TREK Diagnostic Systems

TREK TIMES

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A TREK Newsletter for our International Readers

INSIDE THIS ISSUE:

NEW VERSATREK® POSTER CREATES BUZZ AT ASM 2008

By DeAna Paustian, Senior Marketing Specialist
TREK Diagnostic Systems

When new instrumentation enters the microbiology laboratory, validation testing is performed to ensure that current results are equivalent, if not better, compared to the results obtained from the previous device. Generally, this is performed on known or seeded samples. However, to gain a better understanding of the new instrumentation's capabilities, a retrospective analysis comparing both previous and new instrumentation can be performed utilizing "real-world" patient data.

Because no publication, to date, exists for the comparison of the VersaTREK Automated Microbial Detection System's two-bottle media system compared to the BACTEC™ 9240 multi-media options, a retrospective analysis was performed. This analysis compared performance and cost at three sites that converted to the VersaTREK from the BACTEC 9240.

Sites participating in the study included Rhode Island Hospital, Miriam Hospital and Centrex Laboratories, representing a teaching hospital, community hospital and regional laboratory, respectively. To ensure a fair and representative population of data, the same calendar months were analyzed for each system range.

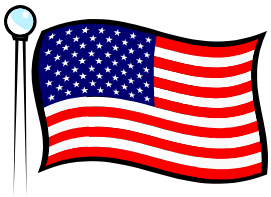
Media used at each site before conversion to VersaTREK include Standard, Lytic and Plus media. Parameters assessed in the analysis of 108,000 blood cultures included: number of sets of cultures, overall positivity rates, isolate recovery of specific organisms groups and contamination rates for both the VersaTREK and 9240 systems. Table 1 below demonstrates parameters and data from the study.

Results from the study illustrate equivalence in positivity between the two systems, with comparable contamination rates. ***Most importantly, the VersaTREK two-bottle media system was equivalent when compared to the BD 9240 Standard, Lytic and Plus media.*** There was also an interesting observation at Centrex Laboratories. During the 19-month study timeframe, Centrex recovered 12 *Campylobacter* sp. in VersaTREK. However, no *Campylobacter* sp. were recovered by the BACTEC.

In summary, VersaTREK's two-bottle media system provides several advantages, including equivalency in organism recovery, simplicity in inventory control, ease of use, ease in direct testing capabilities and potential media cost savings. A five-year cost analysis was performed on the two systems at each participating study site based on acquisition options and media expense. An average of 16.2%-27.1% in total cost savings was observed for VersaTREK customers once they converted from BACTEC. This equates to an average overall cost savings of $145,653!

For more information regarding this poster, *Conversion to the VersaTREK® Automated Microbial Detection System from the BACTEC™ 9240 System: Retrospective Analysis of Data from Three Hospitals,* please contact DeAna Paustian at +1 216-351-8735, ext. 104.

Table 1. Summary of Retrospective Data Examined	Rhode Island	Miriam	Centrex
Community or Teaching Hospital	Teaching	Community	Regional Lab
# of Beds	700	247	719
BACTEC media used prior to VersaTREK conversion	Standard/lytic	Standard/lytic	Plus aerobic/F/lytic
# of Months (analyzed)	9 (Feb. - Oct.)	9 (Feb. - Oct.)	19 (Aug. – Feb.)
Total # of Cultures– VersaTREK	19,659	10,820	30,225
Total # of Cultures– BACTEC	15,622	9,115	23,380
Total # of Positive Cultures– VersaTREK (positive rate)	1990 (10.12%)	1022 (9.50%)	2012 (6.70%)
Total # of Positive Cultures – BACTEC (positive rate)	1583 (10.13%)	803 (8.80%)	1504 (6.50%)
Contamination Rate– VersaTREK	2.77%	2.93%	1.80%
Contamination Rate– BACTEC	2.29%	2.72%	1.70%



SENSITITRE® ARIS® 2X SYSTEM PROVES TO ACCURATELY DETECT OXACILLIN RESISTANCE IN *S. AUREUS* AND COAGULASE-NEGATIVE STAPHYLOCOCCI

By Dr. Kirk Doing, Dir. of Clinical Microbiology, Virology and Molecular Diagnostics, Affiliated Laboratory, Inc.

Staphylococcus aureus (SA) and coagulase-negative Staphylococci (CoNS) are both significant human pathogens. Oxacillin, or a similar beta-lactam antibiotic, remains the drug of choice for treating susceptible strains of Staphylococci. However, increasing resistance in both SA and CoNS to oxacillin continues, requiring laboratories to maintain methods that accurately and rapidly detect susceptibility or resistance. In this study, Affiliated Laboratory, Inc. evaluated oxacillin resistance in SA and CoNS using the Sensititre ARIS 2X System and microdilution plates, coupled with *mecA* real-time PCR and oxacillin salt agar.

SA, arguably the most important Gram positive pathogen, is often associated with benign infections, but severe and life-threatening conditions including cellulitis, pneumonia and sepsis are also common. The broad spectrum of disease, coupled with great environmental adaptability and a unique ability to develop resistance to virtually all antibiotics continues to make SA an impressive pathogen.

Collectively, CoNS are colonizers of the skin and mucous membranes of all animals. Similar to SA, CoNs infections can be a challenge to treat because of their high level of antibiotic resistance, in addition to its production of biofilms.

But not all commercial systems can be relied upon to accurately and consistently detect oxacillin resistance, unless supplemental testing is included- particularly for "rapid" systems, as 24 hours of incubation is necessary to determine the oxacillin phenotype. In a previous study, the ARIS 2X System was evaluated for accuracy as compared to microdilution plates and E-Test strips for Gram negative and Gram positive organisms, including fastidious bacteria. The study found that the ARIS 2X System was the *only* system that supported the susceptibility testing of *all* organisms in the study.

During this study, susceptibility testing was completed on 674 clinical isolates of SA and 85 strains of CoNS using Sensititre plates (Part No. GPN2F). All plates were read automatically by the instrument after 24 hours of incubation, and MICs were determined and interpreted using SWIN software and CLSI standards. SA strains were also tested on Mueller-Hinton agar supplemented with 4% NaCl and 6.0 mg of oxacillin. Real time PCR for detection of the *mecA* gene was performed on all isolates.

As a result, oxacillin resistance was confirmed in 326 (48%) and 53 (62%) isolates of SA and CoNS, respectively. Resistance was accurately detected in all Sensititre plates, except in one strain of CoNS; this isolate was reproducibly PCR positive for *mecA*, and repeatedly yielded an MIC of ≤0.25 µg/ml. For all 759 isolates, the MIC interpretation and the *mecA* PCR result were in agreement 98% of the time. False-negative *mecA* PCRs were noted in 11 instances involving 3 isolates of CoNS and 8 isolates of SA. Salt agar was very reliable in detecting resistance in SA, however, 4 resistant strains, with MICs of 4.0 µg/ml were not identified. All had reproducible MICs of 4.0 µg/ml, and 2 of these isolates were *mecA* PCR positive.

Secondly, and most importantly, the study shows the accuracy of Sensititre microdilution plates for the phenotypic detection of oxacillin resistance in both SA and CoNS. Sensititre microdilution plates closely approximate the reference microdilution procedure described by the CLSI, and they performed exceptionally well in the current evaluation, correctly characterizing the oxacillin phenotype for all 674 isolates of SA, and for 84 of 85 strains of CoNS (99.7% accuracy).

Taken from poster P-2135, ECCMID 2008 in Barcelona, Spain. *Accuracy of Sensititre ARIS 2X Microbroth Dilution Panels in Detecting Oxacillin Resistance in Staphylococcus aureus and Coagulase-negative Staphylococci.* Doing, K.M, Henry, M.J., Hintz, M.S. and Kulikowski, M.L, Affiliated Laboratory, Inc., Eastern Maine Healthcare Systems, Bangor, Maine and Dept. of Biology and Ecology, University of Maine, Orono, Maine.

TREK DIAGNOSTIC SYSTEMS
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ELECTRONIC TECHNICAL INFORMATION SAVES TIME *AND* TREES

TREK is *'going green'*, and making it easier for Sensititre customers to retrieve technical information for susceptibility and identification panels. As of May 2008, Sensititre customers are now able to access all technical information electronically through the TREK website! The electronic technical information replaces the paper copies currently included in the plate boxes.

Customers can now visit www.trekds.com/techinfo to access:

- **Technical Inserts**
- **Performance Data**
- **Quality Control Ranges**
- **Interpretation Documents**
- **SWIN® Barcode Sheets**
- **Quality Control Certificates**
- **Panel Layouts, including specific QC ranges**

The new TechInfo Search Tool gives Sensititre customers easy access to all the documents they need in easy-to- read PDF format, with the added benefit of up-to-the-minute updates. Updated documents are posted directly to the site in real time, so customers do not have to keep track of the most recent hard copies.

In addition to the convenience of the new process, discontinuing paper copies of technical inserts and other documents routinely included in the shipment significantly reduces waste for our customers. Reducing waste and cutting down on paper consumption is a small change that can have a big impact on our environment!

Finally, another big advantage of this global project is the label changes. Labels now contain IVD and CE markings, when appropriate, which allows TREK to streamline manufacturing processes and increase susceptibility plate options globally.

In order to access the site, users need to register and create a user account and password. Once created, they enter the plate type and lot number into the website, and the system automatically retrieves all relevant documents related to the specific combination. Users can then review PDFs, download them to their computer, or print them out as hard copies.

A formal announcement of this change was sent to all Sensititre customers and distributors this past Spring, as well as information related to the new process to access technical information. For any questions relating to this change, please contact TREK at +44 (0) 1342 318777.

Sensititre customers can now access all technical information related to their panels through the TREK website.

After logging in, users enter their panel type and lot number to retrieve information related to their panels.

With the unique combination of panel type and lot number, the new TechInfo Search Tool is able to retrieve all of the relevant technical documents related to a user's panels.

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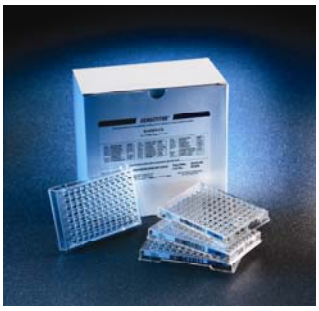

Introducing Newly Updated MIC Plates for Rapid and Slow-Growing Mycobacterium

By Jenny Lorbach, Global Director of Marketing TREK Diagnostic Systems

TREK has recently designed two new MIC plates that can be utilized to test rapid and slow-growing mycobacteria, including nocardia isolates in the diagnostic laboratory. Based on recent feedback from laboratories around the world, TREK has implemented a variety of changes to MIC plate selections to ensure new antimicrobics and appropriate dilutions are contained in each plate format. The MIC plates can be read manually with a mirror or in conjunction with the new Vizion* System (Part No. V2020) that allows technologists to visually determine MICs based on digital software image.

The rapid-growing mycobacteria MIC plate (Part No. RAPMYCO**) has an 18-month shelf life from date of manufacture and is also stored at room temperature. The antimicrobics and corresponding dilutions are as follows:

Part No. RAPMYCO**

Antimicrobics	Dilution Ranges (µg/ml)
Amikacin	1-64
Amoxicillin/ clavulanic acid	2/1-64/32
Cefepime	1-32
Cefoxitin	4-128
Ceftriaxone	4-64
Ciprofloxacin	0.12-4
Clarithromycin	0.06-16
Doxycycline	0.12-16
Imipenem	2-64
Linezolid	1-32
Minocycline	1-8
Moxifloxacin	0.25-8
Tigecycline	0.015-4
Tobramycin	1-16
Trimethoprim/ Sulfamethoxazole	0.25/4.75-8/152

The slow-growing mycobacteria MIC plate (Part No. SLOMYCO**) has a 12-month shelf life from date of manufacture and is also stored at room temperature. The antimicrobics and corresponding dilutions are as follows:

Part No. SLOMYCO**

Antimicrobics	Dilution Ranges (µg/ml)
Amikacin	1-64
Ciprofloxcin	0.12-16
Clarithromycin	0.06-64
Doxycycline	0.12-16
Ethambutol	0.5-16
Ethionamide	0.3-20
Isoniazid	0.25-8
Linezolid	1-64
Moxifloxacin	0.12-8
Rifabutin	0.25-8
Rifampim	0.12-8
Streptomycin	0.5-64
Trimethoprim/ Sulfamethoxazole	0.12/ 2.38-8/152

The new MIC formats will be available for shipment in January 2009. Both formats are available for diagnostic laboratories throughout the world. Contact TREK at +44 (0) 1342 318777 to place your order today!

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

TREK Discovery Workshops

TREK's Discovery Workshops give you the opportunity to learn the scientific principles behind our products from the experts, hear testimonials from actual users and participate in hands-on product demonstrations. Attendees receive 4 P.A.C.E. credits.

TREK has several Discovery Workshops planned for 2009, including:

- Philadelphia, PA– February
- Seattle, WA– April
- Charlotte, NC– August
- Chicago, IL– September
- International dates and sites: to be determined

Keep watching for more dates and locations to be released!

To sign up for a workshop, contact Tracy Jarden at +1 216-351-8735 ext. 205, or tjarden@trekds.com. For more information, email info@trekds.com.

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TREK Proudly Includes Rhode Island Hospital as VersaTREK User

By DeAna Paustian, Senior Marketing Specialist TREK Diagnostic Systems

Here at TREK, we are honored and proud to welcome the prestigious Lifespan hospital system into the TREK family as one of our VersaTREK competitive conversions.

In 1994, Rhode Island's first health system, Lifespan, was founded. This comprehensive academic health system includes both Rhode Island Hospital (700 beds), The Miriam Hospital (250 beds) and Newport Hospital (150 beds).

Recognized for superior cardiovascular service, both Rhode Island Hospital and The Miriam Hospital were named among the nation's top 100 hospitals for cardiovascular care for the second consecutive year by Thomson Healthcare in 2007.

The Microbiology Lab at Rhode Island is the core lab for two other hospitals; Miriam and Newport. Each site has their own VersaTREK, but all positive samples are shipped to Rhode Island for identification. Rhode Island employs 50 medical technologists, and the Microbiology Laboratory has the only Virology Lab in the state, as well as the most comprehensive Molecular Microbiology Division.

In addition to routine laboratory duties, Rhode Island is also a teaching facility for medical students from Brown University, as well as the medical technologists. Prior to converting to the VersaTREK Automated Microbial Detection System, Rhode Island used the BACTEC™ 9240 and the MGIT™ 960 for mycobacteria specimens.

Rhode Island has been part of the TREK family for almost two years, and I recently had the opportunity to speak with Valarie Whitehead, Supervisor at Rhode Island to discuss some of the reasons the site chose VersaTREK over the competition, as well as her thoughts on the system.

What made you decide to move forward with VersaTREK?
"We decided to switch for really 3 reasons. First, the technology detects both gas production and consumption of organisms. We felt that this type of detection mechanism would allow for a rapid and comprehensive recovery of fastidious organisms. Second, the software is much more flexible and user-friendly. Lastly, and the icing on the cake, was the superb customer service!"

What was your impression of the conversion process from BD to VersaTREK?
"This was the first conversion I have taken part in. As with any change there were challenges. However; TREK was extremely helpful and kept coming back until all the kinks had been worked out on our end."

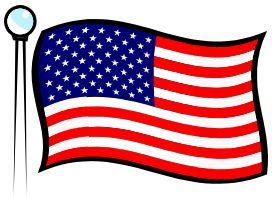
What were your impressions regarding the on-site training?
"The on-site training was very thorough and was conducted on-site with our own instrument. This was different from other trainings I attended where I was trained off-site."

What do you like about the system (instrument, software, etc.)?
"We love all aspects of the instrument. We have bi-directional interface, which makes the techs job easier and there is less chance for clerical errors. The instrument is very user-friendly and easy to operate."

Have you recovered any unusual organisms since the VersaTREK was brought into your lab?
"Yes. Since the implementation of the VersaTREK we have recovered many more anaerobic organisms, *Campylobacter* sp., and unusual Gram negative non-fermenters."

Have you noticed any increase in recovery of certain organisms since bringing the VersaTREK into your lab?
"Our recovery rate has increased from approximately 9% to 11% since we switched to the VersaTREK system."

At this year's American Society for Microbiology exhibition, Rhode Island, Miriam Hospital and Centrex revealed a comprehensive, large-scale retrospective study demonstrating equivalence with VersaTREK's two-bottle media system to BACTEC's 9240 multi-media menu. Please see page 1 for more information regarding this poster.



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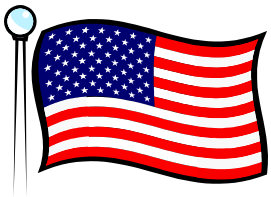


An Interesting Case of *Rhodococcus equi* Sepsis at The Medical Center in Columbus, Georgia

By DeAna Paustian, Senior Marketing Specialist
TREK Diagnostic Systems

A 41-year-old man diagnosed with human immunodeficiency virus (HIV) 16 years ago entered the emergency room at The Medical Center in Columbus, Georgia in June with a three-month history of cough, hemoptysis, shortness of breath, weight loss and night sweats.

After hospital admission, chest x-rays revealed dense pneumonia in his right lobe. A follow-up x-ray the next day demonstrated worsening disease. The patient was prescribed Levaquin, Bactrim, Zosyn and Biaxin, but his condition continued to deteriorate. The patient was transferred to the ICU due to rapid breathing and mildly labored respirations. In addition, the patient suffered from acute renal failure, metabolic acidosis, anemia with no sign of active bleeding and septic shock.

Blood cultures were performed using the VersaTREK Automated Microbial Detection System. The first positive blood culture signaled in 22.8 hours, revealing gas consumption on the VersaTREK graph. The gram stain revealed a gram positive rod.

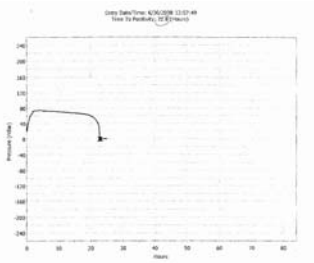
Overnight growth on subculture demonstrated a catalase positive organism with morphology consistent with diptheroids. A second bottle became positive at 24.5 hours and showed the same characteristic gas consumption on the VersaTREK graph. Gram stain once again was reported as Gram positive rods.

At this point, the original blood culture isolate began to develop salmon colored colonies and the microbiology laboratory realized they were not dealing with a diptheroid, as originally suspected. Sputum cultures were also positive for moderate growth of a Gram positive rod. A rapid Gram positive panel was set up, as well as conventional biochemicals to confirm the identification as *Rhodococcus equi*.

The laboratory was able to provide MICs for the following drugs: Vancomycin, Imipenem, Ciprofloxacin, Levofloxacin, Erythromycin and Rifampin. The patient was treated with an aggressive combination therapy and made a full recovery.

Rhodococcus equi is typically an animal pathogen, however, in immunocompromised individuals, the microorganism can cause infection. In fact, the majority of patients infected with *Rhodococcus equi* are immunocompromised with two-thirds of that population testing positive for HIV.[1] The mortality rate for those inflicted with HIV and Rhodococcus infection is greater than 50%.[2]

As mentioned previously *Rhodococcus equi* is a gas consumer, therefore the downward dip in the two graphs pictured above, right (actual graphs from the positive blood culture bottles).



One of the unique and unparalleled characteristics of the VersaTREK is the ability to detect any gas produced or consumed by an organism. Because of this technology, the VersaTREK system is not limited to CO_2 production. In addition, no system limitations exist for low CO_2 producing organisms with VersaTREK.

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We would like to acknowledge Daniel Cullison, Supervisor at The Medical Center, and his staff for sharing this interesting organism with TREK. If your laboratory has an interesting sepsis case that you would like to share with TREK, please contact DeAna Paustian at +1 216-351-8735 ext. 104 or email at dpaustian@trekds.com.

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An Important Message from TREK Technical Support Regarding VersaTREK® Software & Firmware Upgrades

By Monica Chillious, Technical Service Specialist II TREK Diagnostic Systems

As part of our commitment to continuous quality products, software and firmware enhancements are developed to ensure the highest level of performance for the VersaTREK System. Expedient upgrades are an important and necessary process to ensure all VersaTREK systems are operating under the same firmware and software versions. Upgrades are necessary for proper system operation, as well as a means for providing critical system support. Newly developed software and firmware is tested and validated according to the most recently released version. This is important. Because skipping an update may result in an issue with a future system upgrade.

Therefore, we are encouraging all distributors to maintain up-to-date systems. The most current versions of software and firmware are as follows:

VersaTREK
Software:
5.2.9.6 SP2 w 2.2.1 5.4.3.14 (new units)
Firmware:
AT Board: 1.7.1.9
Module Board: 1.15
Main Board: 1.13.1

A number of improvements have been made to the VersaTREK product line. The computer will have a new version of 5.4 software, while the instrument will have firmware upgrades for both the module (v 1.15) and main boards (v 1.13.1). All upgrades have the added advantage of the capability of being loaded via modem.

We are requesting that when a registered device upgrade is completed, a TREK Technical Services be notified at techsupport@trekds.com or +1 216-351-8735 so that current system properties may be documented for future reference.

Training the Trainer: 8 Tips for Successful VersaTREK Installation and Training

1. Before the installation, **make sure the customer has ordered all applicable ancillaries**. This includes blood drawing devices, supplements, etc. If ordering a TREK International PC Kit (Part No. 6128-31), the customer will also require a computer monitor and printer.

2. It is recommended that all **software and drivers are loaded onto the computer prior to its shipment** to the customer site to minimize any installation delays.

3. For quick and efficient troubleshooting by TREK Technical Services, it is recommended that **Symantec pcAnywhere** be loaded onto all computers along with an analog modem line.

4. At least **two users should be trained at the Supervisor level**. This ensures that there is a backup user with complete understanding of the system in the event of a staff change.

5. Before training, **understand the lab and its workflow**. Often, the training may be tailored to fit the needs of the techs that will be using the system.

6. During training, encourage the customer to **report issues as they occur**. Determining the cause and solution for a problem is much easier when dealing with it to scale. For example, a single failed location may result in a single base assembly replacement, while a drawer full may indicate a number of small unreported failures over time or a problem with a board. Understanding when and how an issue occurs, even if it is isolated or rare, is critical in providing a quick and accurate diagnosis.

7. If possible, **observe the training of a technologist** that uses the system infrequently by one of the Supervisors. It is an opportunity to make sure the main operator is comfortable with using the system, and confident in giving accurate training to future users.

8. Finally, **follow up with the customer** after training is complete. Often, there are more questions after the system has been put into use and they've had an opportunity to better understand its capabilities.

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