TREK Diagnostic Systems

TREK TIMES

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Major Duke Study Showing Clinical Excellence of VersaTREK published in ASM Journal of Clinical Microbiology

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

TREK Diagnostic Systems is proud to announce the third party publication of a comparative paper involving the VersaTREK Automated Microbial Detection System and the BacT/ALERT® 3D in the February 2007 Journal of Clinical Microbiology.

The study was performed at Duke University Medical Center, and the clinical objective was to compare the performance of the VersaTREK REDOX two-bottle media system to the BacT/ALERT using standard media. Blood cultures were drawn from adult patients with suspected bacteremia/fungemia per physician request.

The outcome of the study demonstrated that VersaTREK has several advantages over the BacT/ALERT standard bottle:

Adequate fill volumes were found more often with VersaTREK.

Of the 7,762 blood cultures drawn, 69% were compliant meaning that all four bottles contained adequate blood fills (6-9 ml per each bottle). **BacT/ALERT bottles were more than two to three times more underfilled than the REDOX bottles depending on the bottle type** (BacT/ALERT Standard aerobic = 892, BacT/ALERT Standard anaerobic = 638; TREK REDOX 1 = 265, TREK REDOX 2 = 347).

All microbiologists know that volume is the single most important variable in a blood culture and the recommended volume from adults is 20-30 ml per blood culture set. The VersaTREK system demonstrated more consistent adequate fill volumes in this study. In addition, with VersaTREK, when maximum draws are not obtainable (otherwise known as "short draws") the system is cleared for a minimal draw of 0.1 ml without supplementation. The reason for this is the enriched formula of the REDOX media and the fact that both the aerobic and anaerobic bottles work synergistically to provide optimum environments for a broad range or microorganisms

> "There's nothing standard about VersaTREK ... Designed for better recovery, simple ease of use, improved patient care and greater."

VersaTREK significantly recovered more *Streptococci/ Enterococci* sp.

Although both systems were able to recover 60 isolates in the *Streptococci/Enterococci sp.* group, sixteen isolates were recovered only from VersaTREK.

VersaTREK demonstrated trends in recovering more *Staphylococcus aureus* and anaerobic bacteria.

When examining the clinically important isolates recovered in this study, it is clear to see that a trend exists with VersaTREK in recovering more *Staphylococcus aureus* and anaerobic bacteria than the BacT/ALERT. Upon further examination of ALL bottle data, regardless of fill volume, the trend now becomes clinically significant and *(continued on p. 2)*

(continued from page 1)

demonstrates better recovery of *S. aureus*, anaerobic bacteria and ALL organisms combined for VersaTREK[1].

This data coincides with a previous study regarding VersaTREK's predecessor the ESP Culture System II against the BacT/ALERT[2].

Significantly more organisms were detected by VersaTREK for patients on antimicrobial therapy.

The higher dilution factor in the REDOX bottles compared to the 40 ml BacT/ALERT bottles, allows the VersaTREK system to dilute out inhibitory host factors as well as the dilution of antibiotics from those patients on therapy. **In addition, no episodes were missed by the VersaTREK regardless of antimicrobic therapy.**

In conclusion, VersaTREK performed well in the study and demonstrated several advantages over the BacT/ALERT standard bottle. For more information on the study please refer to the February 2007 Journal of Clinical Microbiology or email DeAna M. Paustian at dpaustian @trekds.com.

1 Data on file at TREK Diagnostic Systems.
2 Zwadyk, P, L. Pierson, and C. Young. 1994. Comparison of Difco ESP and Organon-Teknika BacT/ALERT 16 Continuous-Monitoring Blood Culture Systems. J.Clin.Microbiol. 32:1273-1279).

TREK Becomes a Magellan Biosciences Company

TREK has become a wholly owned subsidiary of Magellan Biosciences Inc., but will continue to serve customers under the TREK Diagnostic Systems brand name. The existing management team and the company's approximately 150 US and UK-based employees are expected to continue with the company.

"This opens significant new opportunities for TREK Diagnostic Systems, its employees, and customers – providing expanded resources, and increasing our presence in the automated microbiology market," said TREK President and CEO, Mike Burke. "We are excited about the synergies and know-how that exist with Magellan's other operating companies, notably the potential to bring world-class automation capabilities to our customers. We look forward to sharing the strengths that reside among us to reach new customers and serve our existing customers even better with an expanding pipeline of products that improve clinical outcomes."

Magellan Biosciences serves the world-wide clinical diagnostics market with rapid point–of-care analyzers and automated systems for near-patient testing. Scientists use their discovery systems and sensors for cutting edge research to develop a new understanding of health and illness– from disease pathology to biomarker identification.

In addition to TREK, other Magellan Biosciences companies include ESA Biosciences and Dynex Technologies.

What's New in *Streptococcus* species MIC Testing?

By Joan Lamprecht, Associate Product Manager
TREK Diagnostic Systems

TREK is pleased to announce the availability of the only dried, IVD and FDA cleared MIC plate to include Tigecycline, Telithromycin, Daptomycin and Ertapenem along with 15 other antimicrobics for the testing of all *Streptococcus* species isolates (Part No. STP5F).

Just as exciting, is the fact that our customers can read the *Streptococcus* MIC plates using their ARIS 2X completely automated system (Part No. V3000) or AutoReader (Part No. V3029/SW4000), making *Streptococcus* testing easier and more complete than ever.

As always, you can count on Sensititre to deliver the newest antimicrobics with full dilution ranges and the fewest limitations. The room temperature storage and 24 month shelf life make it the perfect option for all size laboratories that test *Streptococcus pneumoniae*, *Groups A* and *B beta hemolytic Streptococci* and *Viridans Streptococci* and other fastidious Streptococcal isolates.

Please see our website www.trekds.com or talk to your Area Account Manager for more information on the new Streptococcus species MIC plate.

Introducing the REDOX® Transporter: Designed for Easy and Quick Delivery of Blood Culture Bottles

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

Meet the newest VersaTREK® product line extension, designed for easy and quick delivery of blood culture bottles through pneumatic tube systems: the REDOX Transporter. Transport via pneumatic tube systems couldn't be any easier!

The REDOX Transporter is versatile in that is can accommodate either the 40 ml or 80 ml REDOX blood culture bottles. In addition, the bottles travel as a set unlike other carriers that can only accommodate one bottle at a time. The precut spaces allow fast and uncomplicated placement of the bottles into the carrier. The device is made of long-lasting foam material that can withstand common disinfection agents used in the laboratory and the durable cross-linked polyethylene foam protects bottles traveling through pneumatic tube systems.

> "The REDOX Transporter... a Fast and Easy Delivery Option for Blood Culture Samples via Pneumatic Tube Systems."

The REDOX Transporter is sold in quantities of 10 to a box.

If you would like to order this product please contact your Area Account Manager or TREK Customer Service at 800-871-8909.

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Does Your Lab Meet CLSI Guidelines for Cumulative Antibiogram Reporting?

By Joan Lamprecht, Associate Product Manager
TREK Diagnostic Systems

What method are you using to calculate your Cumulative Antibiogram reports? The latest CLSI M39-A2 document contains recommendations in order to help your clinicians support clinical decisions for empiric therapy of initial infections. Do you have the software to generate a report according to the following criteria?

- Analyze and present data at least one time annually
- Include any species isolated thirty or more times
- Include only the first isolate per patient
- Include diagnostic, not surveillance, isolates
- Include only drugs routinely tested
- Calculate the percent susceptible, not including percent intermediate

If it is taking too much effort to meet these guidelines, you are not using our latest software. TREK's SWIN Epidemiology Software (Part No. SW120), released in 2006, can pull this information together in printed and chart form in less than five minutes.

Set your facilities parameters, including those used to eliminate duplicates, and save your search criteria. Then, change any parameter (organism, patient locations, specimen type, etc.) to assemble each of the reports your lab needs. You can preview exactly which specimens you have included in your report to get exactly the information you are looking for. Your criteria will be waiting for you when you come back for more reports tomorrow, next week, or next year.

Your Area Account Manager or Technical Sales Specialist can show you how to add SWIN Epidemiology software to your existing SWIN software or show you the complete Sensititre software and equipment lineup.

TREK INTRODUCES
A WHOLE NEW WAY TO
VISUALIZE YOUR
SUSCEPTIBILITY RESULTS

SEE HOW AT ASM 2007, BOOTH #113

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Custom Plates for Custom Labs

By Kimberlee Barwidi, Lab Services Coordinator
TREK Diagnostic Systems

Did you know that TREK offers you the option to design your own custom MIC plates? Although we offer many standard plates to try to fit your needs by including a wide range of antimicrobics, we also offer the option to design your own custom-made plates to accommodate the needs exclusive to your facility.

We offer over 200 different antimicrobials and anti-fungal agents in a wide range of concentrations. Of these, 80 antimicrobics are cleared for FDA and *in-vitro* diagnostic use. Designing a custom plate allows you the flexibility to include some of the newest drugs that have been released to the market as well as new tests recommended by CLSI standards. Each time you place an order for your custom plates, you have the option of re-designing a new plate to accommodate your ever-changing formulary needs.

TREK further diversifies your ordering options by providing the choice of designing a frozen or a dried custom plate, each having unique qualities. Dried plates are available for IVD use or research use labeling and can be stored at room temperature for up to 24 months. Frozen plates are ideal for research studies and are prepared according to CLSI reference guidelines. These plates must be stored at -70°C and can be ordered in quantities as minimal as 10 boxes (100 plates).

Designing a custom panel is as easy as 1-2-3!

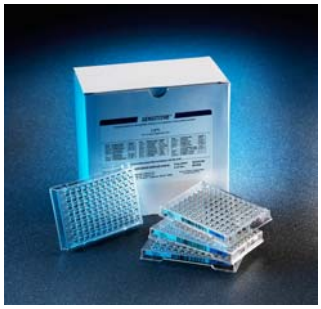
1. **Submit your Formulary**. When you submit your formulary, one of our technical customer representatives (TCR) will review your requests and create a draft layout of the plate you are requesting. At this time, we will advise you of the labeling options and we will communicate any suggestions or restrictions that may apply specifically to your requests. The TCR will also work with you at this time to address ancillary or software needs, which is dependent upon your inoculation preferences and your level of automation for reading the plates.

> “Designing a custom panel is as easy as 1-2-3!”

2. **Finalize Format.** Once we have discussed all of the options for your plate, the TCR will submit a draft format of your layout for internal manufacture approval. We will contact you once the format has been approved and request the paperwork that is required for custom orders.

3. **Submit the Required Paperwork**. When we have your format finalized and it has been approved by TREK for manufacture, the TCR will request that you submit a hard copy of your purchase order and a signed format. The lead time for dried custom plates is approximately 10-12 weeks, and it is approximately 6-8 weeks for frozen plates from the date that the paperwork is received.

With such a wide range of antimicrobials and dilutions available through our Sensititre system, designing a custom MIC plate is a sure-fire way to ensure that all the needs of your laboratory are met.



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Introducing the New Sensititre® Electronic Pipette

By Amy Miskov, Associate Product Manager
TREK Diagnostic Systems

TREK is happy to announce the newest member of the Sensititre family, the Sensititre Electronic Multichannel Pipette (Part No. V4009). TREK has a continued commitment to provide quality, efficient, and ergonomically correct products to our customers. The addition of the Sensititre Electronic Multichannel Pipette is specifically designed for users who inoculate Sensititre plates manually.

The new multichannel pipette offers advanced ergonomics without losing accuracy. One of the most common injuries in laboratories is due to the repetitive stress of pipetting. The Sensititre electronic pipette is the only pipette that keeps your hand in the neutral position recommended by ergonomics experts, increasing comfort, efficiency and accuracy. A spring action design allows for effortless tip ejection. The upright position of the pipette design allows for a comfortable easy grip.

The new pipette offers the most versatile manual plate inoculation system on the market. Features include:

- Can dose a plate in less than 10 seconds!
- Delivers 25 to 1250µl in 5µl increment settings
- Offers multiple programmable settings and easy single delivery set up with the ease of using a touch pad
- Accommodates multiple plate formats with single or multiple isolates and media options

Please contact TREK or your local sales representatives with any questions.

Feeling Limited by Limitations?

By Joan Lamprecht, Associate Product Manager
TREK Diagnostic Systems

Is your routine susceptibility method leaving you with the feeling that you are missing something? Are you running multiple back up methods in your laboratory in order to answer all of your testing needs? Just remember, Sensititre, by design, has the fewest limitations of any automated system on the market. Sensititre also offers the newest drugs to be made available for MIC testing. If you are looking to answer needs in fastidious *Streptococcus* testing, non-fermenter group testing, VRSA testing, Daptomycin testing or Yeast susceptibilities, Sensititre is an easy to set up, easy to interpret solution.

Sensititre is a modular system offering manual to completely automated testing, providing a good solution no matter what your size or budget. Talk to your Area Account Manager and let them present our solutions to you.

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Why Y0-6?

By Amy Miskov, Associate Product Manager
TREK Diagnostic Systems

Due to the increase in clinically significant fungal infections clinicians are requesting, with growing frequency, fungal susceptibilities, and demanding faster turn around times. In the past, a request for a fungal susceptibility result would be sent out to a costly reference lab. The reference lab would take one week or more before results were ready for the clinician.

Sensititre® YeastOne® antifungal susceptibility plates are a quick, easy, and accurate way to perform fungal susceptibilities in-house. YeastOne plates feature:

- 96-well microdilution plate method with alamarBlue® color indicator
- Results based on a simple color change from blue to pink
- Results available in only 24 hours
- 24 month shelf life at room temperature storage

YeastOne is also available in two plate formats:

1. YO-2 (Part No. YO-2) is an FDA cleared dual isolate plate. YO-2 offers 3 FDA cleared antifungal agents Fluconazole, Itraconazole, and 5-Flucytosine.
2. YO-6* (Part No. YO-6) offers the 3 FDA cleared antifungal agents in addition to Amphotericin B, Caspofungin, Ketoconazole, Posaconazole and Voriconazole!

*For research use only. Not for use in diagnostic procedures.

Staying on "D" Cutting Edge

By Amy Miskov, Associate Product Manager
TREK Diagnostic Systems

In today's microbiology lab, susceptibility testing has become more and more complex. Microbiology laboratories are expected to perform more off-line testing with fewer personnel and less money. In recent years there has become an increase in susceptibility testing being performed "off-line." These off-line tests can be costly and time consuming. Sensititre® has recognized the need to bring off-line testing on-line.

One common off-line test is the D zone agar disk approximation test, for determining inducible resistance to clindamycin in macrolide resistant gram positive organisms. This can be a time consuming test to perform and difficult to interpret, thus adding additional time to reporting results to the clinician. Our new broth D zone test* will be included in Sensititre gram positive MIC plates. Laboratories will have the ability to read the test using the fully automated ARIS® 2X system or visually on our manual platform. Results will be available at the same time as all other MIC's for the isolate. Interpretation is simply growth or no growth in a single well. Look for Poster #C-013 at this year's ASM for more information regarding the D-test!

*Not yet available in the United States. Currently in development.

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CLSI: The Importance of TREK's Involvement

By Cindy Knapp, Director of Laboratory Services, TREK Diagnostic Systems

Most everyone involved in laboratory practice has knowledge of the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS). This organization promotes the best practices in laboratory testing. The process utilized to develop these guidelines is based on the use of a voluntary consensus-driven process utilizing viewpoints from industry (Pharmaceutical, Medical device, etc), government, and the healthcare professions. CLSI is a global organization with over 30% outside North America and continuing to increase. It is comprised of >2,000 member organizations and >2,000 volunteers. Presently CLSI produces over 160 voluntary consensus standards, in the clinical and veterinary laboratory areas, and distributes over 75,000 per year.

TREK's commitment to our quality management system involves:

1. maintaining consistent quality of our products,

2. customer service and satisfaction, and

3. continuous improvement to our product lines.

TREK recognizes the importance of being involved up front in the CLSI consensus process. Therefore, TREK employees volunteer to support each of the following subcommittees:

- M27, M38, and M44 Antifungal susceptibility testing, voting member, Cindy Knapp
- M24 Mycobacteria antimicrobial testing, voting member, Scott Killian
- M50 Quality Control for commercial ID systems, Observer, Anne Butler
- M31 Veterinary antimicrobial testing, advisor, Jenny Lorbach
- M100, M11, M7,&M2, Antimicrobial testing subcommittee, Observers, Cindy Knapp, Scott Killian, Jenny Lorbach and Maureen Mansfield

With this commitment to CLSI we work very closely with each of the subcommittee's by participating in studies to set new antimicrobials quality control ranges, develop new standard methodologies for microbroth testing for D-test , cefoxitin Staph aureus screen, Campylobacter, Mycobacterium, Yeast, Aspergillus, and Pasturella species.

With TREK's active involvement in CLSI we can offer our customers earlier new custom plate configurations, specialty broths for new testing methodologies and updated expert rules that will meet the new guidelines.

With TREK's active involvement in CLSI, we can offer new custom plate, specialty broths and updated expert rules quickly, while still meeting new guidelines.

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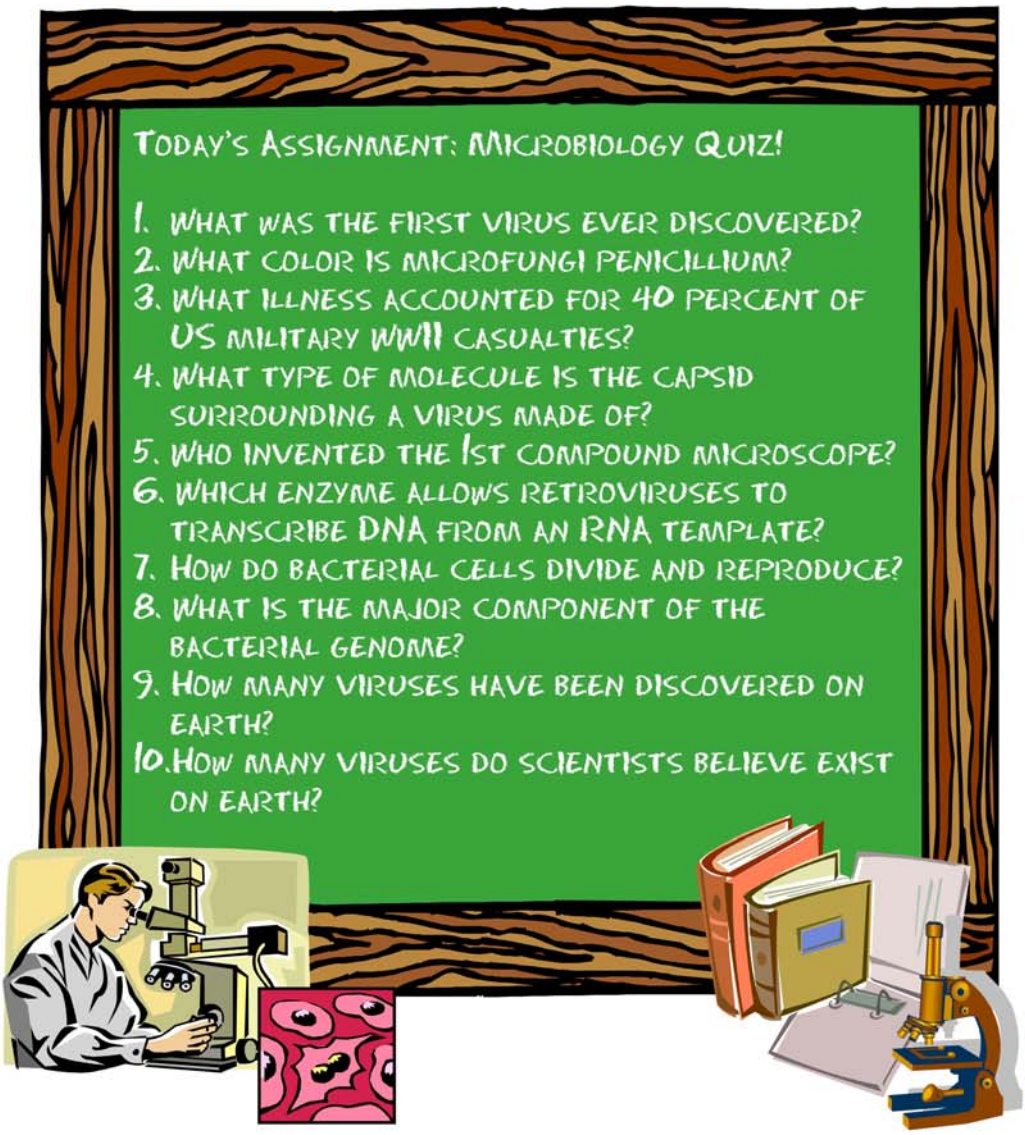

TREK DIAGNOSTIC SYSTEMS SUPPORTS NATIONAL MEDICAL LABORATORY PROFESSIONALS WEEK APRIL 22-28, 2007

HERE AT TREK, WE RECOGNIZE THE VITAL ROLE YOU PLAY IN EVERY ASPECT OF HEALTH CARE. "QUALITY CARE FROM QUALITY PROFESSIONALS" TAKES A COMMITMENT TO LEARNING EACH AND EVERY DAY, AND TREK WOULD LIKE TO TAKE THIS OPPORTUNITY TO THANK YOU FOR ALL THAT YOU DO. YOU TRULY ARE THE HEART OF THE MEDICAL INVESTIGATION TEAM!

Answers: 1. Tobacco mosaic virus 2. Green to bluish gray 3. Influenza 4. Protein 5. Zacharias Janssen 6. Reverse transcriptase 7. Binary fission 8. One double-stranded, circular DNA molecule 9. 4,000 10. 400,000

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TREK's 2007 Trade Show Schedule

NYCASM	April 27	New York City, NY
ASM	May 22-24	Toronto, ON
NACMID	June 18-20	Boxborough, MA
AACC	July 15-17	San Diego, CA
SWACM	Sept. 5-8	New Orleans, LA
ICAAC	Sept. 17-20	Chicago, IL
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

ASM 2007– TREK Booth #113

TREK Diagnostic Systems will present their range of innovative products, including the Versa-TREK® Automated Microbial Detection System, and ARIS® 2X completely automated AST/ID System at the 107th American Society for Microbiology General Meeting in Toronto, Canada May 22-24, 2007.

TREK's will be showcasing their products at booth #113. Don't forget—we will be introducing our newest visual read option to the Sensititre system– the Vizion System! Stop by our booth to *see* a whole new way to *visualize* your susceptibility results and receive a special gift!

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.

TREK has several Discovery Workshops planned for 2007, including:

- Miami, FL: April 24th
- Cincinnati, OH: June 26th
- Los Angeles, CA: August
- Boston, MA: September/October

Keep watching for more dates and locations to be released!

To sign up for any workshop, contact Tracy Jarden at 1-800-871-8909 ext. 205, or tjarden@trekds.com. For more information, email info@trekds.com.

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