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Molecular Testing at NHRMC Has Resulted in Better Patient Care and Helps Reduce Costs

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Molecular testing is bringing big changes to healthcare at New Hanover Regional Medical Center (NHRMC) in Wilmington, North Carolina. Over the last several years, the development of laboratory methods to directly identify organisms by detection of specific DNA or RNA sequences (molecular testing) has revolutionized the field of clinical microbiology. At NHRMC, the Department of Pathology and Laboratory Medicine has led the way in implementing these newer techniques, resulting in faster turnaround times and improved patient care. Some of the tests added include Influenza, *Neisseria gonorrhoeae* (GC), *Chlamydia trachomatis* (CT), *Mycobacterium tuberculosis* (MTB), Rapid Blood Culture ID for Gram Positive bacteria and soon, Rapid Blood Culture ID for Gram Negative bacteria. All of these molecular tests are more specific and sensitive than traditional tests such as culture or immunoassays. In particular, the *Clostridium difficile* toxin and Rapid Blood Culture ID test for Gram-positive bacteria have had a very significant impact on patient care while also helping to reduce costs.

Clostridium difficile is a fastidious anaerobe that causes nosocomial, antibiotic-associated colitis, ranging from mild to severe disease, including pseudo-membranous colitis and toxic megacolon with a potentially fatal outcome. Even with all of the attention paid to the pathogenesis, diagnosis and prevention of *C. difficile* infection (CDI) in recent years, CDI still remains a leading cause of healthcare-associated diarrhea with a profound clinical as well as economic impact. From 2012 to early 2013, NHRMC laboratory performed 3,800 tests using older enzyme immunoassay (EIA) methodology that had a turn-around-time (TAT) of 3-4 days for negative tests and 24 hours for a positive result. Recently developed testing with faster turnaround times would allow specific treatment to be started sooner. Additionally, faster test results could help us better manage procedures and processes to prevent spread of *C. difficile* in the facility. While this has not been a problem at NHRMC, it has been a problem at many large

Con't on pg 5

In This Issue...

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Editor's Page

COL Kris Calero & CPT James Lehman, US Army

KnowledgeLab 2015 was a success! After over two years with no annual venue or meeting, it was an incredible feeling seeing so many SAFMLS members together again. Many of us did not get orders until the last minute, but in the spirit of the uniformed services, no obstacle is too high to surmount.

For the last two years the SAFMLS' board of directors worked hard to ensure SAFMLS remained a relevant society, and partnering with CLMA and utilizing their annual continuing education venue, KnowledgeLab, has only reinvigorated our mission.

Our publication, the Society Scope, remained as a conduit of our activities throughout the time we did not have an annual meeting, providing a relevant platform to SAFMLS members. Now that we are more visible to our civilian counterparts, CPT Lehman and I urge you to consider publishing. During KnowlegeLab, 12 SAFMLS members presented workshops, from general topics such as leadership, to very technical on toxicology. In the same manner, your articles are welcome for publication. Our publication will be visible to CLMA's members, giving you exposure like never before. One reminder, we welcome publishing articles that have been printed in other publications, all you have to do is request permission to reprint. So send those articles to us, and let's continue demonstrating that pride in all we do to our new partners!

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NEW DEADLINES for SAFMLS Society Scope:

Winter	Vol X Number 1	Deadline: 1 Dec
Summer	Vol X Number 2	Deadline: 1 Apr
Fall	Vol X Number 3	Deadline: 1 Aug

President's Message

LUCIA E. MORE, Col, USAF, BSC
Deputy Chief Scientist
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SAFMLS is alive and well thanks to our collaboration with the Clinical Laboratory Management Association (CLMA)! I had the pleasure of attending KnowledgeLab 2015 in Orlando 29 March – 2 April. Despite the last minute conference approval, there were 116 military members there, making up 25% of the non-vendor attendees. We expect the approval process to go more smoothly for the 2016 conference, but don't hesitate to begin your local coordination processes. It will be here before you know it. Next year's KnowledgeLab will be in Orlando, Florida at Disney's Coronado Springs Resort, March 20-23. For more details go to the CLMA.org website.

I believe this collaboration with CLMA will benefit both of us. COL Calero and I attended the CLMA Board of Directors meeting and were both impressed with their dedication to providing members with opportunities to network with other professionals, provide new ideas and information and enhance the clinical laboratory profession. CLMA shares SAFMLS' purpose of maintaining and enhancing high professional standards while creating relationships, developing careers and advocating the value of the laboratory to policy makers and the community. CLMA's Body of Knowledge identifies 10 domains of management responsibility and the skills to master to become an exceptional laboratory leader in much the same way we provide training in management and clinical skills to our military personnel. I think we have much to share and learn from each other.

I was so impressed with KnowledgeLab 2015. Lt Gen Douglas Robb, the Director of the Defense Health Agency, gave the opening general session keynote speech. He shared "Military Perspectives on an Integrated, Affordable, High-Quality Health Service: Lessons for Civilian Clinical Laboratories". With his enthusiastic and interactive presentation he highlighted the laboratory's contributions to both military and civilian healthcare systems. The entire audience was energized by his presentation! The workshops and presentations were educational, the vendor exhibits were comprehensive and the location was perfect! I'm especially excited about the Increasing Clinical Effectiveness (ICE) program. CLMA launched the ICE initiative to showcase case studies of improved patient outcomes brought by laboratory physicians and scientists. Participation in ICE requires the submission of abstracts that describe testing-related interventions and the quantifiable positive impact for patients they produced. (I'd LOVE to see a SAFMLS member's abstract be accepted as an ICE presentation!) "ICE is intended to bring together clinical laboratory physicians and scientists to coordinate a profession-wide approach to clinical effectiveness...and shift the clinical laboratory paradigm from a cost center to a strategic asset critical to the optimization of patient outcomes and healthcare costs." I believe SAFMLS working with CLMA can have a huge impact on enhancing the positive impact of the laboratory on patient outcomes.

There will lots of information in the coming months about the general SAFMLS elections, what our association with CLMA will mean to you and preparing for KnowledgeLab 2016 in Orlando. I hope to see many more of you in Orlando next March!

Consultant's Corner

CAPT (Ret) Cynthia Wilkerson, USN

As I prepare to retire after almost thirty years in the United States Navy, I find myself reflecting on my time spent in service to our country, the places I've been, the things I've accomplished and most importantly the people I've met along my journey. The names are too many to list or count but what most of them have in common is that they are my fellow lab officers from all three branches of the military - and I wouldn't have met most of them without being a member of SAFMLS. I joined my first year on active duty back in 1986 and I must admit that I stayed on the sidelines for the first eight years or so. Then I decided to help present my first workshop back in 1994 and the rest, as they say is history. That started a twenty year history of being an active member of SAFMLS; being a presenter, planning committee volunteer and member of the board of directors. I can truly say that the relationships that I have developed with lab officers from other services would not have been possible without SAFMLS. The annual meeting was a place for us to meet, exchange ideas, strengthen our laboratory expertise, develop professional relationships and renew friendships. I will always attribute my success in navigating the Defense Health Agency leadership office at the Center for Laboratory Medicine Services with the tri-service relationships developed throughout the course of my involvement with SAFMLS. Not a single one of us succeeds without our collective team effort and SAFMLS is a prime example of that. I know that the last few years and the conference travel restrictions have forced the cancellation of too many of our annual meetings. I hope that the new collaboration with CLMA and the success in gaining conference approval from all three services is a sign that the organization can continue to thrive and grow into an even more valuable organization than it has been in the past. Our civilian laboratory peers have much to learn from our military lab officers and we have much to learn from them. I challenge each and every one of you to get active and involved with SAFMLS. You have much talent to share and a unique set of knowledge, skills and abilities. Teach/present a workshop, run for one of the board positions, volunteer to be on the planning committee – don't wait, do something today. You will find that it is one of the most rewarding relationships you will develop in your military career.

How do I say goodbye to the numerous laboratory professionals I have met through my participation with SAFMLS over the years?? I don't think I can, so I will just say until we meet again – at SAFMLS!!

Con't from pg 1

facilities across the U.S. Since implementation of the molecular test, the TAT for C. difficile testing dropped from 3 days to 2 hours and the test volume has decreased, since repeat testing is not required for negative test results. Often the new molecular test is completed within an hour of receipt at the laboratory. With molecular *C. difficile* testing, the positivity rate has gone up which means we are detecting more true positives, enabling earlier treatment and initiation of infection control measures to prevent spread. As we continue to use the test, we have seen the length of stay (LOS) for these patients decrease from a high of 13 days to as low as 8 days. We have also seen a reduction of an estimated 12 colectomies per year due to untreatable *C. difficile* infections, attributable to both better detection and improvements in surgical care. While *C. difficile* infection may be an inevitable consequence of antibiotic treatment it can be managed much more effectively now with better, more sensitive, testing.

Rapid detection, identification and antimicrobial testing of bloodborne pathogens improve antimicrobial stewardship and can greatly enhance patient care. Conventional identification of blood isolates can take up to 72 hours while PCR based identification of direct colonies can take 20-30 hours. See Figure 1.

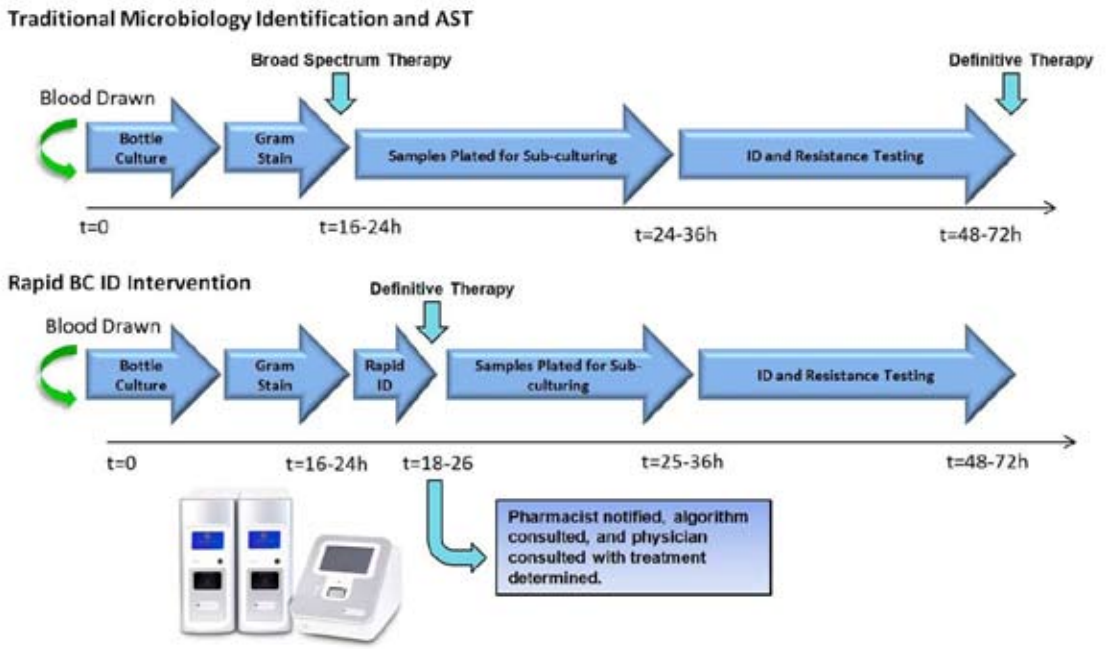

Figure 1. Rapid ID on the Verigene compared to traditional Microbiology techniques and potential impact on time to definitive therapy. Pharmacist notified and worked directly with physician on treatment for each patient. Average time from blood culture draw to intervention was 28.9 hours compared to 77.5 hours for traditional culture (data not shown).

The laboratory recently implemented a multiplexed, automated nucleic acid test for the direct identification from positive blood culture broth of genus, species and genetic resistance determinants for a panel of common Gram positive bacteria. Laboratory staff also worked with Infectious Disease and Pharmacy staff to develop an algorithm of recommended treatment for all of the bacteria identified on the system. This algorithm also included guidelines for when not to treat, since not all positive blood cultures are true infections.

Since last January, we have tested 1,026 patients with positive blood cultures and the rapid ID system correctly identified 995/1,026 (97%) of the intended Gram-positive target organism. The biggest impact has been in time to definitive ID and treatment. The time from bottle positive to definitive ID and treatment dropped from an average of 55 hours to less than 4 hours. This translated into initiation of appropriate antibiotic therapy 50 hours sooner than when using tradition phenotypic identification methods. See Figure 2. This change did require staff to ensure the rapid Gram staining of each positive blood culture bottle coupled with a new call sheet to rapidly contact a pharmacist to start treatment.

Con't on pg 6

Con't from pg 5

Rapid Blood Culture ID 2014 (hours : minutes)

Month	Total Done	Time to Gram stain	Time to Rapid ID	Time to ID culture	Time Saved
Jan	27	1:34	4:16	54:17	50:00
Feb	73	1:40	4:38	53:14	48:36
Mar	97	1:31	3:47	54:08	50:20
Apr	75	1:02	4:08	55:36	51:27
May	99	0:54	4:02	53:05	49:03
Jun	91	0:54	3:40	51:38	47:57
Jul	101	0:59	3:53	53:47	49:53
Aug	103	0:58	3:52	55:07	51:14
Sep	84	1:12	3:47	57:38	53:50
Oct	95	0:52	3:37	56:43	53:05
Nov	81	0:46	3:46	56:53	53:06
Dec	100	0:54	3:49	57:02	53:12
Totals and Averages	**1,026**	**01:06**	**03:56**	**54:56**	**50:59**

Goal is less than 4 hours

Figure 2. . Time to Rapid ID average and time saved compared to identification and AST completed using traditional microbiological culture and ID system.

We believe earlier therapy will result in faster recovery and it did reduce LOS for patients with Gram-positive blood stream infections. Our end-of-year results clearly showed a reduction of 5 days overall in LOS for patients with Gram-positive blood stream infections compared to the two years prior to implementation. See Figure 3.

Year	Total Cultures (Year)	Total Positive Blood Cultures (Year)	Total Contaminated (Year)	Average LOS (Days)
2012	**27,195**	**2,269**	**1,302**	**17.2**
2013	**27,548**	**3,158**	**566**	**15.5**
2014	**25,053**	**2,816**	**423**	**10.5**

Figure 3. Comparison of the overall LOS for the entire population of positive blood culture patients regardless of coding for the year of implementation (2014) compared to previous years (2012, 2013).

Rapid blood culture ID also enabled clinical staff to assess if the positive blood culture was a true infection or a contaminating organism. Of those tested, 41% were considered probable contaminants rather than a true infection. When a contaminant was suspected then the ID staff recommended waiting for a second bottle to become positive before initiating antibiotic treatment. By not treating patients with these contaminants, the pharmacy saved $250,000.00 in antibiotic costs (3 day treatment with broad spectrum antibiotics including vancomycin) which more than offset the increased cost of testing. While the hospital saved money, this change resulted in better antibiotic utilization with less vancomycin use, helping to minimize the development of drug resistance. Based on these results for Gram-positive organisms, Rapid blood culture ID for gram negative bacteria began in December of 2014 and we are collecting similar data. We are also added molecular panels for stool pathogens and respiratory viruses. Each of these new molecular tests is faster, much more sensitive, and has the potential to reduce LOS and result in improved patient outcomes coupled with better antibiotic utilization.

WATER SAMPLING CULTURES AND INTER-DEPARTMENTAL COLLABORATION

Jennifer Tate, MPH, MT(ASCP)
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INTRODUCTION:

Clinics and hospitals on a Native American reservations provide vital care and services to a population that would otherwise not have access to medical treatment. Reservations are typically in remote areas of the United States and many have conditions that are comparable to third world countries. Because most of the tribes on live in close quarters this population is at an increased risk for spreading communicable diseases such as tuberculosis, influenza, sexually transmitted infections. Other medical conditions that are seemingly common on Native American reservations are diabetes, hepatitis, and domestic violence. Indian Health Service clinics are key in controlling the spread of communicable diseases, educating patients on healthy lifestyle choices, and connecting patients to services for psycho-social counseling. I work in an ambulatory clinic setting in Toppenish, WA and serve the Yakama Nation tribe. Some of the key services this clinic provides are: laboratory/ radiology, optometry, dentistry, pharmacy, audiology, maternal/child health services, and public health nursing. The laboratory is has the following departments: Hematology, Chemistry, Microbiology, and Phlebotomy/ send outs area. The medical technologists in the laboratory are generalists and all perform phlebotomy on daily basis since there is only one designated phlebotomist. The Yakama Indian Health Service Unit is the largest and busiest clinic in the region.

The purpose of this article is to describe how the laboratory collaborated with the dental department to create a water sample testing program in house. Performing this testing in house saved our facility about $200 per test when contracted with an outside company. Also, the results were easily accessible since the cultures were performed in the facility and the results were available within 48 hours. Furthermore, creating the water sampling program encouraged laboratory personnel to think beyond the usual day to day patient testing and helps to build relationships with another department.

PURPOSE:

As a part of the dental department's accreditation, the water lines connected to the tools used for procedures have to be monitored for bacterial growth, cleaned, and maintained. Since these are environmental samples and are not sterile, some levels of bacteria are allowable and will not cause any harm to the patients. Although, infections from microbial contaminated dental water lines appear to be rare, it has been shown that microbial levels in untreated dental lines were beyond the 500 CFU/mL, which is more than what is allowed in standard drinking water[1]. This may be of concern in the immunocompromised and the elderly populations, possibly placing them at an unnecessary risk. The Centers for Disease Control and Prevention (CDC) recommends that coolant water used for non-surgical procedures in dental departments follow the same EPA has for drinking water: which is equal to or less than 500 CFU/mL of heterotrophic bacteria.

Testing the water that comes out of the lines is essentially testing the cleanliness of the tubing and the dental department's staff's methods of cleaning the lines. As laboratory personnel, we all know that water (moisture) and warm air is a recipe for growing bacteria. Because of the ideal breeding environment, dental water lines are known for harboring a wide variety bacteria, fungi, and protozoa. Regular testing of the water lines is a sensible way of monitoring the levels of bacteria and if necessary identifying pathogenic organisms that may be present in the lines. Upon implementing the water sampling program at our facility the following outcomes resulted: cleaning practices and types of sterilizers were reevaluate for effectiveness, revealing which lines were in need of more cleaning, and provided the lab staff with education in environmental testing.

PROCEDURE:

The water testing is a simple procedure that I modified from a veterinary research laboratory at a past assignment. Water samples are collected by the dental department staff into sterile cups and brought to the

Con't on pg 8

Con't from pg 7

laboratory for testing. Two types of culture plates are used for each sample: Blood Agar and MacConkey. The blood agar plates are used to count the numbers of heterotrophic colonies and the MacConkey is used to count the number of coliform (Gram Negative) bacteria, as well as identify any potential pathogens. Using a 200 microliter pipet, the water is pipetted from the cup and spread on to each plate. With a regular culture loop, the 200 microliters of water on each plate is spread over the entire surface of the plate. The plate is rotated each time the surface is covered with water until all of the water is seated into the agar. The blood agar and MacConkey plates are initially incubated at 37 degrees Celsius for 24 hours to recover pathogens that can dwell in the human body. Preliminary results can be reported at the 24 hour reading if there are organisms growing (especially if they are coliforms bacteria). After the 37 degrees incubation, the plates are then placed at room temperature for an additional 48 hours. In our facility since the clinic is closed over the weekend, we call this the "weekend incubation" period and the plates are then read on Monday. The room temperature incubation allows for environmental organisms to grow. These organisms are more representative of what is most likely to be found in the water lines since the lines are at room temperature. One of the biggest advantages of performing the water sample tests in house is that if there is a predominate organism, especially if it is Gram Negative, the culture can be set up for identification. The results for the 37 degrees incubation and for the additional 2 days room temperature incubation are reported in a chart format with the water lines identified in one column and a column for each plate with numbers of colonies counted in colony forming units. Since the results are reported as CFU/mL, the numbers of colonies counted are multiplied by 5 to convert the microliters units to milliliters. For example, if 10 colonies are counted on the blood agar plate then the result would be as follows: 10 CFU/200uL = 50 CFU/mL. The reporting style (i.e. chart format, listing, or dialogue format) can be tailored to each individual facility.

Example of the reporting style at our facility:

Dental Water Cultures

DAY ONE: October 24, 2014

Sample #	General Environmental Bacteria Colony Count	Gram Negative Colony Count
2B	No Growth	No Growth
5A	No Growth	No Growth
2A	No Growth	No Growth
4D	No Growth	No Growth
1A	No Growth	No Growth
1C	No Growth	No Growth
2C	No Growth	No Growth

Con't on pg 9

Con't from pg 8

Room Temp Weekend Incubation: 10/27/14

Sample #	General Environmental Bacteria Colony Count	Gram Negative Colony Count
2B	No Growth	No Growth
5A	No Growth	No Growth
2A	No Growth	No Growth
4D	No Growth	No Growth
1A	No Growth	No Growth
1C	No Growth	1 CFU/200uL=5 CFU/mL
2C	No Growth	No Growth

ADVANTAGES and IMPLICATIONS

Performing cultures of dental water samples in house provides faster turnaround times for results, more accessible results, allowance for organism identification, reduction in costs, and builds inter- departmental relationships at a facility. Preliminary results can be available within 24 to 48 hours of testing and the plates are accessible by anyone who may want to see what is growing. Having results available quicker and knowing what types of bacteria are growing, allows for faster action to sanitize the water lines and perhaps gives the dental staff a better idea of what type of disinfectant that may be better in cleaning the lines. Additionally, performing the water cultures in house can aid in establishing a baseline for initiating a dental water line testing procedure. Once it is identified which lines are growing more bacteria or the ones that may be growing coliforms, the dental department can create a program that allows for more routine testing and scheduled cleanings. The culture results can also reveal if the current methods of cleaning and the type of cleaning agents are effective. Some facilities may find performing the dental water cultures in house in addition to the routine patient testing more cost effective than using an independent company. A sleeve of blood agar and MacConkey plates are about $5.00 each, depending on what kind of agreement the facility has with the supplying company. Setting up the each culture takes about 5 minutes due to the spreading of the water over each plate. The microbiology department can coordinate with the dental department to set up a schedule so that the microbiology staff is not overloaded with too many cultures from dental. Furthermore, setting up and reading environmental cultures gives the medical laboratory scientist one more skill to learn and become proficient at. Learning environmental sampling and set up breaks up the monotony of the everyday clinical work and introduces the technologist to another aspect of microbiology testing.

Another important advantage to performing the dental cultures in house is the building of inter –departmental relationships. Even though we work in the laboratory and are generally isolated from the rest of the facility we are located in, we can still foster relationships with other departments. Every employee at the clinic or hospital main objective should be to do what is in the best interest of the patients we serve. Building relationships with other departments that improve the care delivered to the patients is an excellent way of creating a sense of *esprit de corps;* making employees feel like that they are a part of one cohesive unit with the mission in mind. Moreover, working with other departments to achieve a common goal, such as establishing a water testing and cleaning program, allows each department to share ideas that may be applicable to their own departments. For example, before working with the dental department at my facility, I had no idea about the dental water lines and what types of bacteria and other organisms that could be growing in the lines if not properly maintained. Working with the dental staff opened another door to a new skill that I can undertake and share with others. Because of this common goal, our facility now has a functioning dental water line sampling, culturing, and sanitizing protocol thus keeping the department and facility in compliance and beyond with the accreditation agencies.

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