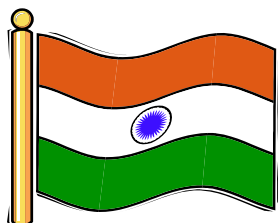


TREK TIMES

A TREK Newsletter for our International Readers



INDIA RIDES A WAVE OF TECHNOLOGY WITH GREAT RESULTS

By Sameer Saral,
Trivitron Diagnostics Pvt. Ltd., India

India has the second largest population and ranks first among the countries worldwide with the highest number of tuberculosis cases.

According to the World Health Organization's *Global Tuberculosis Control: WHO Report 2004*, more than one-fifth of all TB cases worldwide were in India. TB remains the leading infectious cause of death in India, killing close to 500,000 people each year. TB mainly affects Indians of lower economic classes, who are unable to afford treatment or susceptibility testing.

In addition, physicians prescribe drugs directly in order to save treatment costs. This has led to a number of outbreaks with multi-drug resistant cases in TB. The problems of HIV and multi-drug resistance makes the tuberculosis epidemic in India much worse.

India also has a high prevalence of infectious

diseases. This scenario requires a culture system with faster time-to-detection (TTD) with low reagent cost, such as the VersaTREK® System.

Until 2004, BD and BMX were the market leaders in the microbiology testing segment in India. In 2004, Trivitron launched TREK products in India. Trivitron, one of the top 5 medical technology companies in India, specializes in handling closed systems. Since launching TREK products in India, Trivitron has set up 11 VersaTREK installations all over the country.

As a promotional activity, Trivitron organized a successful series of scientific symposia on automation in microbiology across the country, with Dr. Vince LaBombardi from New York City as a guest speaker. These were attended by the leading decision makers in the field of microbiology. Thanks to Mr. Paul Daga and Ms. Maureen Mansfield from

TREK Diagnostic Systems for their support.

Metropolis Laboratory, Mumbai, who started off with the VersaTREK 96 bottle model, currently uses two VersaTREK 240 instruments and experiences faster TTD and almost no false positives. Operators are very satisfied with the new detection and VorTrexing™ technology, as well as overall performance. The LIS capability is also highly regarded by the lab staff.

Other VersaTREK customers, such as Gokula Metropolis, Bangalore praise its enhanced sensitivity which has enabled technicians to recover distinct organisms even from neonatal samples.

A new TREK Sensititre® system (AutoReader and SWIN™ software) has been recently installed in Guwahati. According to the end user, "It is a great instrument with good software and hardware features." The

only thing which might affect the promotion of this product in India is the hardware and reagent prices, which are high for the Indian market. The reagent plate format does not meet Indian standards. This restricts us from offering complete solutions for automated microbial testing.

Trivitron is working with TREK to customize the ID and Susceptibility systems to suit Indian requirements. We hope customized plates will offer the best solutions to Indian customers and provide TREK with an edge over other manufacturers.

Be sure to check out the article on page 4 regarding Trivitron's first VersaTREK instrument installation in Seychelles!

“This study demonstrated that the VersaTREK REDOX 1® bottle is the MOST productive SINGLE bottle with or without blood supplementation.”

THE VERSATREK® SYSTEM PREVAILS IN DUKE FASTIDIOUS ORGANISM STUDY

By DeAna Paustian, VersaTREK Product Manager, TREK Diagnostic Systems

This year at the 2005 ASM, TREK presented a poster performed at Duke University Medical Center in Durham, N.C.—“Comparison of the VersaTREK and the BacT/ALERT Blood Culture Systems for the Growth of Fastidious Microorganisms”. The objective of the study was to determine the performance of the VersaTREK Automated Microbial Detection System versus BioMérieux’s BacT/ALERT in regards to the isolation of fastidious microorganisms.

The seeded study was performed by utilizing 37 bacterial strains from 16 species. Aerobic and anaerobic bottles from both systems were tested with and without blood as a supplementation. In addition, three isolates each of fastidious bacteria that

were previously isolated from patients was used.

This study demonstrated that the VersaTREK REDOX 1 bottle is the MOST productive SINGLE bottle with or without blood supplementation. When no blood was added, VersaTREK yielded a faster time to detection (TTD) for 15/16 organisms (Table 1). In addition, the BacT/ALERT did not recover *N. gonorrhoeae*, *C. hominis*, *Eikenella sp.*, *Kingella sp.* or *C. jejuni* in the aerobic bottle! This further substantiates the fact that REDOX’s highly enriched media does not rely on blood for supplementation to recover some fastidious organisms.

When blood supplementation was used, VersaTREK yielded faster TTD

versus BacT/ALERT in 100% of the isolates tested (16/16) (Table 2). The BacT/ALERT did not recover *N. gonorrhoeae hominis*, nor *C. jejuni* in the aerobic bottle. Worth noting is that BacT/ALERT totally missed isolating *N. meningitidis* in both the aerobic and anaerobic bottles.

In summary, the REDOX 1 bottle was the MOST productive SINGLE bottle with or without blood supplementation in this study. In low volume situations which occur in neonates, pediatrics and some geriatric patients only one bottle is generally inoculated. That bottle is more often than not the aerobic bottle. This study demonstrates that the BacT/ALERT system would have missed several of the fastidious organisms if only the aerobic bottle was utilized.

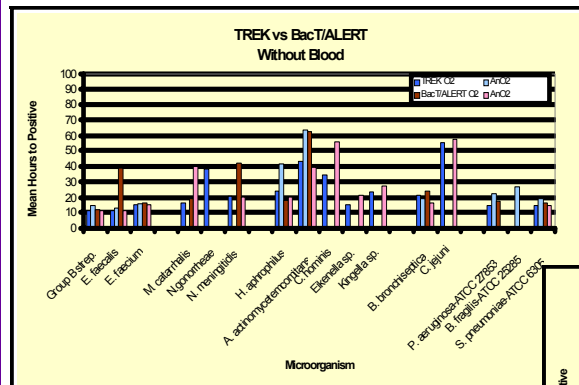


Table 1

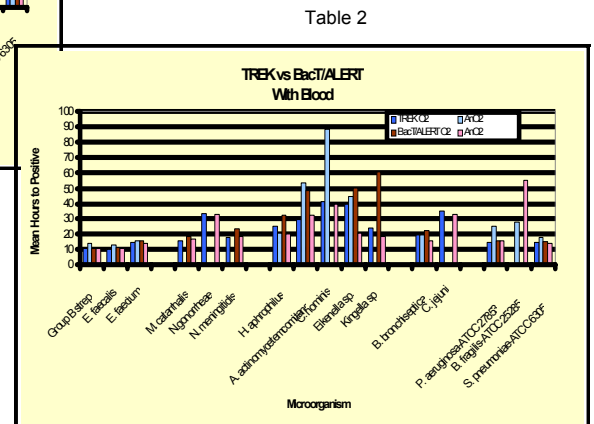


Table 2



MEXICO MEETS INTERNATIONAL STANDARDS WITH SENSITITRE® SYSTEM

By Dr. Alexis Galvan, Clinic Laboratory Chief, Hospital General Texcoco, Mexico

The Hospital General Texcoco initiated operations in February of 2004. We were committed to attending to a population of about 200,000 inhabitants with a 180 bed hospital, including a 10 bed ICU facility.

Texcoco is a city in Mexico State, Mexico, located to the east of Mexico City at 19.52° N, 98.88° W. The city stands at about 2,250 meters above sea level. The population is about 200,000 people.

At the beginning of operations, we faced a large list of nosocomial infections due to a lack of Microbiology personnel training. The manual tests were run using the Kirby-Bauer Method. Since the acquisition of

the Sensititre® System our problems have substantially decreased. This is because we now perform our work with a system that meets international standards. This has allowed us to rationalize the inter-hospital antibiotic use, diminishing our inter-hospital infection rates and time reduction of the patients staying at our hospital facilities.

TREK Diagnostic Systems developed two plates specifically for Mexico. These are the Gram-positive and Gram-negative combination plates (the plate includes identification and susceptibility.)

Currently the acceptance of MICs has become more prevalent among our medical staff. Infec-

tious disease doctors work closely with our clinic and laboratory facilities. In other words, we have become more interdisciplinary. One of the biggest benefits that this system has contributed to is that the combo panels can be designed in accordance to our needs which has been a very important achievement.

We are very satisfied and happy with the results currently achieved, which have been validated by internal and external quality assurance controls, and have been acknowledged within our hospital.



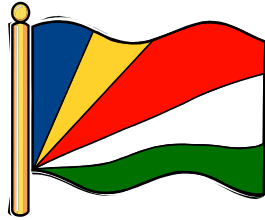
“This system has allowed us to rationalize the inter-hospital antibiotic use, diminishing our inter-hospital infection rates and time reduction of the patients staying at our hospital facilities.”



Dedicated to Quality with ISO 13485 Certification

TREK Diagnostic Systems is ISO 9001:2000 and ISO 13485:2003 accredited for all facilities in the U.S. and U.K.. We have always been committed to quality and customer satisfaction and obtained these certifications to ensure the quality and efficiency of our products and services, and to demonstrate our commitment to increasing customer satisfaction.

Receiving ISO certification further guarantees our commitment to incorporating consistent, reliable processes to meet customer needs on an ongoing basis.



TRIVITRON PLACES FIRST VERSATREK® INSTRUMENT IN SEYCHELLES

By Sameer Saral, Trivitron Diagnostics
Pvt. Ltd., India

In mid-June, the first VersaTREK® instrument in Seychelles was installed. Located in the Indian Ocean, a thousand miles from Africa, there is only one hospital in the Archipelago of Seychelles (around 115 islands in total) at the capital island Mahe - The Victoria Hospital under the Ministry of Health.

The total population of Seychelles is around 70,000 and there are high incidents of renal failure and cardiac problems. Their economy is primarily dependent on tourism with private islands, casinos, etc. and they are a very popular and exclusive tourist destination. There are exclusive private island resorts one can rent for U.S. \$1,500 - to \$2,000+ per night!

We have been awarded the project at Seychelles

for their laboratory upgradation and automation, under which scheme the VersaTREK system has been supplied to them. We are outsourcing some of the services while we will manage the instruments part ourselves.

Dr. Ramadoss, the Special Advisor to Ministry of Health in Seychelles, has been the person instrumental in proposing and getting the proposal approved by the President of Seychelles for their laboratory upgradation. They inaugurated the new laboratory facilities on June 18th, which is their National Day. The Laboratory Management has been given to an Indian laboratory chain called Metropolis Health Services Private Limited based in Mumbai, India.

As a part of their health awareness program, they

plan to run a campaign for the public for Master Health Check-Up (sponsored by the government), which includes biochemistry tests for diabetes profile, renal profile, and cardiac profile. They have allocated a big budget to accomplish this goal. Ultimately they want to retain their popularity too with the masses!



TIGACIL™ (TIGECYCLINE*) NOW AVAILABLE FOR CUSTOM MIC PLATES!

By Jenny Lorbach, Sensititre Product Manager, TREK Diagnostic Systems

We are pleased to announce the availability of Tigecycline on custom Sensititre® susceptibility plates. **We are the first diagnostic manufacturer to offer Tigecycline on custom dry format microbroth dilution trays.** Plates can be designed up to a concentration of 128 ug/ml for gram positive or negative formats.

Wyeth Ayerst recently received FDA clearance for Tigecycline in the U.S. for the following indications:

Complicated skin and skin structure infections caused by *Escherichia coli*, *Enterococcus faecalis* (vancomycin-susceptible isolates only),

Staphylococcus aureus (methicillin-susceptible and -resistant isolates), *Streptococcus agalactiae*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Streptococcus pyogenes*, and *Bacteroides fragilis*.

Complicated intra-abdominal infections caused by *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Enterococcus faecalis* (vancomycin-susceptible isolates only), *Staphylococcus aureus* (methicillin-susceptible isolates only), *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S.*

constellatus), *Bacteroides fragilis*, *Bacteroides thetaiotaomicron*, *Bacteroides uniformis*, *Bacteroides vulgatus*, *Clostridium perfringens*, and *Peptostreptococcus micros*.

We are in the process of submitting our data to the FDA to receive 510K clearance within the next few months. **We will add Tigecycline to our Gram-positive and Gram-negative standard MIC formats in the fall of 2005 for automated and manual read methods.** In the meantime, you can place your custom plates orders containing Tigecycline now!

* Not available for sale in U.S.

“We are the first diagnostic manufacturer to offer Tigecycline on custom dry format microbroth dilution trays.”

FDA Approved Interpretive Criteria for Tigecycline (referenced from Tygacil Pack Insert)

Susceptibility Test Result Interpretive Criteria for Tigecycline Minimum Inhibitory Concentrations (µg/mL) using microbroth dilution methods

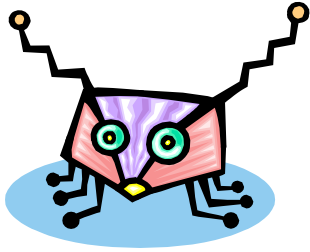
Pathogen	S	I	R
<i>Staphylococcus aureus</i> (including methicillin-resistant isolates)	≤0.5 ^a	-	-
<i>Streptococcus</i> spp. other than <i>S. pneumoniae</i>	≤0.25 ^a	-	-
<i>Enterococcus faecalis</i> (vancomycin-susceptible isolates only)	≤0.25 ^a	-	-
Enterobacteriaceae ^b	≤2	4	≥8

^a The current absence of resistant isolates precludes defining any results other than “Susceptible”. Isolates yielding MIC results suggestive of “Nonsusceptible” category should be submitted to reference laboratory for further testing.

^b Tigecycline has decreased in vitro activity against *Morganella* spp, *Proteus* spp. and *Providencia* spp.

THE VERSATREK® SYSTEM GETS ANOTHER ONE!

By DeAna Paustian, VersaTREK Product Manager,
TREK Diagnostic Systems



Many thanks to Verna Morton and her staff at Cox Health Center in Springfield, Missouri, USA for notifying TREK of another fastidious organism their VersaTREK Microbial Detection System found in two blood culture bottles in only one day! The organism found this time was *Anaerobiospirillum succiniciproducens*, a motile Gram Negative spiral bacillus with bipolar tufts of flagella.

This fastidious organism is rarely a causative agent of bacteremia in humans, however when encountered it is generally from those that are immunocompromised. This organism actually resides in feline and canine feces and was first discovered in 1976 by Davis et. al.

The patient in this case was brought to the emergency room after com-

plaining of abdominal pain and GI bleeding in addition to abdominal distention. Two sets of blood cultures were drawn. The REDOX 1® bottle of the later drawn set signaled at 24.4 hours and the REDOX 2® bottle of the same set signaled at 28.2 hours. Initially the tech thought this may be *Campylobacter*, however the morphology was more spiral rather than “sea-gull” shaped and the bacteria stained well with safranin (something not seen with *Campylobacter*). The blood cultures were subbed to blood and chocolate agars and incubated aerobically, anaerobically, and in a microaerophilic environment. After three days the agar did not yield any growth. The blood culture bottles were sent to the Mayo Clinic where molecular testing was performed along with electron microscopy showing the bipolar tufts

of flagella which confirmed that this was an *Anaerobiospirillum succiniciproducens*.

Unfortunately, the patient in this case succumbed to the infection. Some documented cases have demonstrated full recovery when treated with Cefuroxime, Tetracycline, and Chloramphenicol.

If your customers have any unusual organisms recovered by VersaTREK please let us know by contacting ddziak@trek.com.

With its unique and superior comprehensive detection system, simple “universal” two-bottle media format, enhanced ergonomics and user friendly system— The VersaTREK System remains the system of choice for your laboratory!



DISABLING LOCATION

By Steve Shemo, Technical Services Supervisor,
TREK Diagnostic Systems

In an effort to maximize the number of available locations on your Versa-TREK instrument, TREK is asking our customers to keep detailed information regarding the disabling of locations. With this detailed information, your local distributor and/or TREK Technical Service Representative will be able to quickly assess and repair disabled locations without lengthy diagnostic procedures. In turn, this will minimize the amount of down time you may experience from any faulty location.

Below is a brief synopsis on the reasons why a location would and would not be disabled.

Before disabling any location, please print the location status and save a copy for your local distributor and/or TREK Technical Service Representative.

Bottle Alerts

Leak Alert – A location should only be disabled after two consecutive Leak Alerts.

Saturation Alert – A location should only be disabled after two consecutive Saturation Alerts.

No Movement Alert – A location should only be disabled after two consecutive No Movement Alerts.

Invalid Insertion – Does not require disabling unless directed by Technical Services.

Erroneous Insertion -- Does not require disabling unless directed by Technical Services.

Hardware Failures:

eePROM failure – Bottle should be removed and relocated to a new location. Location should then be tested with an un-inoculated test bottle to verify location. Disable only upon direction from

Technical Support.

Motor failure – Bottle should be removed and relocated to a new location. Location should then be tested with an un-inoculated test bottle to verify location. Disable only upon direction from Technical Support.

Transducer failure – Bottle should be removed and relocated to a new location. Location should then be tested with an un-inoculated test bottle to verify location. Disable only upon direction from Technical Support.

Thank you for your attention to this matter and your continued support of TREK Diagnostic Systems.

Please do not hesitate to contact your local distributor or the TREK Technical Service Dept. at 216-351-8735 with any questions.

AUTOINOCULATOR ALERT STATEMENT

By Steve Shemo, Technical Services Supervisor,
TREK Diagnostic Systems

On Thursday June 30, 2005, we issued an alert statement to our valued Sensititre customers, in an effort to help your laboratory personnel maximize their safety when handling Sensititre® test tubes used for inoculation with TREK's AutoInoculator. It is strongly recommended

that after inoculation of the panel has been completed, the dosing head should not be removed separate from the test tube. The test tube and the dosing head should ALWAYS be discarded together as one unit. Care should be exercised when screwing the dose head to the test tube to

prevent cross threading.

Please do not hesitate to contact your local distributor or the TREK Technical Service Dept. at 216-351-8735 with any questions.

“Many of our competitive conversion customers notice an increase in the number of fastidious organisms recovered since they switched to the VersaTREK system compared to their previous blood culture system.”

THE IMPORTANCE OF VERSATREK® GRAPH READING AND FASTIDIOUS ORGANISMS

By DeAna Paustian, VersaTREK Product Manager, TREK Diagnostic Systems

It is widely known by TREK's customers that the VersaTREK Microbial Detection System is an excellent system of choice for not only detecting common blood and sterile body fluid pathogens but for detecting fastidious organisms as well. In fact, many of our competitive conversion customers notice an increase in the number of fastidious organisms recovered since their switch to VersaTREK compared to their previous blood culture system.

The VersaTREK Microbial Detection System is an extremely reliable blood culture system. In fact so reliable that it even detects organism growth before an organism can be seen in the gram stain. This was the case for our very good customers at LabOne in Cincinnati, Ohio.

As you can see from the three attached graphs below VersaTREK signaled positive for three out of four bottles at respectively 73.3 hours,

66.3 hours, and 73.3 hours. Interestingly, no organisms were seen on the initial gram stain from any of the bottles. The bottles were subcultured to appropriate media and then placed back onto the instrument. Upon viewing the plated media the organism that grew was a *Brucella* sp.

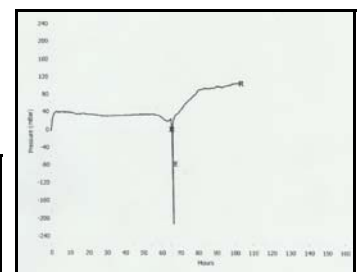
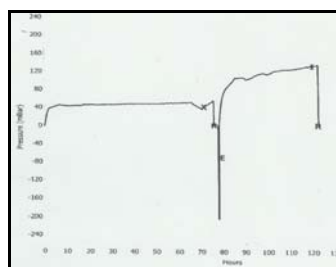
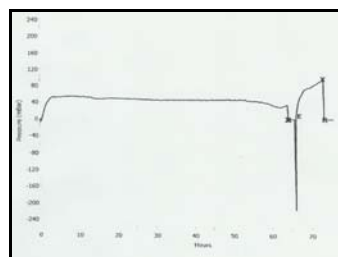
The patient in this case had traveled to India in August and had suffered from fevers for 6-8 weeks before being diagnosed. This patient had undergone many screenings to determine a cause for their illness before the positive blood cultures were detected. The culture was sent to the CDC for further speciation and it was determined that the organism is *Brucella melitensis*.

This case demonstrates the importance that graph reading can have in the early detection of blood and sterile body fluid pathogens. VersaTREK was able to detect the organisms long before the bacteria were able to

be seen on gram stain. It should be recognized that *Brucella* can be difficult to see in a gram stain because the organism is so small that many times it tends to “blend” into the background of the gram stain. Dr. Judith Rhodes from LabOne commented that “the organism was recovered and in record time compared with current descriptions in textbooks”

At TREK we recognize the advantages of using graphs to troubleshoot the blood culture system as well as using them as a “backup” to gram stains. Our US training program has been slightly modified to give extra attention to the understanding and importance of graph reading!

Because graph reading is such an important tool, we will be sending a VersaTREK Graph Reading Troubleshooting Guide to your institution. This guide should be quite useful during training sessions!





CONTINUED SUCCESS WITH SURVEILLANCE INITIATIVES: CANADIAN STYLE

By Jenny Lorbach, Sensititre Product Manager, TREK Diagnostic Systems

Over the last two years, a surveillance initiative has become truly ingrained within Canada. Canada has implemented their own program, named CIPARS, based largely on the NARMS (National Antimicrobial Monitoring System) model. Therefore we have been able to expand truly automated international surveillance initiatives focused on *E. coli* 0157, *Salmonella*, *Enterococcus*, in addition to manual microbroth dilution techniques for *Campylobacter*.

The principal objectives of these surveillance programs are:

- Monitor antimicrobial resistance among bacteria that cause intestinal infections.

- Provide a platform for studies to determine factors contributing to resistance and public health impact of resistance (e.g. field investigations, case-control studies)

- Guide intervention efforts to mitigate antimicrobial resistance.

The following institutions have implemented Sensititre® automated platforms in their diagnostic laboratories for research purposes:

- Alberta F&R Division Agriculture Food Lab Edmonton, Alberta
- Health Canada Department of Health Guelph Ontario
- Ministry of Agriculture Food and Fish Animal

Health Center Abbotsford, British Columbia

- Atlantic Veterinary College Charlottetown, Prince Edward Island

- Department of Health, St. Hyacinthe, Quebec

To help out with “internal growth pains”, we introduced the NARMS Sensititre MIC plates as standard products within the last year. This means that any customer can order a box or more of plates at any time rather than place a custom order.

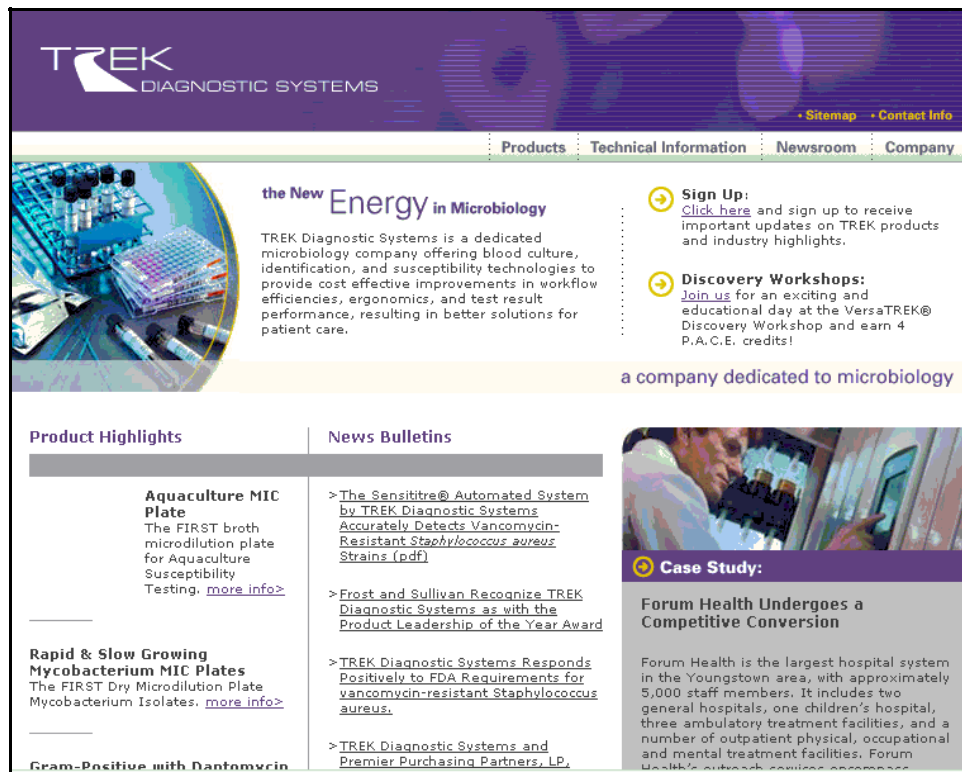
To view these formats, go to http://www.trekds.com/products/sensititre/vet_ssmic.asp or contact your local distributor or TREK Customer Service.

“Over the last two years, a surveillance initiative has become truly ingrained within Canada.”

What is NARMS??

The National Antimicrobial Resistance Monitoring System (NARMS) combines the activities of the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture (USDA) to create a nationwide monitoring system. As a part of NARMS, isolates of foodborne bacteria including *E. coli*, *Salmonella*, *Enterococcus*, and *Campylobacter* from humans, retail meats, and animals are collected and tested to monitor changes in resistance to antimicrobial drugs. The human samples for NARMS are collected from sick people and tested by CDC. The human samples are sent to the CDC National Center for Infectious Diseases in Atlanta, Georgia by participating state and local health departments. The animal samples are gathered from healthy farm animals, animal clinical specimens, carcasses of food animals at slaughter, and ground products at processing plants and are tested by USDA. Bacterial isolates of animal origin are collected from sites across the U.S. and sent to the Agricultural Research Service Antimicrobial Resistance Research Unit of USDA in Athens, Georgia. Animal isolates also come from federally inspected slaughter and processing facilities, USDA’s animal health monitoring studies on farms, and veterinary diagnostic laboratories. The retail meat samples are collected from grocery stores in states participating in the Foodborne Diseases Active Surveillance Network. Participating laboratories from FoodNet states isolate bacteria of interest and forward the isolates to the FDA Center for Veterinary Medicine Office of Research Laboratory in Laurel, Maryland for further analysis.

BRAND NEW TREK WEBSITE!
 By Liz Lloyd, Global Marketing Communications
 Manager, TREK Diagnostic Systems



We are pleased to announce that our website (www.trekds.com) has undergone a "makeover". The redesigned site is now live! Please take a moment of your time to familiarize yourself with the new website.

I hope that you will find that the homepage is less "cluttered" than the previous site. We have added a Product Highlights to the homepage and streamlined the content and organization for News Bulletins and Recent Papers. We also now showcase a Case Study on the Homepage, which will be rotated with other case studies. (If you would like to submit a case study for our website, please forward your

information to me at elloyd@trekds.com.)

The Products and Technical Information sections are much better organized and easier to follow than our previous website. For example, the Technical Information is broken into categories, such as FDA Clearances, Technical Papers, White Papers, Poster/Abstracts, MSDS, Product Specifications, and Tutorials.

In addition, we have a Newsroom tab that will allow the user to link to any of the following categories -- Tradeshows, Press Releases, Newsletters, Awards.

A Company Tab will allow the user to link to our

company Overview, Mission and Vision, Values, Awards, ISO Certification, and Employment.

If you have any questions, or suggestions for improvements, please feel free to contact me at 216-351-8735 ext. 109 or via e-mail at elloyd@trekds.com.

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