycin
Tetracycline
Trimethoprim/
Sulfamethoxazole
Vancomycin

Part No. NF

Amikacin
Ampicillin/Sulbactam
Aztreonam
Carbenicillin
Cefepime
Cefoperazone
Cefotaxime
Ceftazidime
Ceftriaxone
Chloramphenicol
Ciprofloxacin
Gentamicin
Imipenem
Levofloxacin
Lomefloxacin
Piperacillin
Piperacillin/Tazobactam
Sulfisoxazole
Tetracycline
Ticarcillin
Ticarcillin/Clavulanic Acid
Tobramycin
Trimethoprim/
Sulfamethoxazole

Part No. STP3F

Amoxicillin/Clavulanic Acid
Azithromycin
Cefepime
Cefotaxime
Ceftriaxone
Cefuroxime
Chloramphenicol
Erythromycin
Gatifloxacin
Gemifloxacin
Levofloxacin
Linezolid
Meropenem
Moxifloxacin
Penicillin
Tetracycline
Trimethoprim/
Sulfamethoxazole
Vancomycin

ARE WE DOING THIS RIGHT?

By Cindy Knapp, Director of Lab Services, TREK Diagnostic Systems

When a new methodology is introduced into a lab, there are numerous questions and concerns, especially after a training session has ended.

One question often asked is, "How do we know if we are doing this right?" Other common questions: "Will I be able to train my staff?" and "How will I know the test is performing correctly in our hands?"

To help alleviate these concerns, we have put together Training Sets for Sensititre® Susceptibility Plates. Each set consists of 10 isolates. The follow-

ing is a list of available training sets:

Campylobacter species, (Part No. CAMPY)

Candida species, for YeastOne® plates (Part No. T5102)

Haemophilus influenzae, for HPB plates (Part No. T5100)

Streptococcus pneumoniae, for STP3F plates (Part No. T5101)

When you order a Training Set, you will be supplied with the isolates and their expected MIC results. You can then utilize the organ-

ism sets as a teaching and training tool for the techs in the lab for both the set-up procedure and reading the endpoints of the new methodology system in place.

If you are interested in obtaining any of these Training Sets, please contact your Area Account Manager or Customer Service at 1-800-871-8909.

Please allow two weeks for delivery. Sensititre Susceptibility Organism Training Sets are shipped via charcoal swabs. Each set is sub-cultured prior to shipping to ensure viability.

CONTINUOUSLY IMPROVING THE WAY WE DO THINGS AT TREK

By Roger Grist, Director of Microbiology R&D, TREK Diagnostic Systems

Diagnostic companies have to comply with a plethora of regulations. What does this mean for users of their products? TREK's facility in East Grinstead, England undertakes research and development and manufactures Sensititre dried panels. It complies to ISO 9001:2000, ISO 13485:2003 and FDA regulations as well as various European Community (EU) directives.

FDA ensures that susceptibility panels meet rigorous performance criteria. Fresh clinical and challenge organisms are tested to ensure that resistant organisms are reliably detected. Overall essential agreement compared to reference CLSI (formerly NCCLS) must exceed 90%. Very major errors must not exceed 1.5% of the resistant strains tested while

major errors must not exceed 3% of the sensitive strains tested. Results must be reproducible. FDA registered facilities are periodically inspected to ensure compliance with product development and manufacturing standards. This covers instrument, software and consumables. Many product issues have historically arisen out of inadequate development. They are often difficult to correct later. All standards now recognize this and lay down rules for the management of development. Management is by teams made up of individuals from relevant departments. Specifications are drawn up and reviewed, risk analysis undertaken and claims substantiated.

Remaining problems are eliminated by a process of continual improvement.

Companies must have a system for formally reviewing all complaints and internal failures, implementing corrective action and verifying its effectiveness. The new ISO 9001 & 13485 standards go one step further and demand that companies measure customer satisfaction and incorporate these findings into their cycle of continuous improvement. Executive staff must play an active part in its management.

The end result is that companies need to get closer to their customers and develop a culture based on high quality throughout the organization. Consistent quality, continuous improvement and customer service and satisfaction is one of TREK's Values that every employee is measured on.

"Consistent quality, continuous improvement and customer service and satisfaction is one of TREK's Values that every employee is measured on."



UPDATE ON INTERNATIONAL SALES

By Paul Daga, V.P. of International Sales

Well 2004 is now over and we are well into 2005 with its new challenges and objectives. Did we achieve what we wanted to achieve in 2004? Last year was a very busy one for International Sales at TREK Diagnostic Systems. It is one thing to sell a product into Thailand but it is IMPERATIVE that we provide the necessary support to our local distributor to enable them to support their customers.

India took a significant number of VersaTREK units in 2004 which culminated in some seminars in Madras and Mumbai with an invited speaker from the U.S., Dr. Vincent LaBombardi from St. Vincent's Medical Center in New York City. Dr. LaBombardi did an excellent job, even though he had spent 24 hours on an airplane. Good thing he liked spicy

food!!!

Thailand also took a significant number of VersaTREK units. The first international customer, Ms. Sukon Chalachiva, ordered a second unit for Myco testing. The local distributor organized a launch meeting for VersaTREK with over 130 key customers attending.

One huge headache for any international business is the local registration of products in some countries; this can cost a fortune and require enough paper to build the Empire State Building! Luckily for me, Teri Anacker, TREK's QA/RA Manager in Sun Prairie, WI, and her group are very good at producing all this paperwork very quickly. They must suffer from many small paper cuts!!! However, this has culminated in the successful registration of Versa-

TREK for sale in China in 2005, so thanks to all those involved.

What about Sensititre? 2004 was very busy with the rollout of SWIN™, the new Sensititre software. For the first time we had a product that could cope with all the different languages, so Allin Winter, Technical Services Manager, and Maureen Mansfield, International Sales Manager, decided the first customer would be Polish. The installation was very successful. SWIN works with Polish XP.

Our Dutch distributor, MCS, has done a great job expanding his Sensititre sales into Austria and Switzerland. Keep up the good work Mr. Thijssen!

Looking forward to 2005, I see many opportunities and challenges. Oh well, nothing changes.

Come see us at one of the following shows!

Spring/Summer Tradeshow Schedule

MSCLS – 3/11-3/12; Annapolis, MD

ECCMID – 4/2-4/5; Copenhagen, Denmark

SCACM – 4/14-4/16; Elizabeth, IN

NYCASM – 4/22; New York City

ORV-CLMA – 4/26-4/28; Ft. Mitchell, KY

AVM Heartland Chapter – 5/5-5/7; Fargo, ND

ASCLS Ohio – 5/11-5/13; Columbus, Ohio

ASM – 6/5-6/9; Atlanta, GA

NACMID – 6/13-6/15; Portland, ME

National AVM – 8/11-8/14; Biloxi, MS

SWACM – 9/7 – 9/10; Tulsa, OK

2005 Discovery Workshop Schedule

Join us for a day-long workshop to gain hands-on experience with both VersaTREK and Sensititre systems.

Earn 4 P.A.C.E. credits!

New York City

Chicago

Houston

For more information on Discovery Workshops, go to www.trekds.com or e-mail us at info@trekds.com.

THE IMPORTANCE OF GRAPH READING AND FASTIDIOUS ORGANISMS WITH THE VERSATREK® AUTOMATED MICROBIAL DETECTION SYSTEM

By DeAna Dziak, Product Manager, TREK Diagnostic Systems

It is widely known by TREK's customers that the VersaTREK Microbial Detection System is an excellent system of choice for not only detecting common blood and sterile body fluid pathogens but for detecting fastidious organisms as well. In fact, many of our competitive conversion customers notice an increase in the number of fastidious organisms recovered since they switched to the VersaTREK system compared to their previous blood culture system.

The VersaTREK Microbial Detection System is an extremely reliable blood culture system. In fact, so reliable that it has even been known to detect organism growth before an organism can be seen in the Gram stain. This was the case at LabOne in Cincinnati, Ohio.

As you can see from the three attached graphs be-

low, VersaTREK signaled positive for three out of four bottles respectively at 73.3 hours, 66.3 hours, and 73.3 hours. Interestingly, no organisms were seen on the initial Gram stain from any of the bottles. The bottles were subbed to appropriate media and then placed back on the instrument. Upon viewing the plated media the organism that grew was *Brucella* sp.

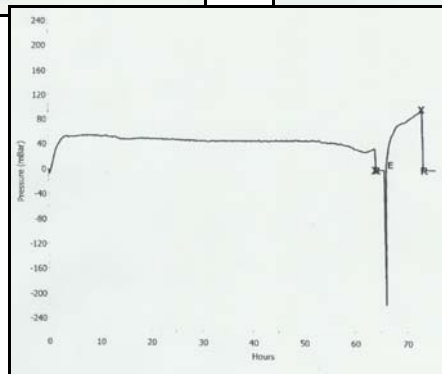
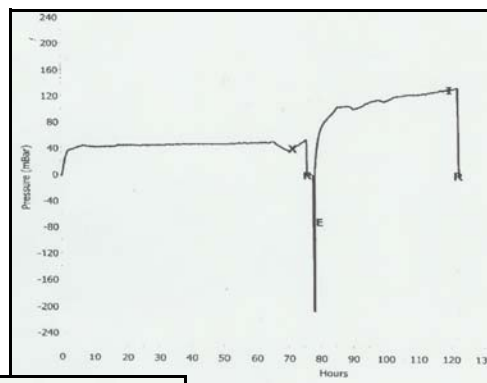
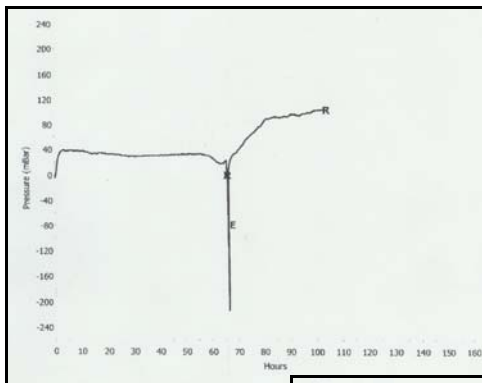
The patient in this case had previously traveled to India and had suffered from fevers for 6-8 weeks before being diagnosed. This patient had undergone many screenings to determine a cause for their illness before the positive blood cultures were detected. The culture was sent to the CDC for further speciation and it was determined that the organism is *Brucella melitensis*.

This case demonstrates the importance that graph read-

ing can have in the early fight against blood and sterile body fluid pathogens. The VersaTREK system was able to detect the organisms long before the bacteria were able to be seen on Gram stain. It should be recognized that *Brucella* can be difficult to see in a gram stain as the organism is so small that many times it tends to "blend" into the background of the gram stain. Dr. Judith Rhodes from LabOne commented that "the organism was recovered and in record time compared with current descriptions in textbooks."

At TREK we recognize the advantage of using graphs to troubleshoot the blood culture system as well as using them as a "backup" to Gram stains. Our training program gives extra special attention to understanding the importance of graph reading!

"Many of our competitive conversion customers notice an increase in the number of fastidious organisms recovered since they switched to the VersaTREK system compared to their previous blood culture system."



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TREK CELEBRATES NATIONAL MEDICAL LABORATORY WEEK, APRIL 24-20, 2005!

This year, National Medical Laboratory Week will be held April 24-30, 2005. The theme for this year's NMLW is "Laboratory Professionals - The Heart of the Medical Investigation Team".

Once again, TREK plans to celebrate NMLW and honor those who put their hearts into such a valuable profession. Medical technologists contribute so

much to the overall betterment of patient care. TREK wishes to recognize the commitment of the medical laboratory professional, and appreciates all that medical technologists do to improve patient care.

As a thank you for the tireless and excellent work you perform each and every day of the year, we would like to invite you to visit our website at www.trekds.com

and fill out the NMLW form on the homepage to qualify for an appreciation gift for you and your microbiology laboratory!

Once you fill out the online form, you will also be able to request our "TREK Gets the Tough Bugs" for you and your laboratory staff, while supplies last.

UPGRADE TO OUR NEWEST YEASTONE® PLATE WITH CASPOFUNGIN*!!!

Sensititre YeastOne Plate YO-4 (**Part No. YO-4**) will be discontinued, effective June 30, 2005. All customers are currently transitioning to our new plate format (**Part No. YO-5**). If you have additional questions regarding price or availability of the YO-4 or YO-5 plates, please contact our Customer Service Department at 1-800-871-8909.

* For research use only. Not for use in diagnostic procedures.