Public Health Laboratories
Analysis, Operations, and Management

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Dedication

To my wife, Heather, whose enthusiastic support helped make this possible;

and to my young sons, David and Michael, whose endless curiosity is an inspiration for me.

About the Author

Wiley D. Jenkins, PhD, MPH, is currently a Research Assistant Professor at the Southern Illinois University School of Medicine in Springfield, Illinois. His primary role is Director of Research and Program Development for the Department of Family and Community Medicine, and he is also a faculty member of the Public Health Laboratory Science program in the Department of Medical Microbiology, Immunology, and Cell Biology. He joined the School of Medicine in August of 2007 after 13 years with the Illinois Department of Public Health, Division of Laboratories, where he held positions as laboratory chemist, section supervisor, division bioterrorism coordinator, and laboratory operations manager. In 1999, he was awarded a Centers for Disease Control and Prevention Graduate Certificate Program Scholarship and attended Tulane University in New Orleans, graduating with an MPH in Epidemiology in 2003. He then attended the University of Illinois at Chicago, graduating with his PhD in Health Policy and Administration in 2007. Current research interests include the development and implementation of novel chlamydia and gonorrhea interventions involving primary care physicians.

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- Pete Sutton for the Blood Lead section

I also thank Scott Becker and Eva Perlman at the Association of Public Health Laboratories of their contribution of Chapter 1, "Overview of Public Health Laboratories." The Association is the preeminent organization for the recognition, development, and coordination of public health laboratories in the United States. In the past 20+ years, they have been an instrumental partner in transforming public health laboratories from a collection of individual facilities with varying capabilities and fragmented coordination into a much more robust and united network able to provide a cohesive response to terrorism and infectious disease outbreaks.

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Foreword

The field of laboratory science is continuously expanding, not only from the perspective of truly remarkable benchwork accomplishments, but also in the creation of supportive technological innovations. It has also steadfastly proven its critical role in the arenas of the public and private health sectors, law enforcement, and national defense and security. This book brilliantly encapsulates this swiftly evolving and complex field of modern laboratory sciences. First, the fundamental concepts relating to microbial analysis and quality control are explored to provide background. The book then moves on to delineate concepts pertaining to the fields of chemical and radiological analysis. Clinical testing is also covered in detail, as it relates to biological and chemical agents and genetic abnormalities. Chapters are also devoted to the increasingly important domains of environmental safety concerns related to water, food, and air testing. The book then turns to a laboratory perspective on biological and chemical terrorism preparedness and response issues. It must be stated that, in this arena, laboratories are at the very forefront of our national defense strategies. Laboratory operations and management issues are described in detail and are essential for regulatory compliance, as well as for strategic and financial planning. These topics are vital to the maintenance, and very existence, of our national infrastructure of laboratory systems that are indispensable in our efforts to prevent and treat morbidity and mortality throughout our nation. The critical issues of laboratory data uses and communications are explored in great detail. This has particularly important implications for a nation poised to construct and implement a national health information technology exchange system. Finally, a chapter is devoted to the links between laboratory work and other public health disciplines. Never before has collaboration between the laboratory partners, in the areas of epidemiologic and biostatistical analysis, community health, and health policy and administration, been as important to the overall success of the laboratory system as a whole as now. The laboratory system is essential for guiding clinical diagnosis and treatment, as well as response efforts during manmade and natural disasters on a continuous basis. It is clear that such a book is not only timely, but serves as an invaluable resource and reference for those engaged directly in, or tangentially associated with, the discipline of laboratory sciences. Finally, I want to commend you for the dedication and commitment to the discipline of laboratory sciences which is so vital to our very existence. Truly through your long hours of dedicated and compassionate efforts and services, miracles occur in all of our lives daily, throughout the nation and world we live in.

COL Damon T. Arnold, MD, MPH

Introduction

To our knowledge, this book is the first of its kind. We know of no other text that seeks to describe the wide range of activities in which public health laboratories (PHLs) are engaged. Popular media often imply that a simple injection into an instrument produces a legally defensible result by the next commercial break. This is simply not the case and many laboratory analyses take days for completion. Some, such as the analysis of samples for tuberculosis, may even take 3 to 4 weeks. Many people also do not recognize the wide range of samples and analytes with which PHLs deal. One laboratory may concurrently analyze bats for the presence of rabies, genital swabs for the presence of chlamydia and gonorrhea, stool samples for the presence of enteropathogenic bacteria such as *E. coli* O157:H7, and blood for the presence of lead. PHLs cross many traditional lines of expertise which often separate clinical analyses from those based on environmental, food, and water samples.

PHLs are also different from most private and commercial laboratories by their mission to ensure the health and safety of the public through laboratory analyses. As government entities, they are not-for-profit and provide analyses that promote the public's health; analyses which may be prohibitively expensive, or outright unavailable, elsewhere. It is the combination of mission and lack of a need for profitability that allows PHLs to offer such a wide array of services under one roof. It is also this mission that requires them to be active in other, non-analysis areas as well. Considerable time and effort is spent by laboratory personnel in such areas as emergency preparedness and response, operations and management, and different aspects of data communication.

The skills used and required for successful laboratory analyses and management are as diverse as the tests performed. We often find analysts with Bachelor's degrees in chemistry, biology and microbiology, virology, molecular and cell biology, and associated majors. Many become certified through medical technologist programs and some pursue graduate education. The high levels of education contribute to the research into test methodology and design performed in many PHLs and presented at national/international conferences and in journals. Individuals with a doctoral level education (MD/PhD) provide critical oversight and supervision of many of the high complexity tests performed and the results released. Non-analysts are also a critical component of a PHL, and section chiefs, managers, and accountants must be able to negotiate federal and state rules and regulations, mixtures of revenue streams which may have different rules and reporting, data and workflow oversight to provide adequate day-to-day coverage and still prepare for emergency response, and personnel issues as they relate to employee retention, union rules, and assignments.

In such circumstances, we had a fundamental decision to make about detail. We did not want to provide a text of such detail that one could use it as a guide for actual sample analysis. We determined this level of detail was inappropriate because of the introductory nature of the book, the wide variety of options for many analyses, and the rapid pace with which commercial instrument vendors are developing new and increasingly automated testing methods and techniques. Any detailed methods presented here could be either readily found in a laboratory performing the analyses, or might be subject to obsolescence within a few years. We have been purposeful in attempting to provide sources of information where the reader may go to find detailed method information such that a particular method may be performed.

On the other hand, a simple listing of a disease and its applicable analyses would be unsatisfactory. The reader may well think "But what of it?" if simply told that tuberculosis is analyzed by culture, staining, and an automated system. This brief description does not educate the reader concerning *Mycobacterium tuberculosis* complex, the length of time and safety level required for analyses, and the importance of drug susceptibility testing. For many diseases or conditions, the reader may also be left wondering "Why?" If malaria is not considered endemic in the United States, why do PHLs analyze samples for this parasite? Why are so many blood samples submitted for analysis for the presence of lead?

For each of the four chapters discussing major testing sections, and many of the individual sections in Chapter 5, we decided to include enough information such that the reader could answer the following questions: What is it? Why do we care? How are analyses performed? The section discussing syphilis therefore contains information on the disease itself (progression and treatment), the extent of the disease in the United States, and more detailed information pertinent to laboratory work. This would include descriptions of the organism itself, the types and manner of sample collection, and a description of the tests performed. We find that there are often many different tests that could be performed, and that laboratories create testing algorithms that determine the course of sample testing such that accurate results are reported with a minimum of time and resources. In this manner, the reader will gain an appreciation for why the laboratory performs the analyses, why some results take longer to report than others, and an understanding of how the results were derived.

That said, this book does not provide the actual steps in a given analyses. As described previously, many of these are readily and publicly available, others undergo relatively frequent revision, and still others are subject to obsolescence by newer tests and/or technological advances such as immunoassays and automation. The book also does not present an exhaustive list of every test performed by every laboratory. Such a list would be even more fluid than a listing of test steps because PHLs adjust their offered services constantly based on local and national need. As an example, the Illinois Department of Public Health laboratories changed their influenza testing algorithm several times in the first half of 2009 in response to the emergence of novel influenza A H1N1. Other tests may be offered only by a select few PHLs, such as tests for the toxins responsible for neurotoxic shellfish poisoning.

The book is designed around the idea of imparting an understanding of PHL activities to the reader, who will quickly notice the diverse nature of chapter topics, even in their tone and level of detail. This was purposeful and is in part a reflection of different aspects of PHL work. Chapter 1 presents an overarching view of PHLs in the United States and globally. It provides a brief description of their history, mission, and core functions; distribution and staffing; coordinated activities; and future directions. From this, the reader will be able to understand the context of the PHL and its importance to local, national, and even global health. This is followed by Chapters 2, 3, and 4, where we provide a general discussion of microbiological, chemical, and radiological analysis techniques. These chapters were written so that the reader would have a better understanding of specific laboratory activities. He or she will know the difference between selective and differential media, between PCR and immunoassay, and between HPLC/UV and GC/MS. Many of these concepts are not taught at the undergraduate level, and especially so across disciplines. So while an individual with a degree in chemistry may be able to describe a mass spectrometer and how it is utilized for chemical analyses, they may have no knowledge of the steps and utility of Gram staining. A basic understanding of these analytical activities will assist the reader in understanding the diverse nature of many tests and testing algorithms described in later chapters. These three chapters in particular were written to be merely general descriptions.

The chapters that follow, Chapters 5 to 8, discuss actual tests. For this edition of the book, they are divided according to sample type: clinical, water, food, and air. These are readily recognizable differentiations and often have quite different rules and regulations. They are also the highest volume types of sample submitted, with other sample types such as animal tissue and soil being extremely variable across PHLs and almost universally in low numbers. It is in these chapters that we will discuss the individual contaminants, their impact, and the associated analyses. The reader will also notice substantial variation in the delivery, types of information, and level of detail. Chapter 5, for example, discusses the analysis of clinical samples. These analyses are most often done to diagnose a disease or condition. There are frequently a large number of options when it comes to these analyses, with the US Food and Drug Administration (FDA) regulating some of the test kits and instruments used for disease diagnosis. However, many of the microbiological identification techniques are based on historically documented organism characteristics (e.g., tuberculosis identification via staining and growth in selective media). The laboratory must therefore simply show itself competent in these procedures in accordance with clinical laboratory regulatory requirements. Testing done for water samples in Chapter 6, on the other hand, has an entirely different basis. These are often done to see if the submitter is in compliance

with federal regulations such as the Clean Water Act and are regulated by the US Environmental Protection Agency (EPA). Because these tests are by nature regulatory, and facilities are potentially subject to action if noncompliant, it is incumbent to the EPA to promulgate suitable methods for analysis that have known limitations. We therefore briefly describe these rules, and also mention the mandated analysis methods.

To highlight the differences, let us consider the analysis of two samples: a clinical sample for chlamydia and a water sample for organochlorine pesticides. In Chapter 5 we find that the clinical sample may be analyzed by a commercially available system using DNA analysis (FDA-approved), by various tests using antibody/antigen reactions (enzyme-linked and direct fluorescence), and by culture. The choice of test(s) is largely up to the laboratory based on costs, need, and required expertise. In Chapter 6 we find that if the water sample analysis is to meet regulatory requirements, the PHL must strictly follow one of the following EPA Methods: 505, 507, 508, 508.1, 525.2, or 551.1. Other methods may be as accurate, but they would not meet the requirements. The analysis of water samples for nonregulated parameters is much more flexible, though methodology often varies case-by-case and laboratory-by-laboratory. Food analyses described in Chapter 7 are a mix of laboratory methods based on organism characteristics, commercial test kits and instruments, and analytical methods promulgated by the FDA. We also find that sample testing procedures may be different for samples submitted as part of regulations versus an outbreak response. Finally, we find in Chapter 8 that air samples submitted for the analysis of regulated pollutants must be analyzed by the allowed EPA method. However, unlike the methods described for water in Chapter 6, these are almost always titled after, and associated with, a specific analytical instrument (e.g., *Andersen Model RAAS10-100 PM10 Single Channel PM10 Sampler* for the analysis of particulate matter 10.0).

From discussion of the different testing sections, we move to other PHL activities. These are critical to laboratory continuing operations and integration with other partners, but seldom noticed or appreciated. Chapter 9 in particular discusses national terrorism and emergency preparedness and the role of the state PHL. This chapter provides a somewhat more lengthy description of individual terrorism agents because of considerable public interest. PHL personnel are considered by many in the public to be experts in such matters and we judged a more thorough review was warranted. Chapter 10 goes on to discuss laboratory operations and management and is complemented by a discussion of laboratory data uses in Chapter 11. Finally, in Chapter 12, we discuss how PHLs and their data impact the research and practice of the five traditional fields of public health: biostatistics, community health, environmental health, epidemiology, and policy and administration. PHLs do not operate in a vacuum for their own benefit, and the data they produce has profound impacts in many areas of public health practice.

Acronyms

AFB	Acid-fast bacilli
APHL	Association of Public Health Laboratories
BL	Blood lead
BT	Bioterrorism
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments (Act)
CT	Chemical terrorism; chlamydia
DFA	Direct fluorescent antibody
ECD	Electron capture detector
EHR	Electronic health record
EIA	Enzyme-linked immunoassay
EPA	US Environmental Protection Agency
FDA	US Food and Drug Administration
FERN	Food Emergency Response Network
GC	Gas chromatography; gonorrhea
GIS	Geographic information system
HIPAA	Health Insurance Portability and Accountability Act
HPLC	High performance (pressure) liquid chromatography
IFA	Indirect fluorescent antibody
IDPH	Illinois Department of Public Health
LRN	Laboratory Response Network
MCL	Maximum contaminant level
MCLG	Maximum contaminant level goal
MS	Mass spectroscopy
NBS	Newborn screening
NIH	National Institutes of Health
PCR	Polymerization chain reaction
PHIN	Public Health Information Network
PHL	Public health laboratory
qRT-PCR	(quantitative) Real time polymerization chain reaction
RT-PCR	Reverse transcriptase polymerization chain reaction
rRT-PCR	Real time polymerization chain reaction
STI	Sexually transmitted infection
TB	Tuberculosis
USAMRIID	US Army Medical Research Institute for Infectious Diseases
USAMRICD	US Army Medical Research Institute for Chemical Defense
UV/VIS	Ultraviolet/visible
WHO	World Health Organization
WNV	West Nile virus

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