TREK Diagnostic Systems

TREK TIMES

A TREK Newsletter for our International Readers

Volume 2, Issue 2

Fall 2006

SENSITITRE ARIS 2X SYSTEM PROVIDES EXCELLENT PLATFORM TO CONSOLIDATE MICROBIOLOGY TEST METHODS

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

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 auto-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.

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.

(continued on page 2)

(continued from cover)

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 Maureen Mansfield at maureen@trekds.co.uk or Paul Daga at paul@trekds.co.uk.

TREK DIAGNOSTIC SYSTEMS

TWO NEW IVD YEASTONE® PLATES

By Maureen Mansfield, TREK Diagnostic Systems

We are pleased to announce two new IVD labeled YeastOne products: YO7* and YO8*.

Y07 contains:
Voriconazole
Amphotericin B
Fluconazole
5-Flucytosine
Itraconazole
Ketoconazole
Caspofungin (newest addition)

Caspofungin is manufactured by Merck Sharpand Dohme and is the first of a new class of antifungal drug, the echinocandins, to be licensed. It is intravenous only.

Caspofungin is approved for the treatment of invasive aspergillosis in immunosuppressed adults who do not tolerate or respond to Amphotericin B or Itraconazole. It has also been proven to be effective in treatment of esophageal *candidiasis* and active in invasive *candidiasis*.

YO8 contains:
Voriconazole
Amphotericin B
Fluconazole
5-Flucytosine
Itraconazole
Ketoconazole
Caspofungin
Posaconazole (newest addition)

Manufactured by Schering Plough, Posaconazole is a novel triazole for treatment of Candiasis and invasive Aspergillosis in patients who do not respond to or are intolerant of other antifungal therapies. This new chemical entity is being developed for the treatment of invasive fungal infections, which most often occur in severely immunocompromised patients, such as organ transplant patients or cancer patients undergoing chemotherapy. Posaconazole provides an alternative oral therapy option for these serious infections, including those fungal infections that are resistant to other antifungal agents.

The current YO3 format will be discontinued at the end of 2006. YO7 is available now. YO8 will be available September 2006.

*Not available in the U.S.

THE BLOOD CULTURE CHECKLIST

By DeAna Paustian, TREK Diagnostic Systems

There are numerous variables to consider when selecting new instrumentation for the Microbiology Laboratory, especially when it comes to blood culture testing. We listened to what our customers had to say and then developed a simple and easy to use Blood Culture Checklist to help them find a Blood Culture System that is the best fit for their laboratory.

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 competitor's 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 competitors would be best represented.

The Blood Culture Checklist is divided into nine sections: Instrumentation, Software, Media, Mycobacteria, Financial, Technical Insert Review, Regulatory, Training, and Technical Support.

Each section offers pertinent questions and information that is needed in the blood culture decision making process. TREK has placed all of this 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 contact Paul Daga or Maureen Mansfield. They would be happy to discuss the blood culture checklist with you!

TREK DIAGNOSTIC SYSTEMS

USER EXPERIENCES WITH THE VERSATREK® SYSTEM

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

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 from page 4)

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.

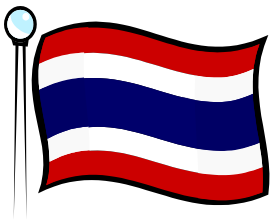
The only question with the Myco system we encountered was in choosing which antibiotic supplement was more appropriate for use in our lab. The VersaTREK System offers 2 supplements: AS and PVNA. PVNA differs in that it contains Vancomycin which may help to reduce contamination (i.e. non AFB organisms) 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



EXPERIENCES WITH AUTOMATED BLOOD CULTURES IN THAILAND

By Dr. K. Lertpocasombat, King Chulalongkorn Memorial Hospital, Bangkok, Thailand

King Chulalongkorn Memorial Hospital is one of the most modern and finest general hospitals in Thailand. The hospital was established in 1914 and offers medical care to the public regardless of their social status.

This large hospital is situated in the heart of the Bangkok business center, and accommodates over 1500 beds. It belongs to the Thai Red Cross Society and is affiliated with the faculty of medicine at Chulalongkorn University which is one of the best medical training facilities in Thailand.

In 2005 we acquired the VersaTREK Automated Microbial Detection System for automated blood culturing. Prior to 2005 the laboratory used manual methods and the Bactec blood culture system. One of the first differences the hospital noticed was the increase in positive samples from BACTEC to the VersaTREK System. The positivity rate increased from 9.4% in 2004 to 17.1% in 2005. In fact, there were significant increases in the number of *Staphylococcus sp.* including *S. aureus, E. coli*, *K. pneumoniae* and *A. baumannii*. Time to positivity was also faster with several isolates recovered in the VersaTREK System, namely Coagulase negative *Staphylococcus, S. aureus, E. coli, K. pneumoniae,* and *A. baumannii*.

The table below summarizes the number of organisms isolated from 2004 and 2005.

The following fastidious organisms were found with the VersaTREK System in 2005:

Abiotrophia adjacens
Brucella abortus
Campylobacter sp.
Rhodococcus equi
Pasturella multocida
Capnocytophaga sp.
Neisseria gonorrhoeae
Neisseria elongate
Haemophilus aphrophilus
Veillonella sp.
Cryptococcus
P. marneffei (mold)

The VersaTREK System was able to recover more organisms than the Bactec when comparing years 2004 (BACTEC) and 2005 (VersaTREK). In addition, the VersaTREK System was able to do this with a faster time to detection for several organism groups. The listing of fastidious organisms recovered demonstrates the wide organism range that VersaTREK System can recover.

Number of Organisms Isolated in 2004 and 2005*

Organism	2004 *(Number of organisms)*	2005 *(Number of organisms)*
Coagulase negative *Staphylococcus*	454	1416
E. coli	246	594
S. aureus	184	311
K. pneumoniae	159	245
Streptococcus sp.	143	190
A. baumannii	103	235
P. aeruginosa	77	127
Yeast	64	139

* This list does not represent all organisms that were recovered.

(continued from page 6)

AN INTERVIEW WITH ANAN CHONGTHALEONG, M.D., M.B.A., FRCPT, MICROBIOLOGY,FACULTY OF MEDICINE AT KING CHULALONGKORN MEMORIAL HOSPITAL

Why did you choose the VersaTREK System for Hemoculture diagnosis at King Chulalongkorn Memorial Hospital?

Actually, we wanted to have this system for more than 10 years, since Difco manufactured the ESP® Culture System II, however, at the time it was not marketed in Thailand. With the VersaTREK System's technology, we discovered it is the most sensitive and reliable instrument, which are the main features required for a hemoculture system.

Which VersaTREK Systems advantages have you been most pleased with?

1. The recovery rate.

2. The blood volume range is between 0.1ml-10ml. Most Asian people have problems with blood collection, but with this range of volume, it is very convenient to collect from newborn to adult.

3. The VersaTREK System's detection has a better recovery rate than other systems on the market.

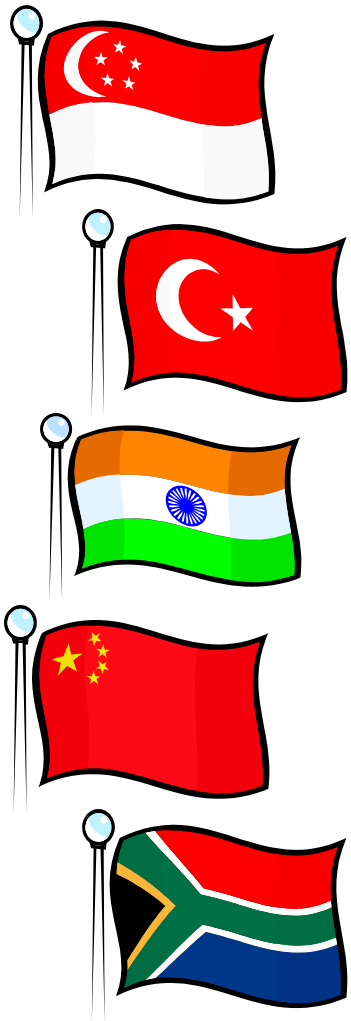
What are your impressions of the VersaTREK System after having it in your laboratory?

After the VersaTREK Automated Microbial Detection System has been operating in our laboratory routinely, we have found it is really effective, especially in term of faster detection of bacteria, which we believe will be beneficial to our patients.

Dr. Tanittha Chatsuwan
Head of Aerobic Bacteria Laboratory

Anan Chongthaleong, M.D., M.B.A., FRCPT.
Head of Department, Microbiology, Faculty of Medicine

TREK DIAGNOSTIC SYSTEMS



DISTRIBUTOR TRAINING

By Jeff Webber, TREK Diagnostic Systems

We would like to congratulate **Innovative Biotech** (Singapore), **Kaan Medical** (Turkey), **Trivitron** (India), **Vastec** (China), and **Separation Scientific** (South Africa) on their successful participation in the VersaTREK® System Distributor Training Program!

The training was held in April at TREK's Sun Prairie, Wisconsin office. Participants took part in a week-long training on the VersaTREK Instrument. Everyone was involved in complete hands-on training that involved both the technical and service aspects of the VersaTREK System.

Steve Dreifuerst, Field Service Manager for TREK Diagnostics, was responsible for the service aspect, and I trained both teams on application/troubleshooting.

The participants included:

Eric Lou
Service Manager at Vastec

Patrick Chua
Product Executive at Innovative Biotech

Evinna Low
Product Manager at Innovative Biotech

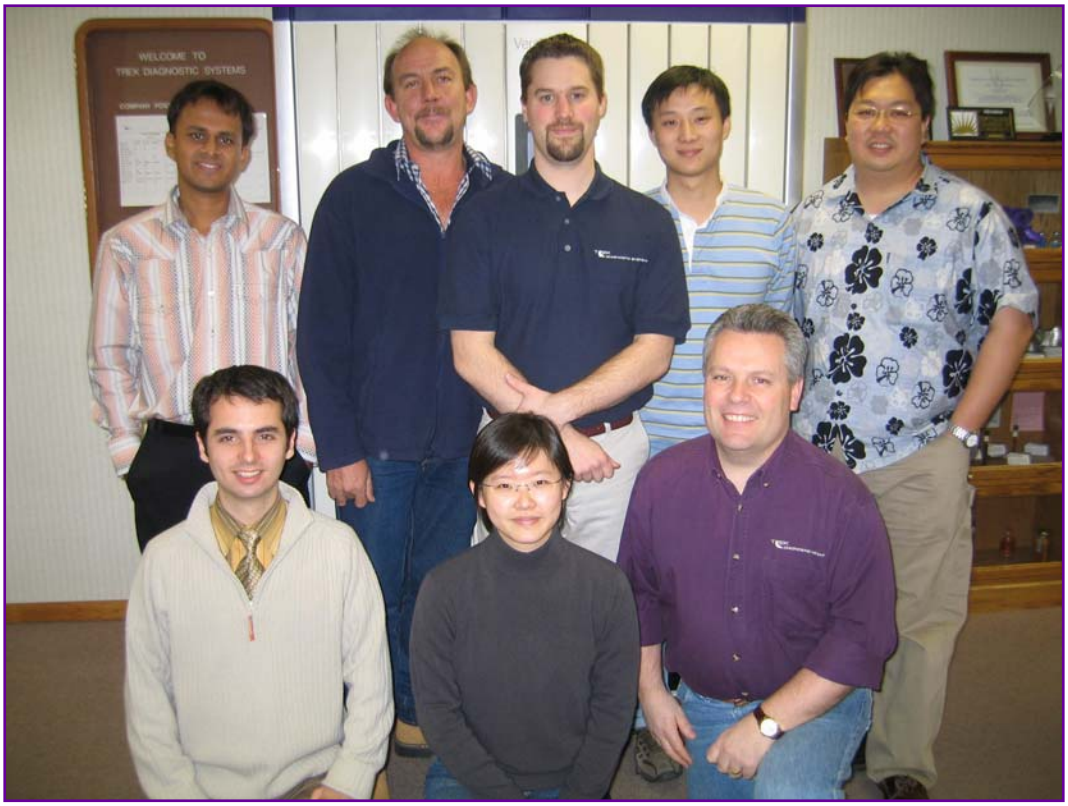
Pankaj Vishwakarma
Product Specialist at Trivitron

Kazim Altinok
Biomedical Engineer at Kaan Medical

David Robinson
Engineer at Separation Scientific

All of the participants are now fully capable of supporting the VersaTREK System.

We'd like to thank all of the participants for their time at our training program. We enjoyed having you!



From right to left: (top row) Pankaj Vishwakarma, David Robinson, Jeff Webber, Eric Lou, Patrick Chua
(bottom row) Kazim Altinok, Evinna Low, Steve Dreifuerst

Imberhorne Lane
East Grinstead, West Sussex
RH19 1QE
England

Phone: 011-44-1342-318777
Fax: 011-44-1342-318666

www.trekds.com

TREK DIAGNOSTIC SYSTEMS