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TREK DIAGNOSTIC SYSTEMS

TREK Times

NEWS AND INSIGHT FOR THE CLINICAL MICROBIOLOGY LABORATORY

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TREK•News

VersaTREK® Retrospective Poster Creates a 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.

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 (page 2) demonstrates parameters and data from the study.

Results from the study illustrate equivalence in positivity rates, with comparable contamination rates between the two systems. The VersaTREK two-bottle media system was equivalent when compared to the BACTEC 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.

"The VersaTREK two-bottle media system was equivalent when compared to the BACTEC 9240 Standard, Lytic and Plus media."

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TREK•News

VersaTREK Retrospective Poster (continued from page 1)

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. A range 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 please contact DeAna Paustian at 800-871-8909, ext. 104 or email at dpaustian@trekds.com.

The VersaTREK demonstrated equivalency to the BACTEC 9240 in organism recovery, while providing a number of additional benefits.

Taken from poster C-177 presented at ASM 2008 in Boston, MA. *Conversion to the VersaTREK® Automated Microbial Detection System from the BACTEC™ 9240 System: Retrospective Analysis of Data from Three Hospitals.* Chapin, Kimberle and Whitehead, Valerie, Rhode Island Hospital, Providence, Rhode Island; Napert, Debra, Miriam Hospital, Providence, Rhode Island; Miller, Jacqueline, Centrex Laboratories, New Hartford, New York.

Table 1. Summary of Retrospective Data Examined

	Rhode Island	Miriam Hospital	Centrex Laboratories
Community or Teaching Hospital?	Teaching	Community	Regional Laboratory
Number of Beds	700	247	719
BACTEC aerobic/anaerobic media used prior to VersaTREK conversion	Standard/Lytic	Standard/Lytic	Plus aerobic/F/Lytic
Number of Months (analyzed)	9 (February- October)	9 (February- October)	19 (August-February)
Total Number of Cultures- VersaTREK	19,659 (25.8%)*	10,820 (18.7%)*	30,225 (29.3%)*
Total Number of Cultures- BACTEC	15,622 (25.7%)	9,115 (27.3%)	23,380 (33.8%)
Total Number of Positive Cultures- VersaTREK (positive rate)	1990 (10.12%)**	1022 (9.50%)**	2012 (6.70%)**
Total Number 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%

*Percent increase in number of cultures
**Percent increase in number of positive cultures

Customer•Profile

TREK Proudly Includes Rhode Island Hospital as VersaTREK User

By DeAna Paustian, Senior Marketing Specialist, TREK Diagnostic Systems

At TREK Diagnostic Systems, 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 Rhode Island Hospital (700 beds), The Miriam Hospital (250 beds) and Newport Hospital (150 beds). A not-for-profit organization, this health care system is guided by a mission to improve the health status of those it serves through high value and friendly services.

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. The Rhode Island Lab employs 50 medical technologists, and the Microbiology Lab 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 Hospital, 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!"

Rhode Island Hospital chose VersaTREK because of its comprehensive detection technology, user-friendly software and superior 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' jobs 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 the VersaTREK was brought 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 (Boston, MA), Rhode Island, along with Miriam Hospital and Centrex Laboratories, 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 recent poster.

If you would like additional information about the truly innovative VersaTREK Blood Culture System, please contact DeAna Paustian at dpaustian@trekds.com or 800-871-8909, x104.

Customer•News

Sensititre® ARIS® 2X System Proves to Accurately Detect Oxacillin Resistance in *S. aureus* and Coagulase-Negative Staphylococci

By Dr. Kirk Doing, Director 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.

Affiliated Laboratory, Inc. used the automated Sensititre ARIS 2X System, along with Sensititre MIC plates, to evaluate oxacillin resistance in SA and CoNS.

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 adaptibility 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.

Susceptibility testing was conducted using Sensititre Gram positive MIC plates, which were then incubated and read using the ARIS 2X.

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.

> "The ARIS 2X System provides results that are reliable, reproducible and cost-effective." *-Dr. Kirk Doing*

Only one MRSA strain with an MIC of >8 µg/ml and positive by PCR for *mecA* failed to grow on oxacillin-salt agar. Overall, there was 98% agreement

(continued- p. 5)

Sensititre ARIS 2X System (continued from page 4)

between all 3 methods, with Sensititre plates being the only one that accurately detected all MRSA strains. Of the 85 isolates of CoNS evaluated, 53 (62%) were resistant to oxacillin with 52 (98%) isolates correctly characterized as oxacillin-resistant using Sensititre MIC plates. The single "false susceptible" result occured in an isolate that was repeatedly *mecA* PCR positive, yet the MIC consistently reproduced at ≤0.25 µg/ml. Colony counts performed from the MIC plate for this isolate confirmed an appropriate inoculum was present in the plate. Three false-negative *mecA* PCRs were noted; all were positive when repeated after MIC values were known. Only one of these isolates had an MIC of 1.0 µg/ml, while the remaining two isolates had MICs of >8.0 µg/ml. Both had PCR completed directly from positive blood culture bottles, while repeat testing was performed from growth on solid medium. Review of the false-negative *mecA* PCR data obtained from the direct specimen testing protocol showed that most of the discordant *mecA* results were obtained when PCR testing was completed on blood culture bottle samples (sensitivity=99%). The apparent decrease in sensitivity on tests performed using blood culture broth has resulted in protocol modifications in an effort to increase the microbial load prior to PCR testing.

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 presented at 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 Main Healthcare Systems, Bangor, Maine and Dept. of Biology and Ecology, University of Maine, Orono, Maine.

NewProduct•Announcement

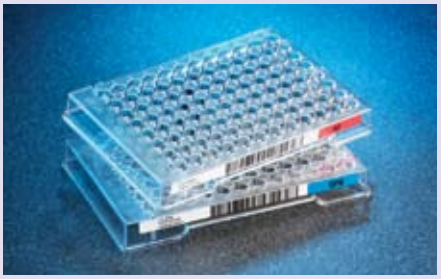
Doripenem- Yes We Can!

By Joan Lamprecht, Associate Product Manager, TREK Diagnostic Systems

When your pharmacy asks if you can provide doripenem MIC results, say, "Yes, we can!" Doripenem IVD broth microdilution MIC results for Gram negative organisms are now available only with Sensititre susceptibility plates. ORTHO-McNeil provides Doribax™, injectable doripenem, for use in serious intra-abdominal and urinary tract infections.

Doripenem is a broad spectrum carbapenem which offers treatment options when resistance to other antimicrobics exists. Indications for use include Enterobacteriaceae, *Pseudomonas* spp. and *Acinetobacter* spp.

Doripenem is currently available on IVD-use dried, Research Use Only frozen and custom MIC formats, and will be available on a new standard Gram negative format in early 2009.



Doripenem is currently available on Research Use Only frozen and custom Sensititre MIC plates, and will be available on the new standard Gram negative format in early 2009.

Contact your Area Account Manager or Customer Service Representative in the U.S. at 800-871-8909, or internationally at +44 (0) 1342 318777 about adding Doripenem to your testing, and continue to look to Sensititre for the latest in antimicrobic availability.

NewProduct•Announcement

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 new rapid and slow-growing mycobacteria MIC plates will be available in January 2009.

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 your Area Account Manager in the U.S. at 800-871-8909, or internationally 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.

Customer•News

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.

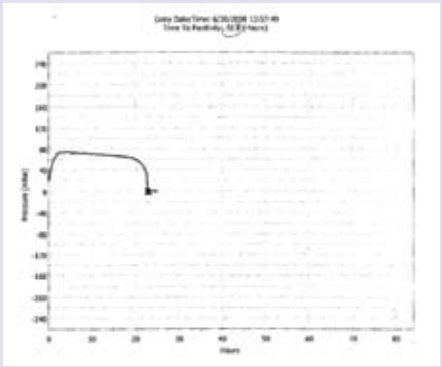
Overnight growth on subculture demonstrated a catalase positive organism with morphology consistent with diptheroids. A second bottle became positive at 24.5 hours and showed the same characteristic gas consumption on the VersaTREK graph. Gram stain once again was reported as Gram positive rods.

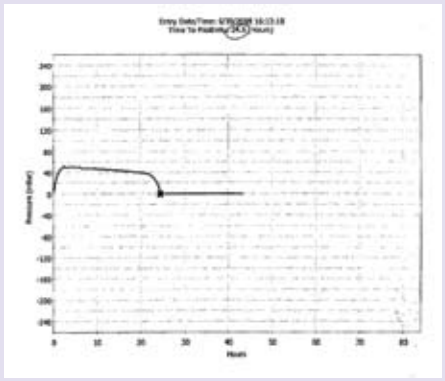
At this point, the original blood culture isolate began to develop salmon colored colonies and the microbiology laboratory realized they were not dealing with a diptheroid, as originally suspected. Sputum cultures were also positive for moderate growth of a Gram positive rod. A rapid Gram positive panel 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 there is a downward dip in the two graphs pictured below and right (actual graphs from the positive blood culture bottles).





One of the unique and unparalleled characteristics of 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.

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 800-871-8909, ext. 104 or email at dpaustian@trekds.com.

1. Weinstock, D.M. & Brown, A.E. (April 2002). *Rhodococcus equi*: An Emerging Pathogen. Clinical Infectious Diseases.

2. Manual of Clinical Microbiology. (8th ed.) Murray, Patrick R.; Baron, Ellen Jo; Jorgensen, James H.; Pfaller, Michael A.; Yolken, Robert H. (2003) Volume 1, pg. 510.

TREK 2008 Trade Show Schedule

Eastern PA Branch, ASM Symposium	11/14	Philadelphia, PA
SEACM	11/13 - 11/15	Myrtle Beach, SC
SCASM	11/14 - 11/15	La Jolla, CA

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