TREK Diagnostic Systems

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INSIDE THIS ISSUE:

Accomplishing Blood Culture Decision Excellence with the Blood Culture Checklist	3
TREK Fall Trade Show Schedule	3
User Experiences with the VersaTREK® System	4-5
Sensititre® MIC Plates Cleared by FDA to Accurately Detect Vancomycin-Resistant Staphylococcus aureus Strains	6
Update Your Contact Information	6
TREK is Proud to Announce Partnership with Henry Ford Health System	7
Tracking Resistance	7
Technical Tidbits from TREK	8
SWIN® Epidemiology Module	8

Sensititre® ARIS 2X® System Provides an Excellent Platform to Consolidate Microbiology Test Methods

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

Susceptibility studies remain among the most important functions performed in the clinical microbiology laboratory; however, mounting resistance, coupled with sometimes novel mechanisms, continue to challenge the ability of commercial Antimicrobial Susceptibility Testing (AST) systems to accurately detect some resistant phenotypes. Indeed, for some organisms, microdilution methods with full 18-24 hours of incubation yield the most accurate phenotypic results. This has forced many laboratories to maintain multiple AST methodologies to generate reliable results for different clinical isolates, which adds cost to overall laboratory operations.

The Sensititre ARIS 2X System has been designed to incubate and then automatically read Sensititre microdilution susceptibility and identification plates. Sixty-four plates can be incubated in each ARIS 2X instrument, with up to four modules (256 plate capacity) being linked to a single computer. Inventory is tracked using barcode information present on each plate. A temperature controlled, and timed incubation is maintained within the instrument, after which, robotics are used to transport plates to the reading unit. Hydrolysis of a fluorogenic substrate by the bacterial isolate is used to measure growth in each well and determine MIC endpoints. Appealing features of Sensititre plates include a traditional doubling dilution format, a large selection of antimicrobics, and the ability to test both fastidious and non-fastidious bacteria using a single AST system.

The Sensititre ARIS 2X System was developed in the 1980s, however, its widespread use in the clinical arena has been limited. Improved plate design, instrumentation, and data management software support the need for direct comparisons of the ARIS 2X to other available instruments and AST methods.

This study focused on verifying the accuracy of Sensititre MIC trays incubated and read automatically by the ARIS 2X for a variety of clinical isolates. Susceptibility results were compared to those obtained with either the Vitek Legacy (bioMerieux, Marcy L'Etoile, France), Pasco frozen microdilution panels (Becton Dickinson, Sparks, MD), the E-test gradient diffusion method (AB Biodisk, Solna, Sweden), or combinations of these methods for 401 clinical isolates comprising multiple genera and antimicrobial resistant patterns. Gram-negative identifications were evaluated using Sensititre GNID panels. The ability to consolidate multiple AST methods currently used in our laboratory onto the ARIS 2X platform was also explored.

A total of 401 clinical isolates were tested against clinically appropriate antibiotics. Bacterial isolates included a "defined" collection of 318 strains (200 gram-negative and 118 gram-positive) collected up to 90 days prior to the start of the study. These isolates were maintained frozen at -70°C until testing, and were selected for species diversity and phenotypic resistant patterns. An additional 83 (69 gram-negative and 14 gram-positive) organisms were tested concurrently with the Vitek Legacy. No duplicate isolates were tested.

TREK DIAGNOSTIC SYSTEMS

"The ARIS 2X System also addresses the difficulty of maintaining multiple AST methods in the laboratory with the ability to consolidate most susceptibility testing onto a single platform."

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Identifications using Sensititre GNID plates were compared with those obtained using Vitek GNI Plus cards (V1311) for 205 gram-negative isolates. Discrepant identifications were settled using an additional commercial identification kit, Crystal ID (Becton Dickinson), API 20 NE strips (bioMerieux), and/or conventional tubed biochemical media (Remel, Inc). Isolates included both patient and laboratory stock cultures.

An essential agreement of 98%, after discrepant analysis, was obtained between the ARIS 2X and the AST methods evaluated. Categorical error rates obtained with the ARIS 2X were within accepted limits, and a very major error rate of <1.5%, was similar to recent studies evaluating the Sensititre ARIS 2X and MicroScan System.

The Sensititre® ARIS 2X® System provides an excellent platform to consolidate microbiology test methods:

Consolidation

Currently many laboratories are forced to maintain multiple AST methods in order to accurately detect antibiotic resistance expressed by the multiple bacterial genera encountered in the clinical setting. An attractive feature of the Sensititre ARIS 2X System is the potential to consolidate susceptibility testing onto a single platform. In the current study, all susceptibility studies, including those for fastidious organisms, were completed on the ARIS 2X using just three different susceptibility plates.

Streamline Set-Up

Inoculation and incubation procedures are basically the same for all Sensititre plates further streamlining workflow. In contrast, three separate Vitek cards, three different Pasco panel configurations, and multiple E-test strips were necessary to complete the same work. Adapting to an 18-24 hour incubation time for susceptibilities may also seem problematic, given data that supports improved patient outcome when rapid susceptibility results are made available to clinicians. However, rapid phenotypic susceptibility testing of gram-positive organisms presents problems, and may not accurately detect beta-lactam or glycopeptide resistance. While combining genotypic and phenotypic susceptibility methods help in addressing this issue, at present, phenotypic susceptibility studies for gram-positive cocci require a full 24 hours of incubation.

Flexible Test Formats

The 96-well microtiter format, number of approved antimicrobials and testing dilutions, coupled with automated plate inoculation procedures lend flexibility to the system and create the potential for unique enhancements to Sensititre plate design.

Reliable System

Unlike Vitek cards, Sensititre plates can be incubated off-line and read visually with results entered directly into the data management software for report generation, computer interface transmission, and statistical archiving; this virtually eliminates instrument down-time.

This study was performed to verify the performance of the ARIS 2X Automated Susceptibility and Identification System for routine use in the clinical microbiology laboratory. The Sensititre ARIS 2X System performed well, and offers a reliable and accurate means to perform routine susceptibility testing of rapidly growing bacteria frequently encountered in the clinical laboratory. The ARIS 2X also addresses the difficulty of maintaining multiple AST methods in the laboratory with the ability to consolidate most susceptibility testing onto a single platform. Instrument design, capacity, and capability to link multiple units to a single computer further support the ARIS 2X as a suitable automated susceptibility and identification system worthy of consideration.

Taken from poster A-045 presented at the ASM 2006 in Orlando, FL, *Evaluation of Sensititre Plates Read on the Automated Incubation and Reading System (ARIS) with Comparison to Vitek Legacy, Pasco Frozen Microdilution Panels, and E-test Strips for Determining Susceptibility Profiles of Commonly Encountered Bacteria,* K. M. Doing and E.C. Rioux, Eastern Maine Healthcare, Affiliated Laboratory, Inc., Bangor, Maine 04401.

For more information, or to request a copy of this poster, please contact Tracy Jarden at 800-871-8909 ext. 205 or via email at **tjarden@trekds.com**.

TREK DIAGNOSTIC SYSTEMS

Accomplishing Blood Culture Decision Excellence

By DeAna Paustian, Global VersaTREK Product Manager, TREK Diagnostic Systems

There are numerous variables to consider when selecting new instrumentation for the microbiology laboratory, especially when it comes to one of the most important tests in the microbiology laboratory today — blood cultures.

TREK's Area Account Managers often times encounter supervisors and directors who simply "do not know where to start" in trying to find a new blood culture instrument.

Because TREK Diagnostic Systems is dedicated to the microbiology community, we listened to what customers had to say and developed a simple and easy to use checklist entitled *"Accomplishing Blood Culture Decision Excellence"* to help during the decision-making process.

We know that finding the right blood culture system to fit the needs of a laboratory can be a tedious process. After all, there are three diagnostic companies to consider, each offering their own technology, media, FDA clearances for specimen testing, regulatory records, etc.

In developing this tool for the laboratory we contacted customers who use various blood culture systems not just TREK product, so that all three companies would be best represented.

The comprehensive checklist is divided into nine sections:

Instrumentation

Software

Media

Mycobacteria

Financial

Technical Insert

Regulatory

Training

Technical Support

Each section offers pertinent questions and information that is needed in the blood culture decision making process. All information is placed into a concise booklet with room to take notes and fill-in the checkmarks where applicable.

Many sites that have used the checklist were glad they did as it made the decision making process simple!

If you are in the market to replace your blood culture instrumentation and would like a little help starting the evaluation process, please call your TREK Area Account Manager. They would be happy to discuss the *"Accomplishing Blood Culture Decision Excellence"* document.

Visit us at one of our Fall Trade Shows!

SCASM	November 3rd-4th, San Diego, CA
SEACM	November 8th-11th, Myrtle Beach, SC

TREK DIAGNOSTIC SYSTEMS

"When comparing the two systems, I concluded the following: The "time to positivity aspect" of a blood culturing instrument is a critical performance measurement, regardless of patient population targeted."

User Experiences with the VersaTREK® System

By Daniel Cullison, Microbiology Supervisor, The Medical Center, Columbus, Georgia

The Medical Center is a 413 licensed-bed teaching facility which serves the west central region of Georgia. We are the home of Fort Benning Military post, the AFLAC duck, and are within a 90 minute drive to a Braves game.

Approximately 2 years ago we became part of the VersaTREK family (I say "family" because of their outstanding online support and customer service). In the past we have worked with both the Bactec and BacT/ALERT instruments for processing blood cultures. Our average daily volume is approximately 35-40 bottles.

While using one of the competitive systems, we had become dissatisfied with the customer support and began to investigate options for another blood culture system. Two years ago we converted to the VersaTREK System and have experienced several advantages that I would like to share.

First and foremost, during this time there has never been any downtime associated with the instrument or software, truly a 24/7 workhorse. The software is user-friendly and the initial on-site training was straight forward and easy to follow. As with any new instrument, validation process consumed the first 3-4 weeks of testing with seeded samples of recommended test organisms. Something that we noted quite early on was the "time to positivity" seemed shorter than with our previous instrument. This was especially apparent with anaerobes and slower growing organisms such as yeast and *Brucella sp.* Most fastidious organisms such as *Neisseria gonorrhoeae* and *Haemophilus sp.* became positive within 10-16 hours.

Within a few months of having gone "live" with the VersaTREK System, I was asked to become part of a committee associated with our High Risk Nursery. The head of the Neonatology unit had foresight to bring together a group from several different backgrounds including Pharmacy, Infection Control, Nurse Practitioners, Physicians, and a Microbiologist. The purpose of the group was to brainstorm ways to reduce overuse of antibiotics and, at the same time, identify risk factors for infections associated in a very sick and vulnerable population. One of our areas of focus was to try and evaluate ways to distinguish sepsis from contamination.

As you would suspect, the average amount of blood collected on these preemies is usually quite small (usually between 1.0 to 1.5 mls). The VersaTREK System is the only instrument on the market that can accept as small as 0.1 mls. of blood. We decided that when a bottle became positive that we would add to the patient's report "time to positivity". We were printing a graph of all positive bottles anyway and this information was easy to find since it's formatted at the top of each printout. All babies received two blood cultures; one from a central line (CVC) and the other from a peripheral vein (PV). As the bottles became positive then a "differential time to positivity" could be calculated by the physician. If a blood culture from a CVC became positive at least 2 hours before the PV then that could indicate that a biofilm could exist in the central line which would indicate contamination as opposed to true sepsis. That central line could then be replaced without necessarily having to start a regime of antibiotics. So far, this has worked quite well and has been extended to other patient populations as well.

As part of the study, I went back through 6 months of data and calculated that the "average time to detection" with the VersaTREK System to be 16.0 hours. I then went back and reviewed the

(continued on page 5)

TREK DIAGNOSTIC SYSTEMS

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last 6 months of data with our previous system and found the average time to detection to be 20.1 hours, a difference of more than 4 hours!

When comparing the two systems, I concluded the following: The "time to positivity aspect" of a blood culturing instrument is a critical performance measurement, regardless of patient population targeted. Any sepsis detection is directly related to the bacterial load whether it's transient, intermittent, or continuous. Earlier detection times are an excellent measure of an instrument's sensitivity.

Another area that I was able to do a comparison study was in relation to Mycobacteria detection. I was fortunate enough to perform my validation studies with the VersaTREK System in parallel with the MB Bact/ALERT over a 3 month period with duplicate samples of concentrated patient specimens.

Once the AFB concentration procedure was completed, separate aliquots were inoculated into both MYCO (VersaTREK) and MB (BacT/ALERT) bottles. Both instruments were able to correctly detect all patient positives for AFB as well as seeded studies that were performed. The difference was, again, the time to positivity. The advantage was clearly towards the VersaTREK Instrument. We average approximately 10-15 concentrations per week. During this 3 month period, three new patient positives were detected with the results listed in the table below.

The only question with the Myco system we encountered was in choosing which antibiotic supplement was more appropriate for use in our lab. The VersaTREK System offers 2 supplements: AS and PVNA. PVNA differs in that it contains Vancomycin which may help to reduce contamination (i.e. non AFB organisms) that may survive the concentration procedure. We determined the AS was more appropriate for us as long as we used the 4.0% solution of NaOH for the NALC concentration procedure.

I believe the implication of this data is clear: decreasing turnaround times clearly improves patient outcomes. The sooner a physician can initiate antibiotics, the more likely the patient will respond favorably from episodes of potentially life threatening sepsis. And in the case of patients with Tuberculosis, the sooner these patients are identified, the sooner isolation precautions can be set in motion.

Overall, we have been very satisfied with this instrument allowing us to stay on the cutting edge of diagnostic healthcare. In the future, I hope to interface our LIS with the VersaTREK System. From this I hope to prevent clerical errors of data entry, determine contamination rates more easily by ward, and identify phlebotomists with poor techniques to reduce contamination rates.

	MB BacT/ALERT (in days)	VersaTREK System (in days)
Pt. #1	6.0	3.6
Pt. #2	11.5	2.5
Pt. #3	10.0	7.6

TREK DIAGNOSTIC SYSTEMS

Sensititre® MIC Plates Cleared by FDA to Accurately Detect Vancomycin-Resistant *Staphylococcus aureus* Strains

By Jenny Lorbach, Global Director of Marketing, TREK Diagnostic Systems

Last May, we received FDA clearance for our Sensititre MIC plates to automatically or manually detect and report Vanconmycin-Resistant *Staphylococcus aureus* (VRSA) strains.

Staphylococcus aureus (SA) is a bacterium that is commonly found on the skin and in the eyes, nose, and throat of animals and humans. SA is one of the most common causes of infections worldwide. Though not a problem for healthy adults, SA is potentially virulent and can cause serious infections of the skin, eyes, brain, blood, and respiratory and digestive tracts, as well as bone and connective tissue. Some SA infections, such as bacteremia, have death rates of 40 percent.

Throughout history, *Staphylococcus aureus* (SA) has been a dangerous pathogen once it has successfully breached the normal defense system. The first effective antibiotic against SA was penicillin. Shortly after, SA evolved resistance to penicillin, and by the late 1950s, 50 percent of all SA were resistant. Today, fewer than 10 percent of SA infections can be cured with penicillin. The next lines of defense against SA, were methicillin and cephalosporins. But by the late 1970s, some strains of SA had evolved resistance to these drugs. Today, as many as 50 percent of SA isolated from U.S. hospitals are resistant to methicillin. However, the increasing use of vancomycin has set the stage for the evolution of vancomycin-resistant SA (called VRSA). Antibiotic use and resistance represent a vicious cycle: The more doctors use vancomycin, the more they create an environment that encourages the evolution of VRSA.

The Sensititre System performed very well for initial detection of the original VRSA strains. We welcomed the opportunity to work closely with the CDC in determining how our ARIS 2X System could be improved to consistently detect all VRSA strains. Our customers will now have the advantage of utilizing the automated or manual results directly from Sensititre MIC plates rather than performing offline tests for *Staphylococcus aureus* versus Vancomycin.

With a long history of developing and manufacturing cost effective customized susceptibility and identification plates, TREK Diagnostic Systems offers a full range of services for clinical trial management worldwide, including custom susceptibility plate design, MIC testing for new drug clearance, resistance surveillance testing, antifungal testing, and frozen CLSI reference plate manufacturing. TREK provides full diagnostic support for laboratories in the United States and in Europe.

To view our plate formats, please visit our website at www.trekds.com or type the following link into your web browser: http://www.trekds.com/

Update Your Contact Information!

Due to a recent merging of our internal contact databases, we wanted to take this opportunity to ensure that we captured your contact information correctly! If you would like to provide us with your most updated contact information, so that we may better serve you, please visit www.trekds.com/myinfo to complete the online form.

TREK DIAGNOSTIC SYSTEMS

TREK is Proud to Announce our Partnership with Henry Ford Health System

By DeAna Paustian, Global VersaTREK Product Manager, TREK Diagnostic Systems

It is with great pleasure that TREK Diagnostic Systems welcomes the Henry Ford Health System to our VersaTREK world! Henry Ford was founded in 1915 by yes, you guessed it, auto pioneer Henry Ford. It is located in Michigan and is one of the nation's leading comprehensive and integrated health systems. It is a large facility comprised of two neighboring hospitals: Wyandotte Hospital and Bi-County Hospital. The Henry Ford Health System provides financing and health care delivery including acute, specialty, primary and preventive care services.

Dr. Eileen Burd, Microbiology Division Head at Henry Ford commented, "We are pleased to continue our relationship with TREK and the opportunity to take advantage of the improved efficiency and software enhancements incorporated in the new VersaTREK System."

Before the installation of the VersaTREK System at the three sites that comprise the Henry Ford Health System, a conversion team was established with personnel from both the Henry Ford Health System and TREK Diagnostic Systems. The conversion team met frequently and assigned action items to several TREK team members so that the transition at the sites would flow effortlessly. Some variables to consider were the conversion of one site from BD (Bi-County) and the other from bioMeriéux (Wyandotte). In addition, four VersaTREK 528 units had to be installed at Henry Ford in Detroit.

Henry Ford and Bi-County were installed this past May and Wyandotte in August. Installation and training at the sites went very smoothly. At TREK we take great care in our training and installation programs to ensure that everything "goes as planned" and are delighted to add these three sites to our VersaTREK family.

Tracking Resistance

By Joan Lamprecht, Associate Product Manager, TREK Diagnostic Systems

The Sensititre® product line's specificity and high reproducibility, along with the power of SWIN Software (Part no. SW4000) and the new SWIN Epidemiology Software (Part no. SW 120), tracks both categorical and essential susceptibility changes, which allows microbiology professionals to monitor slight shifts in MICs and predict future resistance among organism groups.

In May of this year, Sensititre products, both manual and automated, were cleared by the FDA for the detection of Vancomycin resistance in *Staphylococcus aureus* without the need for additional offline testing.

Currently, an increasing number of Enterobacteriaceae contain the carbapenemase (KPC) enzyme which confers low level resistance to all B-lactams. TREK has been working closely with the CDC and other experts to be certain that our susceptibility system is correctly detecting these organisms.

Streptococcus pneumoniae and *Candida* species are also known to have changing resistance patterns which can be specific by geographic area. We recommend monitoring shifts in resistance with the use of our *Streptococcus pneumoniae* (Part no. STP3F) and YeastOne® (Part nos. YO2 or YO6) plates.

TREK DIAGNOSTIC SYSTEMS

New SWIN® Epidemiology Module

By Joan Lamprecht, Associate Product Manager, TREK Diagnostic Systems

In the spring of 2006, we released our latest addition to Sensititre SWIN Software. The new SWIN Epidemiology Module allows busy clinical laboratories to generate fully customizable reports.

Our current SWIN Epidemiology customers are amazed at how easily they can tailor their reports for specificity and how quickly their reports are generated.

If you are a SWIN Software user, the SWIN Epidemiology Module can be added to your system to give you report capabilities which access all of the organism identification and susceptibility data on your system. If you do not already have SWIN Software (Part No. SW4000) as part of your Sensititre product lineup, the SWIN Epidemiology Module may be enough to convince you to join our SWIN family.

Talk to your Area Account Manager about ordering the SWIN Epidemiology Module for your laboratory today!

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