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The Need for Dedicated Microbiology Leadership in the Clinical Microbiology Laboratory

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Abstract (75 words)

Clinical microbiology laboratories play a crucial role in patient care using traditional and innovative diagnostics. Challenges faced by laboratories include emerging pathogens, rapidly evolving technologies, healthcare-acquired infections, antibiotic-resistant organisms and diverse patient populations. Despite these challenges, many clinical microbiology laboratories in the United States are not directed by doctoral level microbiology-trained individuals with sufficient time dedicated to laboratory leadership. This manuscript highlights the need for medical microbiology laboratory directors with appropriate training and qualifications.

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Leadership in a Full Service Clinical Microbiology Laboratory in the United States: Needs and Challenges

Clinical microbiology is an essential subspecialty within laboratory medicine. It supports a wide range of clinical services, from infectious disease diagnosis and treatment, to infection prevention and control, and antimicrobial stewardship, and thus contributes directly to patient care, policy, and practice at individual, institutional, and community levels (1-3). For the individual patient, the clinical microbiology laboratory's main task is to detect and identify pathogens from clinical specimens and, where applicable, characterize the associated antimicrobial susceptibility profiles. As rates of resistance to antimicrobial agents continue to escalate, clinicians increasingly rely on the clinical microbiology laboratory to navigate the spectrum of constantly evolving resistance mechanisms and aid in identifying specific therapeutics that can treat their patient's infection (4, 5). At the institutional level, the clinical microbiology laboratory plays a significant role in quality metrics regarding antimicrobial stewardship, and the detection, control, and prevention of healthcare-acquired infections (HAIs). The ability of the microbiology laboratory to impact institutional performance in these areas has been well established and has taken on added significance in light of recent global disasters such as the coronavirus disease 2019 (COVID-19) pandemic and the spread of multi-drug resistant microorganisms (6-8). Finally, the clinical microbiology laboratory makes essential contributions at the community level by partnering with public health departments to aid in detection of disease outbreaks, communicate cases of reportable diseases, in order to minimize the impact of infectious diseases in the community (9, 10).

The services provided by the clinical microbiology laboratory vary by the size and needs of the associated health care institution(s). For the purposes of this manuscript, a full-service

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clinical microbiology laboratory is defined as one which provides an array of low, moderate and high complexity testing for identification and characterization of bacteria, mycobacteria, fungi, viruses and/or parasites to support the care of the patients. A full-service clinical microbiology laboratory employs a range of testing methodologies for pathogen detection and analysis, and is instrumental in implementing new technologies to improve patient care. Methodologies employed by a full-service clinical microbiology laboratory may include microscopy, culture, serology, proteomic analysis (e.g. mass spectrometry), and nucleic acid-based tests. Full service laboratories are not limited to large academic centers or commercial entities but also serve community hospitals and large integrated healthcare systems.

The scope and complexity of a full service clinical microbiology laboratory make it logical and necessary for healthcare institutions to recruit a trained, doctoral-level medical microbiologist to be at the helm, and making evidence-based decisions to meet the needs of the patients, institution, and community (9, 11, 12). Often these full-service clinical microbiology laboratories lack a dedicated director with adequate time, resources and/or training to accomplish his or her roles in a satisfactory manner. In these settings, leadership decisions are commonly delegated to laboratory technologists, laboratory supervisors, and operations managers who are focused primarily on the technical and administrative aspects of the laboratory rather than unmet medical and scientific needs. Unfortunately, recent challenges in US healthcare, combined with declining reimbursement rates for microbiology services, have exacerbated this situation by contributing to the erroneous view that medical microbiology leadership position(s) are a luxury within laboratories.

Given the complexity of the full-service clinical microbiology laboratory and the challenges faced in providing optimal patient care, the authors and supporting organizations of

this manuscript fervently advocates that full service clinical microbiology laboratories be directed by medical microbiologists, and that these individuals be allotted sufficient professional time to provide laboratory oversight and maintain professional competence. This manuscript serves as a resource to medical microbiologists for demonstrating their value, and to laboratory leadership for justifying the hire of dedicated medical microbiologists.

The Definition, Roles and Value of the Medical Microbiologist

In order to demonstrate the value that a dedicated medical microbiologist provides to the healthcare system, it is first necessary to define the position and outline the roles that individuals in the position serve. Medical microbiologists are defined here as doctoral-level scientists or physicians who have received specialized training in medical microbiology. There are several routes to acquiring this training, and these are detailed below in the section entitled "Recommended Qualifications for Medical Microbiologists".

Medical microbiologists serve multiple essential roles across eight generalizable areas of healthcare (13-17). These are listed in Table 1 and detailed below in the context of the value that the medical microbiologist brings with each of the roles. Value can be difficult to define when considering only the benefit to the laboratory as the position does not lend itself to supplemental billing or generation of the relative value units (RVUs) used in the US Medicare reimbursement formula for services (18). Furthermore, there are no studies comparing patient outcomes, incremental revenue or cost savings from laboratories with and without medical microbiologist leadership. However, numerous benefits can be identified, along with concrete examples, when expanding the analysis to encompass the value provided to the entire healthcare system relative to the investment required. Thus, this is the framework in which the value of the medical

104 microbiologist is best described. These benefits and representative examples are described
105 below.
106
107 *Clinical Consultation*
108 First and foremost, medical microbiologists support patient care through the provision of
109 clinical consults to guide appropriate laboratory test selection, interpret test results, and aid in the
110 selection of therapeutic options. The National Academy of Medicine Report on Improving
111 Diagnosis in Health Care in 2015 recommended that the diagnostic process should be a team
112 based approach that includes appropriately trained laboratory professionals (19, 20). In this
113 setting the medical microbiologist, as the subject matter expert, is an essential part of the
114 diagnostic management team (21). Unlike other members of the clinical microbiology
115 laboratory, medical microbiologists have the training and experience to unravel the complex
116 factors that impact laboratory results and interpret results in the context of the individual patient.
117 For example, the medical microbiologist can review a sputum bacteriology culture result and
118 interpret the findings for the clinical team in the context of the accompanying Gram stain, other
119 laboratory test results, radiologic imaging findings, and the patient's clinical history.
120 Positive outcomes from medical microbiologist consultation have been well-documented
121 in the literature. Prime examples include increased appropriate antimicrobial treatment, reduced
122 time to appropriate therapy, maintained compliance with practice guidelines, de-escalation of
123 unnecessary antimicrobial therapies, lowered antibiotic costs, and reduced number of overall
124 ICU bed days (2, 22-24). Medical microbiologist consultation is particularly important when
125 antimicrobial susceptibility test (AST) results does not meet expected patterns. For example,
126 some Enterobacterales can express a combination of porin mutations, efflux pumps and other

resistance mechanisms that mimic carbapenemase expression, which could lead to the use of less effective and potentially toxic antibiotics. Medical microbiologists with the appropriate knowledge and tools can correctly evaluate the AST results and communicate their interpretation to the clinical teams to facilitate effective therapy (25); in contrast, this expertise is not possessed by most medical laboratory scientists , laboratory supervisory staff and physicians.

The Infectious Disease Society of America (IDSA) specifically recognizes the value of medical microbiologists in their guidelines for antimicrobial stewardship, in which they state that a comprehensive stewardship program *requires a medical microbiologist as a core member of the team*. They further indicate that this multidisciplinary team could reduce antibiotic usage significantly (22-36%), resulting in significant annual cost savings ($200,000-$900,000) to institutions both at the community and academic level (26). Given the potential complexity of antimicrobial susceptibility testing and result interpretation, it is unsurprising that surveys of infectious disease physicians indicate that the perception of quality of laboratory results is greatest when the laboratories are directed by dedicated qualified individuals (27).

Another important example of how clinical consultation by a medical microbiologist can measurably improve patient care and decrease healthcare costs is through guiding optimal test utilization (i.e., diagnostic stewardship). Laboratory test menus and testing guidelines have become increasingly complex and many ordering providers struggle to keep up with advances in laboratory medicine. Furthermore, patient expectations, today's risk averse climate, and a desire to decrease the need for multiple return visits may place pressure on the provider to order excessive diagnostic testing. Combined, these factors may result in overutilization, underutilization or mis-utilization of laboratory testing. Overutilization of laboratory testing not only increases the cost of care, but may also negatively impact the positive and negative

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predictive value of individual tests when the tests are ordered in low prevalence settings in which there is a low pre-test probability of disease (28). Alternatively, underutilization is estimated to occur in up to 55% of common disorders across laboratory medicine, and can also negatively impact patient care and length of stay (28, 29). Finally, test mis-utilization may occur when an incorrect laboratory test is ordered instead of a correct test. Multiple national and international quality guidelines, including The Choosing Wisely initiative (https://www.choosingwisely.org/), provide evidence-driven recommendations for optimal test utilization. Medical microbiologists play an important role in contributing to, interpreting, disseminating, and enforcing these guidelines in their practice. Test utilization and creation of diagnostic testing algorithms is discussed in greater detail under Test Evaluation, Verification, Implementation, and Oversight, below.

Scientific Oversight

Another key area in which medical microbiologists provide substantial value is in monitoring developments in the field and adapting their laboratory practices to meet patient, institutional, and societal needs. Appropriate adaptations may include creation of new or modified testing algorithms in collaboration with other members of the clinical care team, incorporation of new testing options (see Test evaluation, verification, implementation, and oversight below), changes to laboratory reports, and addition of new quality assurance practices. This level of oversight requires an engaged and dedicated medical microbiologist who maintains expertise in the field and is committed to life-long learning.

In the setting where diagnostic algorithms often need to be tailored to meet diverse local needs, the cost of having professional expertise onsite is dwarfed by the potential impact on

patient care and savings realized by the institution. Medical microbiologists, Pinsky and Hayden, recently published a comprehensive review of cost-effective testing for respiratory viruses, and how optimal testing strategies varied by the patient population, types of testing, and turnaround time needed for desired outcomes (30). Results of observational case-control study of inpatients highlighted by this report found that positive results of rapid respiratory virus testing (including direct fluorescence antigen and nucleic acid amplification tests) was associated with increased appropriate antiviral use, less antibacterial use, significant reductions in the duration of hospitalization and cost savings to the healthcare institution. These types of studies are generally conducted by medical microbiologists in partnership with other clinicians, as they require a high level evaluation of laboratory testing in the context of the entire health care setting and not just the clinical microbiology laboratory. Similar studies have been conducted by medical microbiologists to demonstrate the utility of newer, multiplex, nucleic acid amplification "syndromic" panels, such as those used for detecting upper and lower respiratory tract infections, gastrointestinal infections, meningitis/encephalitis, and blood stream infections. These expensive panels can provide significant value to patient care, but only when used judiciously as part of clinical testing algorithms (31-33).

The value of medical microbiologist oversight has been especially highlighted by recent outbreaks of novel and emerging pathogens such as 2009 H1N1 influenza virus, Ebola virus, Zika virus, and Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Outbreaks of previously-unknown pathogens pose extraordinary challenges to the clinical microbiology laboratory and require rapid decision making by laboratory leaders (34, 35). In particular, the emergence of a novel pathogen, (SARS-CoV-2), necessitated a rapid, scientifically driven, review of sparse and sometimes conflicting data in order to design safe specimen collection,

transportation and testing processes. Many high level scientific issues had to be addressed on an ongoing basis throughout the pandemic, such as whether to report PCR cycle threshold (Ct) values to predict patient infectivity and outcomes, use alternative specimen types not typically accepted by the clinical microbiology laboratory (e.g., saliva for detection of respiratory pathogens), produce testing supplies (e.g., viral transport media) in-house, and adopt non-standard practices testing such as pooled patient specimen testing (36). These evaluations required a level of knowledge and experience generally found at the medical microbiologist level, and not usually present at the medical laboratory scientist and supervisor levels (37).

The future of clinical microbiology will continue to bring new pathogens and pandemics, and there will be many new technologies and platforms that need to be carefully considered for use in patient care. Examples on the horizon include the use of the microbiome and host immune response profiles to diagnose and characterize infectious and non-infectious disorders (38). The challenges associated with new approaches such as these are many, including a lack of standardized protocols and interpretive criteria. This further emphasizes the need for medical microbiologists to take the lead in the evaluation, development, implementation and utilization of these technologies for patient care (39).

Test Evaluation, Verification, Implementation, and Oversight

A central responsibility of the medical microbiologist is to continuously evaluate the suitability and performance of testing methodologies to ensure that the laboratory's test menu meets the clinical needs of the healthcare institution. As new methodologies and discoveries become available, medical microbiologists must evaluate them in the context of the existing laboratory practice and determine if new tests and technologies should be verified and

implemented for patient care (see section on Scientific Oversight above) (40-42). Laboratory tests have an entire lifecycle, from the initial evaluation, to verification, implementation, ongoing oversight, and finally, retirement. Each component may present multiple challenges and should be overseen by a medical microbiologist.

When considering new tests, medical microbiologists must periodically evaluate the laboratory's referral (i.e., "send-out") testing menu to determine if testing is appropriate for the population that they serve. Although referral testing provides patient access to essential tests that are not available locally, such testing could be a significant financial burden to the healthcare institution, particularly when not used judiciously. The laboratory is responsible for all testing that is performed for their patients, including tests performed at outside laboratories, and therefore laboratory leadership must review the quality and medical necessity of referral testing. In some situations, it may be beneficial to bring a test in-house for the benefit of the patients, even if it is not financially beneficial for the laboratory. Medical microbiologists receive extensive clinical training which allows them to evaluate the impact of a new test to the clinical practice, while considering the costs and benefits to the laboratory and the institution (43) .

The next step in the test lifecycle after new test evaluation is verification. The laboratory must be able to reproduce the test's performance characteristics as determined by the manufacturer, including accuracy, precision, reportable range, and reference range. A well-designed verification process can detect important test limitations that may impact patient care. For example, medical microbiologists discovered that an FDA-cleared automated susceptibility platform failed to reliably detect inducible clindamycin resistance in a *Staphylococcus aureus* isolate. This failure could have had potentially fatal consequences but was detected by medical microbiologists when performing an in-depth instrument verification (44).

Following successful test verification studies, the test can be implemented in the laboratory. This step can be complex and requires a full understanding of laboratory workflows and patient care needs. While some tests can be easily implemented into the routine workflow, others require high level oversight and planning. For example, "total laboratory automation" (TLA) is arguably the future for culture-based microbiology testing, and provides numerous gains in efficiencies and standardization in the clinical laboratory (45, 46). However, it presents numerous challenges including adaptation to local testing practices, successful integration of hardware and software, and significantly, a seven-figure price tag for an entire TLA system. Implementation of multifaceted, capital intensive platforms such as TLA systems may not provide the expected return on investment unless overseen by medical microbiologists who can adapt the technology to best serve patient needs (47).

When planning the test implementation, the medical microbiologist must simultaneously consider how the new test will be incorporated into new and existing diagnostic testing algorithms. The level of knowledge and experience provided by the medical microbiologist is essential for successful implementation, as lack of adequate medical oversight can negatively impact patient care. This has been observed recently in regards to rapid multiplex molecular platforms - marketed for their ease of use – but having limitations that medical laboratory scientists and medical providers may not be adequately aware of because they are not described in package inserts (48-51). One commercially-available multiplex molecular meningitis platform was recently noted to produce as many false positives as true positives for some analytes, while also demonstrating a significant lack of sensitivity for other analytes (52). If implemented by a laboratory, the medical microbiologist must determine how the multiplex molecular meningitis platform would be used in concert with other laboratory tests to overcome its observed

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limitations. Others have noted that failure to appropriately utilize and incorporate novel platforms into diagnostic algorithms tailored to institutional needs can impose a significant financial burden on the institution and limit their impact on patient care (40, 53, 54). Mercuro *et al* showed that failure to align the use of multiplex molecular panels with appropriate clinical interventions negated the benefits of the platform (53). Medical microbiologists can effectively collaborate with clinical and pharmacy colleagues, so that novel technologies are used in a cost effective manner that improves patient outcomes. Studies have shown that such partnerships can result in the reduction of healthcare costs (>$1,000,000-$2,000,000) far beyond what could be otherwise achieved by reducing laboratory costs and personnel alone (55-58). Simple approaches spearheaded by medical microbiologists such as incorporating educational and interpretative comments into laboratory reports have also been shown to positively impact patient care and reduce unnecessary antibiotic usage (59, 60).

Once testing is live, the medical microbiologist must continuously review test performance, ongoing quality metrics, and how test results correlate clinically. There are many things that can go wrong during testing in the pre-analytical, analytical and post-analytical stages. In the US, the CLIA (Clinical Laboratory Improvement Amendments) laboratory director is ultimately responsible for the results produced by the laboratory (61). While the laboratory director may also serve as the medical microbiologist, larger laboratories usually have a number of doctoral-level scientists and physicians in charge of sections of the laboratory. In this situation, it is essential to have an experienced and knowledgeable medical microbiologist at the helm of the clinical microbiology laboratory. There are numerous instances in the literature in which medical microbiologists detected errors in the test process that could have led to patient harm. For example, it is well-known that some automated commercial instruments will

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misidentify certain bacteria and/or produce inaccurate antimicrobial susceptibility results (62, 63). Similarly, newer technologies such as MALDI-TOF and 16S rRNA gene sequencing misidentify certain microorganisms (63, 64). In one dramatic example, misidentification of *Brucella melitensis* as *Ochrobactrum anthropi* by MALDI-TOF led to the failure to timely detect infection and resulted in the dangerous exposure of laboratory staff to *Brucella* (64). By keeping current with the science and published literature, on-site medical microbiologists can recognize important situations such as this and ensure that additional testing is safely and rapidly performed.

The last stage in the test lifecycle is test retirement. It can be challenging to retire a test, particularly when there is a cohort of providers who routinely order it. Thus, the medical microbiologist may need to make the case for retirement based on widely recognized guidelines and patient outcomes data. Theel and colleagues examined commercial and Medicare medical claims data from Optum Labs (Cambridge, MA) to evaluate test mis-utilization of *Helicobacter pylori* serology (65). Although guidelines from major professional organizations state that *H. pylori* serology should be largely avoided due to its poor clinical performance characteristics, the authors found that serologic testing remained the most common test for evaluation of *H. pylori* infection, indicating that there was poor provider adherence to the published guidelines. Importantly, they calculated that the use of serology with its poor positive predictive value may have resulted in the misdiagnosis and inappropriate treatment of approximately 7,500 individuals. The lead author, a medical microbiologist, ultimately used these data to justify retiring the *H. pylori* serology test. This type of medical microbiologist leadership is essential for addressing an issue at the overall healthcare level rather than simply at the individual laboratory level.

Test development and Validation

Through ongoing scientific oversight in the field (See section on Scientific Oversight above), medical microbiologists may determine that novel tests, or modified versions of commercially-available tests, are needed for providing optimal patient care. In this situation, the medical microbiologist may choose to modify an existing test to address a patient care need (e.g., by adding an additional specimen source to a FDA-cleared/approved test) or develop and validate a novel test within the laboratory (i.e., laboratory developed tests; LDTs). Both strategies require a significant amount of expertise and scientific knowledge to accomplish, beyond what is usually available by bench level technologists and supervisors.

While modifying an existing commercial assay may seem relatively straightforward, important pitfalls can occur if sufficient medical oversight is not provided. For example, some specimen types, collection devices, and specimen transport media are not suitable for use with commercial assays, as they may provide indeterminate or inaccurate results. An important example of this scenario was described by Bachmann and colleagues in 2009 when reviewing the use of NAATs for detection of *Neisseria gonorrhoeae* in non-genital specimens (66). These authors noted that some widely-used NAATs would detect commensal oropharyngeal *Neisseria* species such as *N. subflava* and *N. cinerae,* and thus potentially produce false positive results. False positive gonorrhea results would clearly have important patient care and public health implications.

The design, validation, implementation, and continued oversight of LDTs provide further challenges. Organizations such as the American Society for Microbiology, Infectious Disease Society of American (IDSA) and the College of American Pathology (CAP) have recognized the

critical need for LDTs (67, 68). However, the FDA has cited a number of cases where inappropriately developed or validated LDTs resulted in patient harm and has expressed concerns about the safety and effectiveness of such tests (69). Thus, it is essential for medical microbiologists and other appropriately-trained individuals to be actively involved throughout all stages of test design, development, and implementation. Medical microbiologists also play an important role in ensuring correct utilization of LDTs, and providing accurate interpretation of results.

The COVID-19 pandemic, in particular, provided a strong use case for LDTs, as delays in development of commercial testing systems for SARS-COV 2 hindered the pandemic response early on (70). In the absence of commercially available assays for the detection of SARS-COV 2, medical microbiologists successfully pushed the FDA to streamline the Emergency Use Authorization (EUA) process to allow them to develop assays for the detection of SARS-COV 2 at institutions across the US (71). Medical microbiologists played a central role in maintaining COVID-19 testing capacity even when shortages of essential supplies hampered testing efforts. During the peak of the pandemic, patients and providers experienced significant delays (>7 days) in obtaining results from large reference laboratories (72). The local expertise of medical microbiologists was crucial for bringing COVID-19 testing closer to the patient and providing results in a timeframe for meaningful interventions to take place. Many institutions without onsite medical microbiologists and the expertise for developing and implementing COVID-19 LDTs struggled to provide the required rapid test development and oversight to be able to implement testing quickly. Institutions without medical microbiologists would not have been able to submit FDA EUA applications in a fashion to support the testing need.

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Regulatory and Administrative Oversight

In addition to providing scientific oversight, medical microbiologists are responsible for the regulatory and administrative oversight of the laboratory. In the US, clinical microbiology laboratories operate under CLIA and undergo annual inspections to ensure that all requirements are satisfactorily met (61). While the laboratory accreditation process is a necessary component in providing human clinical testing, it does not fully assess the laboratory's ability to keep pace with scientific advances. Thus, medical microbiologists play an essential role in building upon minimum accreditation requirements to incorporate quality measures to reflect the state of the science. An example of this process occurred through a multicenter collaboration of medical microbiologists in which a baseline for Gram stain error rates was established in the absence of other available performance standards. The outcome of this collaboration allowed laboratories to measure their performance against their peers and improve their practices accordingly (73). Medical microbiologists are able to combine technical expertise with the clinical knowledge required to assess the significance and impact of laboratory errors and the measures needed to address them.

Institutional Leadership

The sections above provide numerous examples of how medical microbiologists take on key leadership roles within institutions, working in collaboration with other health care providers to optimize test utilization, create algorithms for clinical care, and modify practices to meet the challenges posed by emerging pathogens, syndromes and antimicrobial resistance patterns.

Another specific example of essential leadership provided by medical microbiologists is in preventing and controlling healthcare-associated infections (HAIs) by partnering with other institutional stakeholders. Risk mitigation supported by dedicated, onsite medical microbiologists is increasingly important in today's modern healthcare system. In 2014, the Centers for Medicare and Medicaid Services (CMS) implemented a program to provide an incentive for the reduction of HAIs by penalizing hospitals that failed to control rates of HAIs (74). These HAIs are primarily defined by laboratory results and include infections with methicillin-resistant *Staphylococcus aureus* and *Clostridioides difficile*, as well as catheter associated urinary tract infections (CAUTI) and central line associated bloodstream infections (CLABSI). CMS planned to accomplish their goals by reducing Medicare reimbursements by 1% for organizations that fall into the lower 25th percentile when scored using a system based on incidence of HAIs (74). For large institutions, this can translate to millions of dollars annually; in 2016, CMS penalized 769 hospitals for failing to meet HAI goals, at a total of $430 million in associated penalties (75). Medical microbiologists serve as key members of institutional taskforces for the reduction of CAUTI, CLABSI and *C. difficile* by providing recommendations on optimal testing strategies and advising on the impact of changes in testing practices. When medical microbiologist leadership is lacking, hospital administrators and non-microbiologist laboratorians may take inappropriate approaches to microbiology testing, in order to bring their hospital performance in line with their peers (76). CMS noted that these strategies not only falsely appear to improve institutional performance, but have the potential to cause serious harm to patients (77).

Most recently, medical microbiologists were key members of institutional pandemic response teams that directed testing strategies during the COVID-19 pandemic. They worked

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with other healthcare providers to assess the balance of risk, benefit, and costs for various testing options and select the most appropriate testing algorithms for their patients.

Education and Research

The last two major roles played by the microbiology microbiologist are in providing medical education and conducting patient-centered research. Medical microbiologists provide immeasurable value in training the next generations of laboratory technologists and physicians, and in providing ongoing education to their colleagues. Medical microbiologists are ideally situated to monitor the state of the science, distill the information into relevant, easily-digest able information, and then deliver that information to different audiences. They also participate in clinically-relevant research to evaluate test performance, guide testing protocols and define best practices. In many cases, grant- and industry-sponsored research also provides an important source of revenue to the institution. The ability of a laboratory to support this breadth and depth of continuing education and scholarly activity depends heavily on the presence of dedicated medical microbiologists.

Recommended Qualifications for Medical Microbiologists

Given the multitude of responsibilities provided by medical microbiologists, it is essential that these individuals received adequate training and preparation for their duties as laboratory directors. In the US, the qualifications of laboratory directors are determined by CMS through the Clinical Laboratory Improvement Amendments (CLIA). Specifically, part 493, Subpart M, outlines the requirements for personnel performing non-waived testing (61). Among the various qualifications, a director of a laboratory that performs high complexity testing must hold a

doctoral degree in medicine, osteopathy, or a chemical, physical, biological or clinical laboratory science, and meet additional training and licensure requirements.

The three most commonly chosen routes for obtaining these qualifications in the United States are to 1) for a physician to complete a residency in anatomic and/or clinical pathology (3 to 4 years) with an optional 1 year fellowship in medical microbiology, 2) for a physician to complete a residency in internal medicine or pediatrics (3 years) followed by fellowships in infectious diseases (2 to 3 years) and in medical microbiology (1 year), or 3) for a doctoral scientist or physician to complete a 2-year fellowship in medical microbiology. There are two types of accredited fellowships that are available in the US. The post-graduate programs in medical and public health accredited by the Committee on Postdoctoral Educational Programs (CPEP: https://www.asm.org/index.php/about-cpep) are available to individuals with doctoral level degrees (PhD, MD, DO) and take 2 years for completion. A one-year Accreditation Council for Graduate Medical Education (ACGME) fellowship is available to those who have completed medical residency in anatomic and/or clinical pathology, internal medicine or pediatrics, with the latter two residencies followed by an infectious diseases fellowship. The accreditation exams that can be taken at the end of each these fellowships are 1) the American Board of Medical Microbiology(ABMM) (https://www.asm.org/index.php/abmm-about), or the 2) the American Board of Pathology which offers board certification in Medical Microbiology (http://www.abpath.org/index.php/to-become-certified/requirements-for-certification?id=45) which is only for graduates of the above described one-year ACGME fellowship training. These fellowships and certification are highly recommended for microbiology laboratory directors of full-service clinical microbiology laboratories but may not be required provided that specialized microbiology training and a thorough understanding of the complex regulatory systems (such as

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the Clinical Laboratory Improvement Amendments) that govern the clinical laboratories have been obtained through a combination of prior training and experience. Regardless of the route taken, the most important outcome of the training is that the individual(s) have the necessary skills and that a full time equivalent (FTE) is available to provide oversight of a high complexity microbiology laboratory and deliver comprehensive consultative clinical services toward the care of the patient.

Other developed countries have similar requirements for accreditation of clinical microbiologists. The Union of European Medical Specialties (UEMS) recognizes medical microbiology as a separate specialty and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) has strongly endorsed the pivotal role of locally based medical microbiologists as part of integrated healthcare teams (9, 11, 12). This view is also shared amongst both clinical and medical microbiology communities within Canada which recognize the discipline of clinical microbiology as a separate and unique skill set within the laboratory community and as a dedicated medical specialty. To be considered a Medical Microbiologist in Canada, a person must be certified as a Fellow of the Canadian College of Microbiologists (CCM), a certification which shares reciprocity with the ABMM and requires training either in accredited CCM/CPEP programs or in Royal College of Physicians and Surgeons of Canada (FRCPC) microbiology residency programs (http://www.ccm.ca/certifications/fccm/).

Concluding Remarks

There is a clear need for medical microbiologist leadership in full-service clinical microbiology laboratories. According to the American Hospital Association, there were 925 hospitals in 2017 with 300 or more beds, and 523 hospitals with 400 or more beds (http://www.aha.org). Many of these hospitals and networks have grown in size over recent years and serve increasingly diverse and complex patient populations, making it essential that these laboratories have adequate leadership by appropriately trained individuals. The commitment to ensure that medical microbiologists are part the standard of care serves to improve healthcare and encourage continued development of the field at this time of increasing drug resistance, rapid expansion of testing technologies, and regular occurrence of novel pathogens and pandemics.

It is with the noted support of The American Society for Microbiology (ASM), Infectious Diseases Society of America (IDSA), American Association of Clinical Chemistry (AACC), Pan American Society for Clinical Microbiology (PASCV) and Society of Infectious Disease Pharmacists (SIDP) that we conclude the following:

1. Full-service clinical microbiology laboratories should have at least one dedicated, full-time medical microbiologist, and the individuals selected to fill this position should have appropriate qualifications and training.
2. The leadership of full service clinical microbiology laboratories should not be delegated on an ad hoc basis to directors who are unable to dedicate adequate time to this position.
3. Medical microbiology directors significantly impact healthcare at the patient, institutional and community levels. The value brought by the medical microbiologist

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must not be considered only in the context of billable services, but must account for contributions made to the entire healthcare system.

4. Healthcare institutions must consider the laboratory workload, test menu complexity, patient complexity, teaching/research commitments and geographic area served by the laboratory when determining the number of medical microbiologists needed to lead the clinical microbiology laboratory .

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References

1. Baron EJ, Miller JM, Weinstein MP, Richter SS, Gilligan PH, Thomson RB, Jr., Bourbeau P, Carroll KC, Kehl SC, Dunne WM, Robinson-Dunn B, Schwartzman JD, Chapin KC, Snyder JW, Forbes BA, Patel R, Rosenblatt JE, Pritt BS. 2013. A guide to utilization of the microbiology laboratory for diagnosis of infectious diseases: 2013 recommendations by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM)(a). Clin Infect Dis 57:e22-e121.
2. Avdic E, Carroll KC. The role of the microbiology laboratory in antimicrobial stewardship programs. Infect Dis Clin North Am 28:215-35.
3. Canton R. 2005. Role of the microbiology laboratory in infectious disease surveillance, alert and response. Clin Microbiol Infect 11 Suppl 1:3-8.
4. Schwaber MJ, De-Medina T, Carmeli Y. 2004. Epidemiological interpretation of antibiotic resistance studies - what are we missing? Nat Rev Microbiol 2:979-83.
5. CDC-NHSN. 2017. Centers for Disease Control National Healthcare Safety Network. www.cdc.gov/nhsn. Accessed 3/23/2018.
6. Peterson LR, Noskin GA. 2001. New technology for detecting multidrug-resistant pathogens in the clinical microbiology laboratory. Emerging Infectious Diseases 7:306-311.
7. Liao S, Rhodes J, Sopirala M. 2016. Out of Sight, Out of Mind: Impact of Cascade Reporting on Escherichia spp and Klebsiella Infections. Open Forum Infectious Diseases 3.
8. Langford BJ, Seah J, Chan A, Downing M, Johnstone J, Matukas LM. 2016. Antimicrobial Stewardship in the Microbiology Laboratory: Impact of Selective Susceptibility Reporting on Ciprofloxacin Utilization and Susceptibility of Gram-Negative Isolates to Ciprofloxacin in a Hospital Setting. J Clin Microbiol 54:2343-7.
9. Read RC, Cornaglia G, Kahlmeter G, European Society of Clinical M, Infectious Diseases Professional Affairs Workshop g. 2011. Professional challenges and opportunities in clinical microbiology and infectious diseases in Europe. Lancet Infect Dis 11:408-15.
10. Peterson LR, Hamilton JD, Baron EJ, Tompkins LS, Miller JM, Wilfert CM, Tenover FC, Thomson Jr RB, Jr. 2001. Role of clinical microbiology laboratories in the management and control of infectious diseases and the delivery of health care. Clin Infect Dis 32:605-11.
11. Struelens MJ, Van Eldere J. 2005. Conclusion: ESCMID declaration on meeting the challenges in clinical microbiology and infectious diseases. Clin Microbiol Infect 11 Suppl 1:50-1.
12. Finch R, Hryniewicz W, Van Eldere J. 2005. Report of working group 2: healthcare needs in the organisation and management of infection. Clin Microbiol Infect 11 Suppl 1:41-5.
13. Morency-Potvin P, Schwartz DN, Weinstein RA. Antimicrobial Stewardship: How the Microbiology Laboratory Can Right the Ship. Clin Microbiol Rev 30:381-407.
14. Kolmos HJ. 1999. Interaction between the microbiology laboratory and clinician: what the microbiologist can provide. J Hosp Infect 43 Suppl:S285-91.
15. Perez JL, Ayats J, de Ona M, Pumarola T. The role of the clinical microbiology laboratory in solid organ transplantation programs. Enferm Infecc Microbiol Clin 30 Suppl 2:2-9.
16. Thomson RB, Doern GV. 2011. What Will the Role of the Clinical Microbiology Laboratory Director Be in 2015? J Clin Microbiol 49:S68-71.
17. Thomson RB, Jr., Wilson ML, Weinstein MP. 2010. The clinical microbiology laboratory director in the United States hospital setting. J Clin Microbiol 48:3465-9.
18. Nurok M, Gewertz B. 2019. Relative Value Units and the Measurement of Physician Performance. JAMA doi:10.1001/jama.2019.11163.
19. Ball JR, Balogh E. 2016. Improving Diagnosis in Health Care: Highlights of a Report From the National Academies of Sciences, Engineering, and Medicine. Ann Intern Med 164:59-61.

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20. Graber ML, Rusz D, Jones ML, Farm-Franks D, Jones B, Cyr Gluck J, Thomas DB, Gleason KT, Welte K, Abfalter J, Dotseth M, Westerhaus K, Smathers J, Adams G, Laposata M, Nabatchi T, Compton M, Eichbaum Q. 2017. The new diagnostic team. Diagnosis (Berl) 4:225-238.
21. Laposata M. Nov 2017 Diagnostic teams: five barriers but the time is now. CAP Today.
22. Huang RS, Guervil DJ, Hunter RL, Wanger A. Lower antibiotic costs attributable to clinical microbiology rounds. Diagn Microbiol Infect Dis 83:68-73.
23. MacVane SH, Hurst JM, Steed LL. The Role of Antimicrobial Stewardship in the Clinical Microbiology Laboratory: Stepping Up to the Plate. Open Forum Infect Dis 3:ofw201.
24. Arena F, Scolletta S, Marchetti L, Galano A, Maglioni E, Giani T, Corsi E, Lombardi S, Biagioli B, Rossolini GM. Impact of a clinical microbiology-intensive care consulting program in a cardiothoracic intensive care unit. Am J Infect Control 43:1018-21.
25. Yang S, Hemarajata P, Shevy L, Maciariello M, Culbreath K, Bush K, Humphries R. 2018. Unusual carbapenem resistant but ceftriaxone and cefepime susceptible Klebsiella oxytoca isolated from a blood culture: Case report and whole-genome sequencing investigation. IDCases 11:9-11.
26. Dellit TH, Owens RC, McGowan JE, Jr., Gerding DN, Weinstein RA, Burke JP, Huskins WC, Paterson DL, Fishman NO, Carpenter CF, Brennan PJ, Billeter M, Hooton TM, Infectious Diseases Society of A, Society for Healthcare Epidemiology of A. 2007. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. Clin Infect Dis 44:159-77.
27. Peddecord KM, Baron EJ, Francis D, Drew JA. 1996. Quality perceptions of microbiology services. A survey of infectious diseases specialists. Am J Clin Pathol 105:58-64.
28. Baird GS, Jackson BR, Dickerson J, Sikaris K, Croal B, Laposata M. 2018. What's New in Laboratory Test Utilization Management? Clin Chem 64:994-1000.
29. McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, Kerr EA. 2003. The quality of health care delivered to adults in the United States. N Engl J Med 348:2635-45.
30. Pinsky BA, Hayden RT. 2019. Cost-Effective Respiratory Virus Testing. J Clin Microbiol 57.
31. Ramanan P, Bryson AL, Binnicker MJ, Pritt BS, Patel R. 2018. Syndromic Panel-Based Testing in Clinical Microbiology. Clin Microbiol Rev 31.
32. Dien Bard J, McElvania E. 2020. Panels and Syndromic Testing in Clinical Microbiology. Clin Lab Med 40:393-420.
33. Graf EH, Pancholi P. 2020. Appropriate Use and Future Directions of Molecular Diagnostic Testing. Curr Infect Dis Rep 22:5.
34. Burd EM. Ebola virus: a clear and present danger. J Clin Microbiol 53:4-8.
35. McAdam A, Rowlinson M-C, Binnicker M, Miller M. 2020. SARS-CoV-2 Testing: Sensitivity Is Not the Whole Story, *on* ASM. https://asm.org/Articles/2020/November/SARS-CoV-2-Testing-Sensitivity-Is-Not-the-Whole-St. Accessed Jan 20th, 2021.
36. Babady NE, McMillen T, Jani K, Viale A, Robilotti EV, Aslam A, Diver M, Sokoli D, Mason G, Shah MK, Korenstein D, Kamboj M. 2021. Performance of Severe Acute Respiratory Syndrome Coronavirus 2 Real-Time RT-PCR Tests on Oral Rinses and Saliva Samples. J Mol Diagn 23:3-9.
37. Rhoads D, Peaper DR, She RC, Nolte FS, Wojewoda CM, Anderson NW, Pritt BS. 2020. College of American Pathologists (CAP) Microbiology Committee Perspective: Caution must be used in interpreting the Cycle Threshold (Ct) value. Clin Infect Dis doi:10.1093/cid/ciaa1199.
38. Flygare S, Simmon K, Miller C, Qiao Y, Kennedy B, Di Sera T, Graf EH, Tardif KD, Kapusta A, Rynearson S, Stockmann C, Queen K, Tong S, Voelkerding KV, Blaschke A, Byington CL, Jain S, Pavia A, Ampofo K, Eilbeck K, Marth G, Yandell M, Schlaberg R. 2016. Taxonomer: an interactive metagenomics analysis portal for universal pathogen detection and host mRNA expression profiling. Genome Biology 17:111.

39. Raoult D. 2017. The study of microbiota needs both microbiologists and medical doctors. Clin Microbiol Infect 23:500-501.
40. Green DA, Hitoaliaj L, Kotansky B, Campbell SM, Peaper DR. Clinical Utility of On-Demand Multiplex Respiratory Pathogen Testing among Adult Outpatients. J Clin Microbiol 54:2950-2955.
41. Huang AM, Newton D, Kunapuli A, Gandhi TN, Washer LL, Isip J, Collins CD, Nagel JL. Impact of rapid organism identification via matrix-assisted laser desorption/ionization time-of-flight combined with antimicrobial stewardship team intervention in adult patients with bacteremia and candidemia. Clin Infect Dis 57:1237-45.
42. Nagel JL, Huang AM, Kunapuli A, Gandhi TN, Washer LL, Lassiter J, Patel T, Newton DW. Impact of antimicrobial stewardship intervention on coagulase-negative Staphylococcus blood cultures in conjunction with rapid diagnostic testing. J Clin Microbiol 52:2849-54.
43. Pritt BS. 2017. Optimizing Test Utilization in the Clinical Microbiology Laboratory: Tools and Opportunities. J Clin Microbiol 55:3321-3323.
44. Bobenchik AM, Hindler JA, Giltner CL, Saeki S, Humphries RM. 2014. Performance of Vitek 2 for antimicrobial susceptibility testing of Staphylococcus spp. and Enterococcus spp. J Clin Microbiol 52:392-7.
45. Bailey AL, Ledeboer N, Burnham CD. 2019. Clinical Microbiology Is Growing Up: The Total Laboratory Automation Revolution. Clin Chem 65:634-643.
46. Culbreath K, Piwonka H, Korver J, Noorbash M. 2020. Benefits Derived from Full Laboratory Automation in Microbiology: A Tale of Four Laboratories. J Clin Microbiol doi:10.1128/JCM.01969-20.
47. Theparee T, Das S, Thomson RB, Jr. 2018. Total Laboratory Automation and Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry Improve Turnaround Times in the Clinical Microbiology Laboratory: a Retrospective Analysis. J Clin Microbiol 56.
48. Gomez CA, Pinsky BA, Liu A, Banaei N. 2017. Delayed Diagnosis of Tuberculous Meningitis Misdiagnosed as Herpes Simplex Virus-1 Encephalitis With the FilmArray Syndromic Polymerase Chain Reaction Panel. Open Forum Infect Dis 4:ofw245.
49. Cepheid. Wake-Up Call: Proficiency Testing for Today's Technology. http://www.cepheid.com/us/healthcare-impact/emagazine/item/12-wake-up-call-proficiency-testing-for-today-s-technology. Accessed 12/17/17.
50. Jerris RC, Williams SR, MacDonald HJ, Ingebrigtsen DR, Westblade LF, Rogers BB. 2015. Testing implications of varying targets for Bordetella pertussis: comparison of the FilmArray Respiratory Panel and the Focus B. pertussis PCR assay. J Clin Pathol 68:394-6.
51. Popowitch EB, O'Neill SS, Miller MB. 2013. Comparison of the Biofire FilmArray RP, Genmark eSensor RVP, Luminex xTAG RVPv1, and Luminex xTAG RVP fast multiplex assays for detection of respiratory viruses. J Clin Microbiol 51:1528-33.
52. Hanson KE, Couturier MR. 2016. Multiplexed Molecular Diagnostics for Respiratory, Gastrointestinal, and Central Nervous System Infections. Clin Infect Dis 63:1361-1367.
53. Mercuro N, Kenney RM, Tibbetts R, Samuel L, Davis SL. 2016. Role of Respiratory Virus Panels in Antimicrobial Stewardship in Immunocompromised Patients. Open Forum Infectious Diseases 3:1866-1866.
54. Freeman K, Mistry H, Tsertsvadze A, Royle P, McCarthy N, Taylor-Phillips S, Manuel R, Mason J. Multiplex tests to identify gastrointestinal bacteria, viruses and parasites in people with suspected infectious gastroenteritis: a systematic review and economic analysis. Health Technol Assess 21:1-188.

55. Nicole M Wilson RMK, Robert J. Tibbetts, George Alangaden, Susan L. Davis , Linoj P. Samuel. 2016. T2 Magnetic Resonance Improves the Timely Management of Candidemia, abstr ID Week, New Orleans, LA, 10/28/2016.
56. Patel TS, Kaakeh R, Nagel JL, Newton DW, Stevenson JG. 2017. Cost Analysis of Implementing Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry Plus Real-Time Antimicrobial Stewardship Intervention for Bloodstream Infections. J Clin Microbiol 55:60-67.
57. Rappo U, Schuetz AN, Jenkins SG, Calfee DP, Walsh TJ, Wells MT, Hollenberg JP, Glesby MJ. 2016. Impact of Early Detection of Respiratory Viruses by Multiplex PCR Assay on Clinical Outcomes in Adult Patients. Journal of Clinical Microbiology 54:2096-2103.
58. Hansen GT, Moore J, Herding E, Gooch T, Hirigoyen D, Hanson K, Deike M. 2018. Clinical decision making in the emergency department setting using rapid PCR: Results of the CLADE study group. J Clin Virol 102:42-49.
59. Cole KA, Kenney RM, Perri MB, Dumkow LE, Samuel LP, Zervos MJ, Davis SL. 2015. Outcomes of Aminopenicillin Therapy for Vancomycin-Resistant Enterococcal Urinary Tract Infections. Antimicrobial Agents and Chemotherapy 59:7362-7366.
60. Mary Musgrove P, Rachel M Kenney, PharmD, Ronald Kendall, PharmD, Robert Tibbetts, Ph.D. D(ABMM), F(CCM), Linoj Samuel, PhD., D(ABMM), Mike Peters, PharmD, BCPS and Susan Davis, PharmD. 2017. Communicating Microbiology Results: It's Not Just What You Say, But How You Say It, abstr ID Week, San Diego, CA, 10/6/2017.
61. CMS. 2017. Code of Federal Regulations. Title 42: Public Health US Government Publishing Office, https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5.
62. Frederiksen W, Tønning B. 2001. Possible Misidentification of Haemophilus aphrophilus as Pasteurella gallinarum. Clinical Infectious Diseases 32:987-989.
63. Angeletti S, Dicuonzo G, Avola A, Crea F, Dedej E, Vailati F, Farina C, De Florio L. 2015. Viridans Group Streptococci clinical isolates: MALDI-TOF mass spectrometry versus gene sequence-based identification. PLoS One 10:e0120502.
64. Poonawala H, Marrs Conner T, Peaper DR. 2018. The Brief Case: Misidentification of Brucella melitensis as Ochrobactrum anthropi by Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry (MALDI-TOF MS). J Clin Microbiol 56:914-917.
65. Theel ES, Johnson RD, Plumhoff E, Hanson CA. 2015. Use of the Optum Labs Data Warehouse to assess test ordering patterns for diagnosis of Helicobacter pylori infection in the United States. J Clin Microbiol 53:1358-60.
66. Bachmann LH, Johnson RE, Cheng H, Markowitz LE, Papp JR, Hook EW, 3rd. 2009. Nucleic acid amplification tests for diagnosis of Neisseria gonorrhoeae oropharyngeal infections. J Clin Microbiol 47:902-7.
67. IDSA. 2015. Better Tests, Better Care: The Promise of Next Generation Diagnostics.
68. Caliendo AM, Couturier MR, Ginocchio CC, Hanson KE, Miller MB, Walker KE, Frank GM, Infectious Diseases Society of A, the American Society for M, the Pan-American Society for Clinical V. 2016. Maintaining Life-saving Testing for Patients With Infectious Diseases: Infectious Diseases Society of America, American Society for Microbiology, and Pan American Society for Clinical Virology Recommendations on the Regulation of Laboratory-developed Tests. Clin Infect Dis 63:151-4.
69. FDA. 2016. The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies Office of Public Health Strategy and Analysis

http://wayback.archive-it.org/7993/20171114205911/https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm472773.htm.

70. **DHHS**. 2020. Summary of the Findings of the Immediate Office of the General Counsel's Investigation Regarding CDC's Production of COVID-19 Test Kits. Department of Health and Human Services, https://context-cdn.washingtonpost.com/notes/prod/default/documents/5610e9fa-86d7-4bd3-8b7a-f8df10c6fc9e/note/7331ef79-a672-4d2d-9eff-f8ce39c2e462.#page=1.

71. Staff WP. 4/18/2020 2020. What we know about delays in coronavirus testing, p *In* Washington Post. https://www.washingtonpost.com/investigations/2020/04/18/timeline-coronavirus-testing/?arc404=true.

72. Feuer W. 2020. Surge in U.S. coronavirus cases causes testing delays across the nation as labs scramble to keep up, https://www.cnbc.com/2020/07/13/us-coronavirus-surge-leads-to-testing-delays-across-the-nation-quest-diagnostics-says.html.

73. Samuel LP, Balada-Llasat JM, Harrington A, Cavagnolo R. 2016. Multicenter Assessment of Gram Stain Error Rates. J Clin Microbiol 54:1442-1447.

74. CMS. 2017. Hospital-Acquired Control Reduction Program. https://www.medicare.gov/hospitalcompare/HAC-reduction-program.html. Accessed 3/23/2018.

75. Rau J. 2016. Medicare Penalizes Hospitals In Crackdown On Antibiotic-Resistant Infections, https://www.npr.org/sections/health-shots/2016/12/22/506489368/medicare-penalizes-hospitals-in-crackdown-on-antibiotic-resistant-infections.

76. Diekema DJ. Rising Stakes for Health Care-Associated Infection Prevention: Implications for the Clinical Microbiology Laboratory. J Clin Microbiol 55:996-1001.

77. CDC-NHSN. 2016. Adherence to the Centers for Disease Control and Prevention's (CDC's) Infection Definitions and Criteria is Needed to Ensure Accuracy, Completeness, and Comparability of Infection Information. https://www.cdc.gov/nhsn/cms/cms-reporting.html.

728 Table 1

Roles of the Medical Microbiologist	
Clinical consultation	- Provides guidance on test selection and appropriate specimen collection - Assists with interpretation of test and antimicrobial susceptibility results
Scientific oversight and vision	- Monitors developments in the field to ensure that laboratory testing meets current needs (e.g. emergence of novel antimicrobial resistance factors, syndromes and/or pathogens).
Test evaluation, verification, implementation, and oversight	- Evaluates and verifies clinical utility and performance of FDA cleared/approved laboratory tests in the local setting - Establishes impact of testing options and algorithms on patient care - Ensures that test results are reported in an accurate and clear manner, with addition of appropriate interpretative guidance as applicable - Ensures cost effective selection and implementation of tests - Creates protocols for laboratory testing practices - Develops test menus and guidelines for optimal laboratory test utilization in collaboration with clinical colleagues - Establishes and monitors quality indicators to ensure maintenance of test performance standards after implementation - Selects and evaluates external laboratories to which specimens are referred for testing - Monitors referral lab testing to ensure appropriate use
Test modification, development and validation	- Validates performance of off-label usage of FDA-approved/cleared assays. - Develops and validates laboratory developed tests as required to support the populations served by the laboratory
Regulatory and Administrative oversight	- Ensures compliance with regulatory/accrediting bodies (e.g., CMS, Joint Commission, CAP) - Establishes and enforces safe laboratory practices - Complies with institutional guidelines (e.g., Institutional Review Board, Biosafety committee)
Institutional Leadership	- Represents the laboratory on institutional committees, including infection prevention and control, and antimicrobial stewardship - Serves on ad hoc committees in outbreak settings (e.g. outbreaks of Ebola virus infection, pandemic influenza)
Education	- Trains residents and fellows from pathology, infectious diseases, pharmacy and other relevant specialties in the field of clinical microbiology - Provides education to physicians, nurses and allied health

	staff on appropriate specimen collection, test utilization and interpretation - Communicates test updates to the local healthcare system
Research	- Participates in clinically-relevant research. Examples may include: o Evaluating test performance in comparative and outcome studies o Assessing cost-benefit and clinical impact of testing protocols o Contributing to the development of best-practice guidelines

729 Abbreviations: CAP – College of American Pathologists, CMS – Centers for Medicare and
730 Medicaid Services, CLIA – Clinical Laboratory Improvement Amendments, FDA – United
731 States Food and Drug Administration
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