TREK Diagnostic Systems

TREK TIMES

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INSIDE THIS ISSUE:

Vizion™ System Consolidates Offline Susceptibility Test Methods

By Amy Miskov, Associate Product Manager
TREK Diagnostic Systems

At the American Society for Microbiology's 107th General Meeting, TREK unveiled its newest addition to the Sensititre® susceptibility platform, the Vizion System. Vizion created excitement and buzz throughout ASM, and the feedback TREK received was overwhelmingly positive. The Vizion System represents true innovation in reading 96 well MIC susceptibility plates.

The Vizion is a digital imaging device that features cost-effective, true MICs with LIS connectivity, allowing users to consolidate all off line testing on a single instrument.

With Vizion, TREK has incorporated current technology into a cost-effective platform for every laboratory. The Vizion is a digital imaging device for Sensititre susceptibility plates that provides laboratories with an easy method to test all organisms that automated microbiology instruments cannot handle. The image is projected on a touch screen monitor with the complete drug format overlaid on it. Touching or clicking the MIC well gives technologists instant feedback. The image can then be stored for later review, and used for teaching or training purposes.

The Vizion System also utilizes the powerful SWIN® Windows®-based software. By utilizing SWIN software, all results are assigned and display the appropriate CLSI or FDA interpretations in real time. SWIN gives the user access to the most *advanced* and *customizable* expert system available, and offers LIS connectivity. The powerful combination of Vizion and SWIN enhances workflow, saves technician time and eliminates transcription errors, all leading to better patient care.

> "The Vizion System Represents True Innovation"

For optimal flexibility, Vizion can be used with any Sensititre susceptibility plate- both standard and custom. Sensititre offers the most FDA cleared antimicrobics with the least limitations of any susceptibility system on the market today. With its unique lighting options, Vizion can be utilized to read even the most fastidious organisms such as *Viridans Streptococcus group*, Beta Hemolytic *Streptococcus*, *Streptococcus pneumoniae*, *Haemophilus* spp. *Mycobacteria* spp., *Candida* spp., as well as any standard gram positive and gram negative organism.

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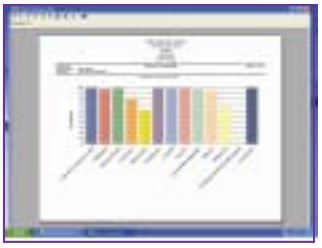

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To address all of your epidemiology reporting needs, Sensititre also offers a comprehensive epidemiology package that can be used with the Vizion System.

The SWIN Epidemiology Module meets all CLSI M39-A2 cumulative reporting criteria, and JCAHO recommendations for epidemiology reporting. SWIN Epidemiology generates complete, real-time reports in just minutes. You can also save and modify existing reports to ensure quick access to the reports utilized most often.

The Vizion System will revolutionize the way your laboratory looks at susceptibility testing, and exciting promotions are now available! For more information on the Vizion System (Part No. V2020), SWIN (Part No. SW4000), SWIN Epidemiology (Part No. SW120) and our current promotions, please contact your Area Account Manager in the US, or your local distributor internationally at 1-800-871-8909.

Validation of the Sensititre® Slow-Growing Mycobacteria Panel by a Colony Count Method

By Ken Van Horn and Carol Audette
Focus Diagnostics, Inc., Cypress, CA

The Sensititre slow-growing mycobacteria MIC panel (Part No. MAISLOW) is designed for susceptibility testing of *M. avium* complex (MAC) and other slow-growing non-tuberculous mycobacteria (NTM). The panel includes 12 antimicrobials in a CLSI-acceptable broth microdilution format. The antimicrobials include: amikacin, ciprofloxacin, clarithromycin, ethambutol, gatifloxacin, linezolid, minocycline, moxifloxacin, ansamycin (rifabutin), rifampin, streptomycin and trimethoprim/ sulfamethoxazole. Once inoculated, most panels can be read in 7 to 14 days.

The main concern for susceptibility testing of MAC is that clinical response has only been shown to correlate with in vitro activity of newer macrolides, such as clarithromycin and azithromycin. However, the American Thoracic Society suggests alternate antimicrobials in patients who may have isolates that do not respond well to macrolides or have non-susceptible isolates. Other NTM show better correlation between in vitro activity and clinical response for multiple agents and therefore more CLSI interpretive guidelines are available.

Focus Diagnostics, Inc. offers routine susceptibility testing on MAC and other NTM. Our previous methodology for performing this testing was a macrobroth method with automated instrument bottles (utilizing up to 30 bottles per isolate due to the number of drugs being tested) and the agar proportion method. Both methods are costly and labor intensive, and agar proportion often requires longer incubation times of over 14 day. The Sensititre panel (Part No. MAISLOW) seemed to fit our

(continued on page 3)

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

TREK DIAGNOSTIC SYSTEMS

continued from page 2

needs for upgrading our AFB susceptibility testing assays.

Our validation protocols were set up to capture the exact MIC by a colony count method similar to the method presented by Parrish, et al. at the 2006 ASM General Meeting, abstr C-335, where they evaluated the TREK panel designed for rapid growing mycobacteria. The colony count method was chosen due to suspected reader or MIC variability that was observed in our preliminary testing results and the lack of availability of a good challenge set of MAC and NTM. There clearly was a distinct learning curve for accurate MIC reading of the mycobacteria panels. Organism growth was noted to be very diffuse, granular to web-like, and clearly less than that observed in classic bacterial MIC panels. Therefore, we believed that the colony count method would be the most accurate method to determine the MIC and our MIC reading accuracy.

Briefly, our method was to plate the initial inoculum to 7H10 agar to obtain the inoculum colony counts. The mycobacteria panels were inoculated according to TREK instructions and the plates incubated and read at 7 days or 14 days if there was insufficient growth at 7 days. Two technologists read the MICs and a range of wells for each antimicrobial agent chosen such that at least one well above and one below the read MIC was tested for colony counts. Each well was mixed and a calibrated loop used to inoculate 7H10 agar to obtain colony counts. The colony count obtained in the MIC well was compared to the colony count of the initial inoculum. Since MICs can indicate killing or inhibition, the colony count MIC was defined as the MIC well where there was no greater than 90% recovery of the initial inoculum CFU/mL.

A total of 210 of the 222 (94.6%) evaluable MIC data points (21 isolates tested) were in agreement within ± one-$\log_2$ dilution for the test MIC and colony count MIC. The percent agreement for isolates tested ranged from 92.9% for MAC isolates (8 isolates tested) to 96.4% for other NTM. Four of the 12 discrepancies were with trimethoprim/sulfamethoxazole and two with rifampin. No other antimicrobial had more than one discrepancy. Six MIC wells were not evaluated due to mould contamination on the colony count plates. Over 2/3 of the panels (13 of 19, 68%) had sufficient growth in the control well and were able to be read by day 7. One each of MAC, *M. simiae, M. xenopi, M. kansasii, M. szulgai*, and *M. gordonae* required 14 d for sufficient growth to read the MICs. Two isolates were not evaluated, one MAC failed to grow in the MAISLOW panel after 14 days and one *M. gordonae* failed to grow on the 7H10 subcultures necessary for colony count evaluation.

We determined that the TREK slow-growing mycobacteria (Part No. MAISLOW) broth microdilution panel for MAC and other slow growing NTM provides accurate MICs that correspond to MICs obtained by a colony count method.

References:

CLSI M24-A. Susceptibility testing of mycobacteria, nocardiae, and other aerobic actinomycetes; Approved standard, 2003.

Griffith, D. E., et al. An official ATS/IDSA statement: diagnosis, treatment, and prevention of nontuberculous mycobacterial diseases. Am J Respir Crit Care Med, 175:367-416, 2007.

Parrish, N. M., et al. Susceptibility testing of nontuberculous mycobacteria using mycolic acid analysis. Abstr. 106th Gen. Meet. Am. Soc. Microbiol., abstr. C-335, 2006.

Van Horn, K. G., and C. Audette. Evaluation by a Colony Count Method of the TREK MAISLOW Panel for Susceptibility Testing of *M. avium* Complex and Other Slow Growing Mycobacteria. Abstr. 107th Gen. Meet. Am. Soc. Microbiol., abstr. C-185, 2007.

New YeastOne® Format Includes Anidulafungin and Micafungin

By Amy Miskov, Associate Product Manager
TREK Diagnostic Systems

Sensititre® YeastOne antifungal susceptibility plates are known for leading the way in antifungal susceptibility testing, consistently offering the latest antifungal agents. TREK continues in that tradition with the introduction of two *brand new* echinocandins: Anidulafungin (Pfizer Pharmaceuticals, Groton, CT) and Micafungin (Astellas Pharmaceuticals US. Inc., Deerfield, IL).

Anidulafungin and Micafungin will make their debut on the upcoming YO9 plate format (Part No. YO9). This new format will also include Posaconzole, Amphotericin B, Fluconazole, Itraconazole, 5-Flucytosine, Voriconazole and Caspofungin. All together, the YO9 contains nine antifungal agents on just one format- *significantly* reducing your cost per test! The YO9 MIC plate will be available in early 2008.

YeastOne antifungal susceptibility plates are a quick, easy and accurate way to perform fungal susceptibilities in-house. With YeastOne, laboratories have better access to antifungal susceptibility testing than ever before.

Please contact your Area Account Manager in the US at 1-800-871-8909, or your local distributor internationally with any questions.

The YO9 format contains nine antifungal agents on just one format- significantly reducing your cost per test!

TREK's Fall 2007 Trade Show Schedule

NE Laboratory Conference	Oct. 17-19	Portland, ME
NW Medical Laboratory Symposium	Oct. 24-26	Seattle, WA
AABB	Oct. 20-23	Anaheim, CA
Eastern PA Branch, ASM Symposium	November	Philadelphia, PA
SCASM	Nov. 1-3	San Diego, CA
SEACM	Nov. 6-10	Spartanburg, SC

TREK DIAGNOSTIC SYSTEMS

Bacterial Platelet Contamination Testing

By DeAna Paustian, Global VersaTREK Product Manager
TREK Diagnostic Systems

It is estimated that approximately four million platelet units are transfused per year in the U.S. alone. Bacterial contamination of platelets remains one of the greatest causes of transfusion-related mortalities, and is estimated to occur in 1 out of 3000 units.

The importance of bacterial contamination testing was formally recognized by the American Association of Blood Banks (AABB) and the College of American Pathologists (CAP) in March 2004. According to the March 2004 Standards for Blood Banks and Transfusion Services, it is mandated that laboratories introduce methods to limit and detect bacterial contamination of platelets. In addition, failure to comply with the standard is a Phase I deficiency, according to CAP.

At this time, numerous and varied technologies exist for the detection of bacteria in platelet testing. Currently there are two methodologies for testing applications in the detection of bacterial contamination: culture methodologies and point of care methodologies. Each has its own set of "pros" and "cons." Examples of both types of test applications include:

- **Visual Inspection** (swirling, color change or clumping)
- **Microscopic Examination** (Gram Stain, Wright Stain, Acridine Orange)
- **Metabolic Measurement** (Blood gas, multi-reagent indicator strips, Glucose and pH)
- **Endotoxin Assays**
- **EIA**
- **Nucleotide-Based Assays**
- **Antibiotic Probes Culture**

As our valued users know, the VersaTREK Automated Microbial Detection System provides rapid and accurate recovery of organisms due to the enriched media of the REDOX two bottle system and comprehensive detection technology in blood and sterile body fluids. Did you know that the same VersaTREK system can also be used for bacterial platelet contamination testing? It's true! According to the AABB Standards for Blood Banks and Transfusion Services, edition 22, it states, "any technique – whether it is an FDA-approved technique used according to the manufacturer's directions or a technique that uses equipment and reagents outside intended or approved application – simply requires validation to ensure that the performance of the technique is as expected."

In a recent poster presented by the National Blood Service in Colindale, London (available at www.trekds.com), VersaTREK was evaluated against the BacT/ALERT for the detection of bacteria in platelet concentrates. Fifteen organisms were tested at two concentrations; 10 CFU/ml and 100 CFU/ml. VersaTREK performed extremely well against the BacT/ALERT. In fact, time to detection for VersaTREK (80 ml bottle) was faster than the BacT/ALERT in 13/15 organisms tested in both the 10 CFU/ml and 100 CFU/ml concentrations.

The conclusion of the study stated "The VersaTREK and BacT/ALERT systems demonstrated their ability to rapidly detect a wide range of organisms that have been reported in bacterial transfusion transmissions. Both systems will allow the screen testing of a large number of platelet concentrates with specific sample identification and low labor costs. VersaTREK potentially offers an alternative to the BacT/ALERT for the screen testing of platelet concentrates to increase blood safety. "

If you are interested in testing for bacterial platelet contamination on your VersaTREK system, call DeAna Paustian 800-871-8909, Ext. 104 for more details.

VersaTREK Customer Profile: Grande Ronde Converts from BacT/ALERT®

By Sandi Larison, Microbiology Manager
Grande Ronde Hospital

Grande Ronde Hospital is a critical access, rural community hospital. We are located in La Grande, Oregon in the beautiful Blue Mountains, 40 miles from either of the 2 nearest hospitals. Our hospital has recently celebrated an enormous milestone: its 100th birthday.

I am the Microbiology Manager and have been using TREK's Sensititre products for ID/AST testing since 1989. Approximately one year ago, my laboratory switched from the BacT/ALERT system for blood culture to VersaTREK, and we are extremely happy with our decision.

If someone were to ask me why I switched from BacT/ALERT to VersaTREK, my answer is simply that I have wanted VersaTREK for years! Every piece of literature that I have read has shown VersaTREK to be superior in organism growth and time to detection. Cost was also a factor and VersaTREK offered our laboratory a cost-effective alternative to our previous system, while improving patient care.

As most of you reading this article can attest, installing a new blood culture system in a laboratory can be a large undertaking. Proper training and good technical support are critical to the success of the system. We felt the training our laboratory received was great. The TREK Technical Support Trainer was very helpful and had good suggestions to help with the validation study. TREK prides itself on building good customer relations through its Technical Support team and Customer Service group. There aren't many times that we have had to call about the VersaTREK; it just takes care of itself.

Simplicity and ease of use describe the Windows®-based VersaTREK software. Information is easy to gather and view. The intuitive icon-driven software allows users to quickly learn how to enter patient demographics, run reports and search on a variety of parameters.

We performed a validation study after VersaTREK was installed. Time-to-detection was faster on VersaTREK over 50% of the time when compared to the BacT/ALERT. We found overall that VersaTREK was better than the BacT/ALERT in low blood volume collections (see Table 1). In addition, VersaTREK anaerobic bottles do not contain any SPS, therefore allowing those organisms that are SPS-sensitive to grow. Two SPS-sensitive organisms were run during the validation study: *Peptostreptococcus anaerobius* and *Gardnerella vaginalis.* Both signaled positive at 36.8 and 39.8 hours respectively in the anaerobic bottle on the VersaTREK. These organisms did not signal positive in the BacT/ALERT bottles.

My technologists haven't had any trouble getting used to VersaTREK's unique design. Bottle loading is easy! They also like the "any bottle anywhere" concept. VersaTREK's design allows aerobic and anaerobic bottles to be placed anywhere in the instrument. Oxygenation of the aerobic bottles does not result in noisy rocking of drawers, but through quiet VorTrexing™ agitation. Each aerobic bottle actually contains a small stir bar that, when placed on the instrument, will begin oxygenating the aerobic bottles.

Overall, our laboratory has been pleased with the performance, detection and reliability of the VersaTREK instrument.

TREK DIAGNOSTIC SYSTEMS

VersaTREK versus BacT/ALERT
Time to Positivity (Hours) Validation Data
Low Blood Volumne

Organism	VersaTREK REDOX 1	VersaTREK REDOX 2	FAN Aerobic	FAN Anaerobic	Volume of Blood (ml)
Haemophilus influenzae (QC Organism)	19.6	NG	16.0	NG	1.0
Bacteroides fragilus ATCC 23745	**NG**	**27.0**	**NG**	**31.5**	**1.0**
Bacteroides uniformis ATCC 8492	**NG**	**33.8**	**NG**	**37.2**	**1.0**
Bacteroides distasonis ATCC 8503	NG	63.0	NG	2.6 days	1.0
Peptostreptococcus Anaerobius ATCC 27337	**NG**	**36.8**	**NG**	**NG**	**1.0**
Campylobacter jejuni ATCC 29428	**38.7**	**NG**	**NG**	**NG**	**1.0**
Aeromonas sp.	**10.8**	**13.2**	**12.7**	**11.7**	**1.0**
Pseudomonas alcaligenes	**22.4**	**NG**	**NG**	**NG**	**1.0**
Gardnerella vaginalis ATCC 14018	**NG**	**39.8**	**NG**	**NG**	**1.0**
Acinetobacter lwoffi ATCC 17925	**16.8**	**NG**	**NG**	**NG**	**1.0**
Yersinia enterocolitica ATCC 23715	**19.5**	**23.1**	**21.3**	**19.8**	**1.0**
Vibrio parahemolyticus ATCC 17802	16.2	NG	13.5	NG	1.0
Burkolderia cepacia ATCC 25416	**20.3**	**30.7**	**22.8**	**NG**	**1.0**
Stenotrophomonas maltophilia ATCC 13637	**23.0**	**NG**	**26.7**	**NG**	**1.0**
Pasturella multocida ATCC 12945	**18.0**	**27.2**	**20.8**	**20.0**	**1.0**
Oligella ureolytica ATCC 43534	**26.1**	**NG**	**26.2**	**NG**	**1.0**

TREK DIAGNOSTIC SYSTEMS

VersaTREK Customer Profile: Children's Hospital of Wisconsin Converts from BACTEC™ System

By Norman Gradowski, Microbiology Team Leader
Children's Hospital of Wisconsin

The Children's Hospital of Wisconsin is a state-of-the-art pediatric specialty hospital located in Milwaukee, Wisconsin. The hospital has a Level One pediatric trauma center- only 1 of 14 in the nation. Specialties include programs for congenital heart defects and heart disease in children, pediatric bone marrow transplantation and pain management in children from infants to adolescents. The site services Wisconsin, Northern Illinois and Upper Peninsula Michigan.

Approximately 8 months ago, our microbiology laboratory switched from the BACTEC 460 to the VersaTREK system for our mycobacterium needs. We have been extremely happy with the VersaTREK system.

Mycobacteria are primarily oxygen consumers, and the VersaTREK system does a good job at detecting the isolates rather quickly. VersaTREK's comprehensive detection technology is the key to faster mycobacterium detection. VersaTREK technology is not limited to CO_2 production. Any gas, N_2, H_2, CO_2, or O_2, produced or consumed by an organism is detected by the VersaTREK system via pressure changes within the headspace of the bottle. It is for this reason- rapid time to detection of mycobacterium isolates and because our BACTEC 460 was old- that we decided to convert to the VersaTREK system.

Our lab has seen a real benefit in regards to workflow with the VersaTREK over the BACTEC 460. While we were using the BACTEC 460, we had to load bottles in the system twice a week and record the GI values in a log book. Now we load the bottles into VersaTREK and wait until they are either flagged as negative or positive. It has saved us considerable technologist time and it is easy to use.

> "There was quicker time-to-detection for mycobacterium with VersaTREK."
>
> *Norman Gradowski, Microbiology Team Leader, Children's Hospital of Wisconsin*

Another benefit to using the VersaTREK is that the software is intuitive and comprehensive. By utilizing a Windows®-based platform, the software is easy to learn and flexible enough to fit in any laboratory. Because the software is Windows-based, anyone who knows Windows can figure it out. Information can be easily accessed at any time.

Finally, it seems like every employee at TREK is committed to customer satisfaction, and our lab has found Technical Support to be especially helpful, knowledgeable and easy to contact.

TREK DIAGNOSTIC SYSTEMS
MAGELLAN BIOSCIENCES

TREK Participates in Antibiogram Workshops

By Joan Lamprecht, Associate Product Manager
TREK Diagnostic Systems

The state of New Jersey is collecting data on oxacillin and vancomycin-resistant *Staphylococcus aureus*, penicillin, macrolide and fluoroquinolone-resistant *Streptococcus pneumoniae*, and ESBL and KPCs in *Klebsiella pneumoniae*. To help laboratories standardize the reporting of this data, the New Jersey Department of Health (NJDOH) and Senior Services Division of Public Health and Environmental Laboratories has been working with Janet Hindler to educate clinical labs throughout the state on epidemiology reporting. Several free audio conferences were held and in May, two Cumulative Antibiogram Workshops including PACE credits, one in northern New Jersey and one in southern New Jersey, were held.

The workshops, organized by Susan Mikorski and Dr. Corey Robertson, gave laboratories the chance to discuss with other laboratorians and Janet Hindler how to optimally use the software in their facilities to gather cumulative antibiogram data in compliance with CLSI M39-A2 recommendations and, especially, the data being asked for by the NJDOH.

AST/ID manufacturers were asked to present their system's capabilities to produce cumulative antibiograms. All participants at the workshops left with a greater understanding of how to handle their data in compliance with the CLSI guideline. Popular topics were the reporting of organisms recovered in small numbers, understanding why some results are best left out of the data set and what constitutes a "significant" change in individual organism antibiograms.

Sensititre equipment allow laboratories to do all of their susceptibility testing, including non fermenters, MRSA and VRSA detection, *Haemophilus*, *Streptococcus*, Yeast and *Mycobacterium* on a single platform, making reporting simple. Ask your Area Account Manager or local distributor about the power of SWIN Epidemiology Software (Part No. SW120).

Sensititre Plates Perform Well in Strep Study

By Nikki Holliday, Project Leader
TREK Diagnostic Systems

TREK's Laboratory Services Department recently conducted a multisite study to evaluate the performance of the Sensititre susceptibility plate for *Streptococcus* spp., including viridans *Streptococcus* group and beta hemolytic *Streptococcus,* against 18 common antimicrobials, including Tigecycline, Telithromycin and Daptomycin.

Both automated and manual reading methodologies were tested against the CLSI-M7 reference broth microdilution method (BMD). The CLSI reference BMD plates were compared to auto read and manually read Sensititre plates. Percent essential agreement (EA) rates within ± one $\log_2$ dilution were determined. EA for the auto read method with the clinical and challenge isolates were 99.7% and 100%. EA for the manual read method with the clinical and challenge isolates was 99.9% and 100. Categorical Agreement with the auto read and manual read methods were 98.9% and 99.2%.

The study compared the Sensititre dried susceptibility plate with the CLSI M7 reference BMD method. The Sensititre plate read both by the AutoReader and manually performed equivalent to the standard reference BMD method. The high level of agreement indicates the potential value of the clinical laboratory using the Sensititre susceptibility plate to determine MIC's for specific antimicrobials.

TREK DIAGNOSTIC SYSTEMS

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, as well.

Attendees have the opportunity to gain hands-on experience with the instruments by attending the two available tracks. Track One features the VersaTREK Automated Microbial Detection System, while Track 2 gives attendees the opportunity to learn more about the Sensititre ARIS 2X System and SWIN Software, as well as our brand new Vizion System!

Our next workshop will be October 2nd at the Hyatt Regency in Irvine, California. RSVP by contacting Tracy Jarden at 800-871-8909 or tjarden@trekds.com.

Keep watching for more dates and locations to be released! For more information, email info@trekds.com.

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