

Medical Modernization at Air Combat Command Agent of Change

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The purpose of this article is to demystify development-and-acquisition activities associated with Medical Modernization and to engender a basic understanding of related processes, more specifically those used by the Medical Modernization Division for Air Combat Command.

Swimming Outside of the Clinical Laboratory Stream

Biomedical Laboratory Officers in the United States Air Force Medical Service usually start their careers as junior Company Grade Officers, learning to manage and lead sections or divisions within a clinical laboratory. As the lab officer advances in rank, education, and experience, the officer typically pursues one of three career development vectors, based on personal interest and the needs of the Air Force: *Clinical, Research, or Command*. Medical Modernization at a MAJCOM or at Air Staff is just one of the potential career broadening opportunities considered part of the Research vector. The purpose of this article is to demystify development-and-acquisition activities associated with Medical Modernization and to foster a basic understanding of related processes, more specifically those used by the Medical Modernization Division for Air Combat Command.

Introduction

The military is an instrument of change. Why do combat forces constantly change? Sun Tzu told us that, in an attempt to gain an advantage, opposing forces continually modify their tactics. When discussing a military force's weak and strong points, Sun Tzu wrote, "Therefore, just as water retains no constant shape, so in warfare there are no constant conditions." (Giles, 1910) In the United States Air Force change appears often and in varied forms; this often frustrating, central, unofficial tenet ends many, well intentioned careers far too early. Maybe the Air Force should consider a fourth Core Value: *Change is Good (and If You Don't Like It, Hit the Road)*.

You might be surprised to learn that the Department of Defense has long recognized this unrelenting reality of constant variability and has provided numerous tools to help subordinate organizations more effectively cope with the evolving tactics of our adversaries. The DoD does not pro-

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Editor's Page

Calling everyone to submit articles! Capt Hase and I cannot stress enough the benefits of publishing in the Society Scope. For starters there are hundreds of SAFMLS members, from all services. Your peers, specialty leaders/ consultants read the Scope; but now, since we are partners with CLMA, the Scope has a wider audience within our colleague's in industry. Publishing gives you the ability to spotlight your accomplishment in your OER/ FITREP or OPR. This gives you a standing above and beyond your peers including a national publication. Articles do not have to be research in nature. If you look through our previous publications at www.safmls.org (Look for Society Scope on the left), you will see we have articles about regulatory compliance, career corner, clinical applications and leadership development, for example. You can send us an overview of your experience from deployment or a spotlight of an event from your current hospital. We love those pictures!

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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
JBSA - Lackland, TX

As I pass the torch to your new President, COL Kris Calero, I am retiring from the Air Force 1 February after 27 years. I attended SAFMLS for the first time a month after becoming an active duty officer in 1989 and SAFMLS has been the cornerstone of my AF career ever since. As a presenter and planning committee member for many years, I have had so many opportunities and made so many friends from all three services. The collaboration between the services during these times of continuing conflict has contributed immensely to the overall knowledge, interoperability and effectiveness of military laboratory science. There have been many changes over the last 27 years, the biggest of which was the loss of our own independent meeting. Although that has slowed down the momentum, I believe the collaboration with CLMA will result in benefits to both organizations. We have much to share and learn from each other.

I ask you all to remember why SAFMLS exists: for the 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. SAFMLS members believe in the value of the organization, they hold themselves to a higher standard, and they are committed to contributing to the growing body of knowledge, to learn from each other and share what they know. CLMA shares those same values. Don't let the changes push you off that course. Now is the time you can make a difference and help forge the way for those who come after you!

It has been my honor and privilege to serve as your president and fellow SAFMLS member. I'll see you all at KnowledgeLab 2016 in Orlando, not in uniform but as a proud Emeritus member!

Lucia



Consultant's Corner

DANNY R. DEUTER, MEd, MPA, MLS (ASCP)
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MS Assistant Corps Chief, Medical Allied Sciences and
MEDCOM Laboratory Program Manager

Soldiers, Sailors and Airmen,

I would like to take the opportunity to thank you for what you do and wish you the best in your careers. I have been blessed with the opportunity to serve this country for over 31 years and have had the luck to work with some of the best laboratory personnel in the Department of Defense (DOD). Having been around as long as I have, you learn a thing or two and hopefully are the wiser for it. In my case I cannot speak for the wiser part but I have learned a thing or two. Take care of your people and they will take care of you. If you do not take care of them, "they will take care of you". As a supervisor, make the time and submit your civilian employees for those honorary awards we often overlook. I know most employees would rather receive a monetary or time off award. However, when it is time for them to retire it is almost impossible to get them the honorary award commensurate with their contributions over a 20 – 40 year career. Higher honorary awards (LOM/MSM or equivalent) have the concert in their justification "Nominees must have established a pattern of excellence, normally demonstrated by the receipt of lower level awards". Therefore, if they have not received a previous honorary award it is pretty hard to justify the more prestigious award. Treat your people fairly, and treat them how you would want to be treated or how you want your family members treated. Most laboratory personnel work long, hard days and truly try to do their best; a little praise or acknowledgement of their efforts goes a long way.

We often hear about what leadership style is best or how to be a better leader. I really don't feel one is better than the other, but rather the style that you are most comfortable with is the best style for you. Remember it is your actions that really dictate whether or not you will be a successful leader. In the Army we often hear about candor (*can-dor, /?kand?r/,* noun "the quality of being open and honest in expression; frankness.") and how being candid is appreciated and desired. During my career I have met many senior leaders who espouse the virtues of candor but I have found very few who appreciate it in their subordinates. Do not be one of those leaders; if you ask something, be prepared for the answer as it often is not what you expect. Before making decisions, think about the 2nd and 3rd order effects of the decision. Think about them from not only your perspective but from the other side of the coin. Be fair and treat people equally. While it may not make you a beloved leader, it will gain the respect of your critics and admiration of your supporters.

Looking back on 31 years, I can honestly say I'm ready to transition to a different life. What I will miss the least and the most about the military is one and the same thing, it is the people. Service members and civilians have brought me the greatest challenges and anguish, yet they have also provided the greatest joy and hope. Yes, I will miss the people and maybe the job a little; however, as I look at the next generation of leaders, I am quite content and feel secure that they too will do what is in the best interest of our military family.

Dan



vide coping mechanisms merely to satiate stressed forces; we must demonstrate agility in adaptation to defend our nation effectively. This need for agility and adaptability is from where the field of military modernization originates. While our line counterparts must modernize the nation's weapon systems and tactics to keep us a step ahead of potential adversaries, military medics must seek to modernize their existing capabilities to keep pace with the wounds, injuries, and diseases that result from those changing military tactics, weapons, and theaters of operation.

The Air Force addresses its medical readiness needs via three Manpower and Equipment Force Packaging (MEFPAK) Responsible Agencies (MRAs): Air Mobility Command (AMC primarily provides for patient evacuation and en route care); Air Force Special Operations Command (AFSOC primarily provides Point-of-Injury or Role 1 care); and Air Combat Command (ACC primarily provides the Air Force's extensive ground medical capabilities, such as the Expeditionary Medical Support—EMEDS—family of assets). Each of these MAJCOMs employs a Surgeon General (SG) with numerous responsibilities within each respective command, including divisions responsible for Medical Readiness (SGX) and Medical Modernization (SGR). ACC's Medical Modernization and Planning Division (ACC/SGR) works on behalf of the ACC SG to: 1) Leverage emerging and existing research, knowledge, and technology to identify, validate, develop, assess, and improve capabilities for expeditionary ground medics; and 2) Drive novel research that modernizes expeditionary medical care, ensuring medically-ready Airmen, and enhancing human performance of all Airmen across the full spectrum of military operations. (Goldhagen, 2014) In pursuit of mission objectives, SGR staff, using the various aforementioned systems and processes, such as the Joint Capabilities and Integration Development System (JCIDS), pursues two primary, broad tasks: *Requirements Management and Military Utility Assessments*; these activities—a few briefly discussed in this article—can be subdivided into numerous, complex subtasks and processes.

Requirements Management

A fighting force is only as effective as the capabilities it brings with it. A capability is “the ability to achieve a desired effect under specified standards and conditions through combinations of” various ways and means (Defense Acquisition University Press, 2009, pp. B-21). For example, the A-10 Thunderbolt II (affectionately dubbed the “Warthog”) has several unique capabilities, such as the instantly familiar, munition-spewing cannon located beneath its nose, and the ability to endure tremendous damage before failure. A solution or capability—whether acquired “off-the-shelf” or developed from inception—is the Air Force's answer to a *requirement*, which is the detailed description of a solution to a *capability gap*. A capability gap is simply the lack of an existing capability, either in quality and/or in quantity, identified through some means; in short, an identified capability gap is the expression of a *need* for something that can fill the gap. (Defense Acquisition University Press, 2009, pp. B-21)

Exactly how can one reliably identify capability gaps? There are several sources (e.g., lessons-learned, exercises, strategic guidance, strategic planning, studies, leadership vectors, etc.) from which to begin. One of the more common methods employed by requirements managers is the *Capabilities-Based Assessment* (CBA). There is no one specific, mandated process to conduct a CBA, but the Joint Chiefs of Staff, J-8, offer requirements managers the *CBA User's Guide* as a starting point. (Joint Chiefs of Staff, JCS J-8, 2009) ACC SG has most recently focused its internally developed CBA process on the experiences of recently redeployed, ground-based medics to produce a rudimentary, prioritized list of operationally focused capability gaps and loose solution descriptions we informally refer to as “requirements.” This list is refined and validated by consultants, subject matter experts, and the Air Force Medical Support Agency's Requirements Division (AFMSA SG5). It is then used to draft the initial, more detailed capability gap and requirement descriptions; describe changes not related to materiel solutions (known as *Doctrine-Organization-Training-[materiel]-Leadership-Personnel-Facilities-Policy Change Recommendations*); or potentially generate research programs. Medical research programs can lead to follow-on materiel development or changes to clinical practice guidelines (i.e., policy).

Continuing with the A-10 example¹, at some point in the past, warfighters described a tool that was missing from their Close Air Support (CAS) toolbox; they broadly expressed a need for better CAS capabilities (e.g., better survivability with improved capabilities to support ground forces and “kill tanks”). Requirements managers

¹The example given is purely illustrational, as Warthog development preceded JCIDS creation by 28 years.

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drafted a JCIDS product known as an *Initial Capability Document* (ICD) that detailed the capability gap and a broad requirement description. (Chairman of the Joint Chiefs of Staff, 2012, pp. B-1) Each JCIDS document must be approved by designated validation gatekeepers—*Requirements Oversight Councils* (ROCs)—organized at various levels throughout the DoD. (Chairman of the Joint Chiefs of Staff, 2012, pp. C-1) ROC activities, such as the Joint Requirements Oversight Council (JROC), Air Force ROC (AFROC), and the Air Force Surgeon General's Requirements for Operational Capabilities Council (SGROCC), validate requirements within their respective purviews, while the *Milestone Decision Authority* (MDA)—a high-ranking official with authority delegated to pursue potentially expensive acquisition programs—manages the acquisition lifecycle that flows from those validated requirements.

Going back to the A-10 example, once the AFROC validated the CAS ICD, an MDA made an official decision to pursue a materiel solution for the gap during the *Materiel Development Decision* (MDD) at the beginning of the *Pre-Systems Acquisition* phase of the acquisition lifecycle. MDAs typically lead *System Program Offices* (SPOs), where a team of acquisition experts intimately manage materiel development efforts for their customers—the warfighter or combat developer. (Note: ACC SG is the Air Force “Expeditionary Ground Medical Combat Developer” or “User,” acting as the ground medical warfighter’s representative in these complex endeavors.) During this early period of the A-10 development process, the experts conducted a *Materiel Solution Analysis*, including an extensive *Analysis of Alternatives* (AoA), to ensure that there were no other available means to address the capability gap. The conclusion of the AoA and the recognition that there were no alternative solutions marked *Milestone A*—the decision by the MDA to enter into Technology Maturation and Risk Reduction (still in the *Pre-Systems Acquisition* phase) of the acquisition lifecycle.

During this stage, a group of operational and technical experts refined the broad definition of that CAS capability gap and produced a more detailed description of a specific materiel solution—a *requirement*—which included the engineering specifications and performance attributes that would be needed to manifest the required capability (e.g., armor at least four-inches thick but preferably six-inches thick, low-speed maneuverability, a rapid-fire 30mm cannon capable of projecting 65 rounds-per-second, etc.). (U.S. Air Force, 2004) That detailed requirement was captured in a JCIDS product called the *Capability Development Document* (CDD) (Chairman of the Joint Chiefs of Staff, 2012, pp. B-1), and the CDD’s validation at the AFROC and the MDA’s decision to continue into the *Systems Acquisition* phase marked the true beginning of materiel acquisition at *Milestone B*—entry into *Engineering and Manufacturing Development* of the acquisition lifecycle. Whereas the ICD broadly described the need for improved CAS, the CDD unequivocally stated the need for the A-10 as a CAS solution. Though it does not always occur, other CDDs—describing additional, specific CAS solutions—could flow from the original, broad CAS ICD.

In pursuit of a materiel solution, combat developers, working within the *Corporate Structure* of the Air Force, must also consider program prioritization and funding through concurrent *Planning, Programming, Budgeting, and Execution* (PPBE) processes. The Core Function *Lead Integrator* (typically a responsibility given to a particular MAJCOM) prioritizes validated requirements and programs, deemed within the scope of a particular Air Force *Service Core Function* (i.e., *Air Superiority, Rapid Global Mobility, Agile Combat Support*, etc.) and its associated *Core Function Support Plan*, against other programs for limited funding. Through complex PPBE activities (too lengthy to address here in detail), funds are eventually allocated to *Program Elements* (PEs) for approved programs. A PE is a budgetary device—somewhat like a bank account—used by financial managers to execute development programs. An MDA cannot approve or manage an acquisition program beyond Milestone B without adequate funding allocated to the program’s associated PE.

As the A-10 acquisition lifecycle continued, the SPO contracted with the Fairchild Republic Corporation to design and develop the proposed CAS system. (U.S. Air Force, 2004) After numerous rounds of development, prototyping, testing, and evaluation lasting many years, Fairchild Republic produced a production representative aircraft (or *Engineering Design Model*). The AFROC validated the *Capabilities Production Document* (CPD) that detailed testable characteristics necessary to initiate *Low-Rate, Initial Production* (LRIP) of the first A-10s (i.e., denoting *Initial Operation Capability*). The MDA’s decision at Milestone C marked the A-10’s entry into *Production and Deployment* of the *Systems Acquisition* phase.

Post-CPD activities involved addressing problems that arose from early LRIP batches, such that engineers addressed all major issues before *Full Rate Production* (i.e., *Full Operational Capability*). The SPO eventually

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transitioned the entire fleet of new aircraft into *Operations and Support* of the Sustainment acquisition phase; it is during *Sustainment* where we find the A-10 today, still utilized and maintained until it is no longer serviceable, culminating in its retirement and disposition. Before this occurs, however, requirements managers will have started these processes anew—working to replace the Warthog with a new CAS capability, more matched to the ever-changing martial environment described by Sun Tzu.

Described here in a simple, generalized manner that only “scratches the surface,” these myriad processes and activities of *Requirements Management*, from capability gap validation to new capability sustainment, illustrated here using the familiar A-10, apply equally to the development of medical materiel needed for Air Force expeditionary ground medics. This is including capabilities such as specialized oxygen generators, patient warming-cooling devices, or even fluid infusion pumps. The MRAs, in response to the constantly evolving wounds and injuries of war, utilize these same complex processes to generate the lean capabilities required to render robust, lifesaving combat casualty care and rapid aeromedical evacuation.

Military Utility Assessments

ACC/SGR partners with ACC/SGX to “modernize” previously fielded ground medical capabilities with commercially available alternatives that meet or exceed the current capability in certain respects (e.g., cost, performance, size, weight, power consumption, etc.). SGX must periodically review its Unit Type Code (UTC)² Allowance Standard to identify fielded capabilities that require replacement. In order to apply analytical rigor to the selection of upgraded capabilities, SGX will identify specific items to SGR for the Military Utility Assessment (MUA) process. The MUA’s purpose is to operationally test and evaluate similar commercial capabilities against *Essential Characteristics* (ECs). ECs are much like the performance specifications described in a CDD (e.g., no heavier than 3 pounds, must have battery power, etc.). The specifications and performance characteristics of the currently fielded item represent the EC baseline or threshold for any specific MUA; SGX and the UTC Pilot Unit may desire increased performance in certain ECs beyond those of the original capability, so the preferred performance in an EC might become the objective for the MUA.

ACC/SGR often works with the Air Force Medical Evaluation and Support Activity (AFMESA), which is the Air Force Surgeon General’s *Operational Test Agency*, located at Fort Detrick, MD, to design MUA test events. AFMESA constructs test plans that mimic operational usage as closely as possible, utilizing the same facilities and personnel that would normally deploy downrange. The test plans they develop take into account the combat developer’s objective ECs and the subjective opinions of users. At the conclusion of the MUA event, ACC uses a report published by AFMESA as the basis for objectively procuring the ideal commercial replacement capability for the UTC Allowance Standard.

For example, if SGX determined it needed to replace electronic thermometers on an Allowance Standard because the thermometers were at the end of their useful lifespan, SGR would work with AFMESA to acquire newer, commercially available thermometers and develop a test plan to evaluate them against ECs, predetermined with SGX’s assistance. Deployable medics would then utilize each thermometer under identical operational field conditions to determine the performance of each compared to the objective ECs; the medics would also describe their subjective preferences and concomitant rationale through a survey. AFMESA evaluators would analyze the objective and subjective data from these tests and publish a report that would compare, summarize, and recommend the most logical replacement thermometer. SGX would use this report to justify procuring the selected thermometer to replace the older technology on the Allowance Standard. Though usually more complicated than illustrated with this example, ACC/SG designed the MUA process to follow these basic phases.

Conclusion

The Medical Modernization Division at ACC/SG utilizes multifaceted toolsets in order to successfully manage requirements and maintain ground medical readiness assets at the cutting edge of technology. Stated simply, ACC/SGR is a change agent for Air Force expeditionary ground medical care. It is an impossible task to describe in this short piece the interminable complexity and quantity of interrelated processes, activities, partnerships,

²EMEDS consist of multiple UTCs representing distinct capabilities.

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and policies used to generate medical requirements and modernize ground medical capabilities to keep pace with the constant evolution of combat casualty care, force health protection, human performance, and humanitarian response. Considerable information was omitted due to the constraints of time and space; the Defense Acquisition University (<http://www.dau.mil>) offers many free educational resources to more thoroughly immerse interested readers into the subjects of requirements, acquisition, PPBE, contracting, testing-and-evaluation, and many others.

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Board Certification for Laboratory Directors and Supervisors

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Since the CLIA '88 regulations were amended in 2003, board certification for laboratory directors has been required. For non-physician laboratory directors, there are only a few options for board certification. One of the CLIA-approved board certifications is provided through the American Board of Bioanalysis (ABB). Doctoral-level scientists can qualify by passing ABB examinations in Clinical Chemistry, Molecular Diagnostics, Microbiology, Public Health Microbiology, Hematology, Immunology, Andrology or Embryology.

Currently, ABB certifies or re-certifies about 700 doctoral-level scientists per year. In order to be ABB certified, the applicant must document at least four years of experience in high complexity testing, of which at least two years must be supervising or directing. The successful candidate is awarded the High Complexity Clinical Laboratory Director (HCLD) certification with

completion of the technical portion of the examination, plus completing a "General Knowledge" examination, which covers administrative, regulatory, and management responsibilities of a laboratory director. For multi-disciplinary types, another option is to pass at least three technical examinations and the "General Knowledge" examination to receive the Bioanalyst Clinical Laboratory Director (BCLD) certification.

For non-doctoral scientists, ABB also offers a Technical Supervisor (TS) certification in all of the above disciplines, which requires passing one of the technical examinations listed above, but not the "General Knowledge" examination. CLIA requires a Technical Supervisor, as well as a Director, for all high complexity testing. The Technical Supervisor certification requires a minimum of a Bachelor's degree and four years of experience or a Master's degree and

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two years of experience. Check out the specifics for the certification at www.abbcert.org

For officers and enlisted laboratorians, the need to certify as a Director or Technical Supervisor is not required in the military; however, when one leaves the military, Directors need to meet CLIA requirements. Advantages include meeting CLIA requirements, setting the highest level of competency by passing specialty examinations, and having the opportunity to interact with hundreds of qualified directors and supervisors across the country. In addition, a CLIA-qualified Director can officially direct up to five clinical laboratories, although some state agencies limit the directorship to three laboratories. A CLIA-qualified Technical Supervisor can supervise an unlimited number of laboratories.

The American Association of Bioanalysts (AAB) holds an annual scientific meeting (in 2016, it will be held at the Red Rock Resort in Las Vegas, May 12-14). At the 2016 meeting, AAB has arranged to hold a 1½-day "military section" program for technical and scientific continuing education. AAB has agreed to reduce the registration fees for

all military, DOD, and DA employees. The program will be provided by military and DOD employees who have volunteered to present updated scientific data applicable to the clinical laboratory. In addition, AAB will present a lecture on the need for certification for officers and enlisted laboratorians. The program will be preapproved for PEER continuing education (CEU) credit. With successful attendance, AAB will consider establishing a Special Interest Group for military educational programs. In addition, the AAB holds a poster session during the annual meeting and welcomes members of the military to present clinical and research data in this format. Two \$250 cash prizes are awarded for the best abstracts, which usually includes one poster and one oral presentation.

For more information, visit www.abbcert.org, email: abb@abbcert.org, or call (314)241-1445.

*Dr. Smalley served in the Army Reserve for nearly 30 years and retired at the rank of Brigadier General and served as the Assistant Surgeon General for the Army and Deputy Commanding General, Army Reserve Medical Command and 807th Medical Command (Deployment Support). He currently serves as president of American Esoteric Laboratories (AEL), a Sonic Healthcare Company, Memphis, Tennessee.

Diagnostic Services available within the DOD

MAJ Yvonne M. Beale, US ARMY
Laboratory Officer, MT (ASCP)
Walter Reed Army Institute of Research (WRAIR)

The United States Army Medical Command (MEDCOM) supports testing at several locations within the Department of Defense (DOD).

These College of American Pathologists (CAP) accredited laboratories are available to provide quality testing to any DOD Medical Treatment Facility (MTF) at minimal cost to the MTF.

Featured this edition is the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD. There are three CAP accredited laboratories on this campus, the HIV Diagnostics and Reference Laboratory (HDRL), the Leishmania Laboratory (LDL) and the Multidrug Resistant organism Repository and Surveillance network (MRSN).

The test menu for each site:

HIV Diagnostic and Reference Laboratory

Serology

HIV Combo Ag/AB

HIV-1 Western Blot (WB) Supplemental

HIV 1/2 Multispot Rapid Test

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Molecular

HIV-1 Viral Load (COBAS AmpliPrep/ COBAS TaqMan)
 HCV Viral Load (COBAS AmpliPrep/ COBAS TaqMan)
 HIV-1 RNA Qualitative Assay (APTIMA)
 HCV RNA Qualitative Assay (APTIMA)
 HIV-1 Resistance Genotype
 HIV-1 Phenotype (sent out to Monogram Biosciences)
 HIV-1 Trofile (sent out to Monogram Biosciences)
 HIV-1 DNA PCR, HIV-2 DNA PCR-2POC

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 Fax: (301)319-9449

Multidrug Resist Organism Repository and Surveillance Network

Identification and Antimicrobial Susceptibility Testing of Staphylococci and Enterococci Phoenix Automated Microbiology System BD

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If there are laboratory tests that you currently send to a commercial laboratory at cost please review the list of services currently available to you in this column and consider the cost savings of sending the test to one of these facilities.



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- Ability to capture and segregate waste for cost-efficient disposal



AGS-1000 **Best Gram Stainer for Low-Volume Labs**

- No waiting to batch slides or waiting at the Gram stain sink
- No more worrying about slide quality on night and weekend shifts
- Self-contained, small footprint fits on the most crowded bench



QuickSlide Plus II **Hematology Stainer**

- Fast and consistent staining
- No pre-fixing of blood smears
- Adjustable stain and buffer times
- No daily maintenance; compact size
- One minute process time



QS-AFB Acid-Fast Bacillus **Rapid Fluorescent Stainer**

- Fast inexpensive first look for TB testing
- No daily maintenance; compact size
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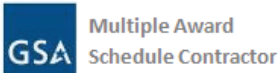


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