A Practical Guide to Board Examination and Laboratory Leadership Resources



FEBRUARY 2018



Table of Contents

Background	3
Laboratory Director Responsibilities	3
Competencies and Learning Benchmarks	4
Quality Management System	5
Ethics	6
Management and Leadership	6
Communication	7
Security	
Emergency Management and Response	،۱ ع
General Laboratory Practice	8
Safety	
Surveillance	8
Informatics	9
Microbiology (and Molecular Diagnostics)	9
Chemistry	
Bioinformatics	
Other Testing Areas	
Research	······
Laboratory Director Certification Programs (CLIA-approved)	
American Board of Bioanalysis (ABB)	
American Board of Clinical Chemistry (ABCC)	12 12
National Registry of Certified Chemists (NRCC)	
American Board of Forensic Toxicology (ABFT)	
American Board of Histocompatibility and Immunogenetics (ABHI)	
American Board of Medical Genetics and Genomics (ABMGG)	
(formerly known as American Board of Medical Genetics (ABMG))	
American Board of Medical Laboratory Immunology (ABMLI)	
Board Examination Comparison Table	
Free Web-based Laboratory Trainings and Educational Resources	
Free TRAIN Learning Network Trainings	
Fee-based Trainings, Educational Programs and Courses	31
Board-Sponsored Resource Guides	
Recommended Reference Books or Journals	
Question Bank Resources	
Flashcard Study Set and APHL ColLABorate Community	
Exam Preparation Tips	
Frequently Asked Questions and Answers	
Contact Information	
Acknowledgments	

Background

Public health laboratories (PHLs) across the nation have evolved dramatically over the past couple of decades with respect to the laboratory services and response activities required to protect the health of the American people. While protecting the public is core to the mission of public health laboratories, it is important to emphasize that the specific testing services or state programs supported by the laboratory can be very different from state to state. PHLs may offer testing services in a few program areas or all areas depending on the size, scope and funding of the particular laboratory. The laboratory testing service areas typically supported by PHLs encompass clinical diagnostics, food regulatory and outbreak response, newborn screening and childhood diseases, toxicology, environmental protection, drinking water, agriculture and consumer services and emergency response.

Today's PHL director (PHLD) must not only have an understanding of a diverse spectrum of state and federal program areas, they also must be knowledgeable of testing which encompasses multiple scientific disciplines including microbiology, serology, chemistry, radiochemistry, molecular biology. Additionally, the duties and responsibilities of a PHLD often require knowledge in non-testing areas including how a laboratory operates, personnel management, budgeting, accreditation, state and federal laws, laboratory safety and security and the list goes on. Currently, there are few specialized fellowship and training programs that fully prepare potential PHLDs, not only to obtain the required board certification to direct a high complexity clinical testing laboratory but also to ensure a solid foundation and understanding of the additional ancillary duties that are critical to the success of the laboratory.

The aim of this resource document is to:

- provide guidance and a curriculum framework for potential PHLDs in order to help with career planning
- outline the unique competencies required of today's PHLD, with the understanding that the specific competencies may differ significantly from one public health laboratory to another
- outline the board certification requirements for laboratory directors of high-complexity clinical testing laboratories as required by CLIA
- provide resources to help individuals review core curriculum materials in preparation for board certification examinations

Laboratory Director Responsibilities

Primary Duties and Responsibilities

- Understand the Core Laboratory Director duties and responsibilities and the level of oversight (direct versus delegated) required for these duties as established by various accreditation agencies (ie. CLIA, CAP, ISO17025, etc.)
- Possess a comprehensive understanding of the laboratory's quality system including policies, procedures, and processes
- Ensure the appropriateness of the laboratory's critical/panic values based on patient population served
- Knowledge and compliance with CLIA notification requirements, such as when there is a change in Laboratory
 Director
- Establish protocols for ongoing review and evaluation of the laboratory's quality assessment plan, quality indicators and quality monitors, problem logs and corrective/preventive actions
- Ensure review of all Laboratory Proficiency Testing (PT) enrollments including:
 - PT testing requirements and consequences regarding PT testing referral or consultation
 - Performance Reports
 - Use of Corrective and Preventive Actions (CAPAs) following unsuccessful PT performance
- Be knowledgeable of the testing equipment and test systems used by the laboratory including:
 - Established Quality Control (QC) Parameters
 - \circ $\,$ Validation and verification criteria for different test methods $\,$
 - Applicability of testing performed for different patient populations

• Ensure a sufficient number of supervisory and testing personnel within the laboratory that are educated, adequately training and competent as documented by competency assessment records

Additional Responsibilities include ensuring:

- Adequate physical and environmental laboratory facilities and conditions
- Laboratory environmental safety for all employees including:
 - Physical, chemical and biological hazards
 - Compliance with safety and biohazard requirements
- Day-to-day supervision for all testing personnel
- · Availability of competent personnel to review test results and reports
- On-site supervision is available for minimally qualified testing personnel performing high-complexity laboratory testing
- Review all testing procedures and laboratory policies and ensure ongoing review and approval
- · All laboratory testing personnel follow laboratory protocols and polices and that competency is documented
- · Laboratory testing responsibilities and duties for all personnel are documented in writing
- · Appropriate test selection and that interpretations of test results are present on laboratory reports
- · Customers and patients have access to consultation regarding test results
- All test methods are properly validated/verified (Accuracy/Precision) and test results are not reported when the system is not functioning properly
- A quality assessment and management program is established and maintained for all phases of testing (Preanalytical, analytical and post-analytical)
- The establishment of acceptable analytical test performance criteria
- A CAPA process is developed and utilized to document deviations and non-conformances
- · Access for all laboratory and/or testing personnel to an orientation and training program
- · Completion of annual performance evaluations and competency documentation for staff
- Opportunities for training and continuing education for personnel
- The laboratory is customer focused

Competencies and Learning Benchmarks

In 2015, Ned-Sykes et al. [MMWR 64(01); 1-81] published a list of competency guidelines, which included the knowledge, skills and abilities necessary for public health laboratory (PHL) professionals to deliver efficient and effective core laboratory services. This publication was the product of a two-year collaboration sponsored by the US Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL), and involved input from experts representing state and local PHLs, clinical laboratories, academia, laboratory professional organizations, CDC and APHL. Fifteen core competencies were identified.

The competency guidelines identified in the MMWR document were developed for leadership professionals in PHLs, including governmental public health, environmental and agricultural laboratories, which provide biological, radiological and/or chemical testing for infectious diseases in human, foodborne and waterborne diseases, environmental hazards, treatable hereditary disorders, and natural and human-made public health emergencies. These 15 identified competency areas have been adopted as the guiding framework for the current *Curriculum Competencies and Resources for Potential and Current Public Health Laboratory Directors*. **Nevertheless, it is important to note that while these 15 core competencies encompass all possible areas within today's US public health community, not all PHLs are the same when considering the volume or scope of testing and the specific competencies required to direct one particular PHL can differ from that of other PHLs.**

Additionally, these competencies also apply to non-PHL professionals working in a variety of other laboratory and work settings. Although the required list of competencies may seem daunting for individuals considering a career as a PHLD, it should be emphasized that there are many individuals within a PHL that share the duties and responsibilities required for many of these competencies and these individuals provide critical expertise and consultation to laboratory directors.

1. Quality Management System

- All phases: pre-analytical, analytical, post-analytical
- Laboratory accreditation, certification and inspection requirements
- Clinical Laboratory Improvement Amendment (CLIA) Regulations
 - \circ Different types of CLIA laboratory certifications
 - Waived, Provider Performed Microscopy (PPM), Moderate Complexity, High Complexity
 - \circ What types of tests fall under each certification type?
 - o Specific educational and experience qualifications for all levels of staffing (ex. Bench to Director)
 - \circ Specific duties and responsibilities of all levels of staffing
 - \circ Requirements for critical staffing for consultation, on-site supervision for the type of testing performed
- Data Reporting Requirements
 - Test interpretations and consultation requirements
 - Required reporting fields, referral reporting, panic values
 - Required information on laboratory test reports
 - Record Retention requirements
- Validation, verification and ongoing performance of test methods and Instrumentation
 - Terms, definitions and calculations (be able to calculate if given data)
 - Control Monitoring
 - Westgard Rules including definitions
 - Common rules (ex. 1-2S, 1-3S, 2-2S, 7T, 10X, etc.) and possible causes for exceeding standard deviation limits when using Levey-Jennings charts
 - Potential causes for warning and out-of-control trending data (ex. shift, drift, dispersion, etc.)
 - Test Performance Criteria
 - Sensitivity versus specificity
 - Standard deviation
 - Coefficient of variance
 - P-values
 - Positive Predictive Value/Negative Predictive Value (PPV/NPV)
 - Precision versus accuracy
 - Mean, median, mode,
 - $\circ~$ Regulations and criteria for Food and Drug Administration (FDA)
 - FDA-approved versus non-FDA approved testing
 - Laboratory Developed Tests (LDTs)
 - Emergency Use Authorization (EUA)
 - Proficiency Testing
 - Requirements for enrollment and frequency
 - Requirements for completing testing and reporting
 - Ethical expectations
 - Acceptable actions following a failed PT
- Corrective and preventive actions (CAPAs)
 - Requirements for initiation of CA versus PA
 - How to conduct a root cause investigation
 - Corrective actions versus corrections
 - Monitoring for reestablishment of conformance

- Standard Operating Procedures (SOPs)
 - How to write SOPs
 - Required sections for a technical SOP
 - Review requirements for SOPs
 - Controlled versus uncontrolled documents
 - o Individualized Quality Control Plan (IQCP) requirements and when necessary
 - Safety requirements

2. Ethics

- Expectations for staff
- Required policies, procedures and training for laboratory staff
- · State and federal laws regarding confidentiality
- Whistleblower
- Rules and regulations relating to protected health information
- Stewardship of resources
- Health Insurance Portability and Accountability Act (HIPAA) Regulations
- Freedom of Information Act (FOIA) vs Subpoena
- Guiding principles regarding ethical conduct in research

3. Management and Leadership

- Personnel and Human Resource Management
 - Staffing levels and position descriptions to include required knowledge, skills and abilities (KSAs)
 - Recruitment and Interviewing process
 - Staff performance planning and evaluations
 - Progressive disciplinary process
 - Short-term versus long-term disability
 - American Disability Act (ADA)
 - \circ $\,$ Termination process $\,$
- Personnel Education, Training and Competency Requirements
 - Orientation and training requirements including immunizations
 - Training and education verifications
 - o Education, training and experience of staff meet accreditation requirements
 - Written testing responsibilities and annual performance evaluations
 - Annual documented competency assessments
- Personnel and labor laws, regulations, acts (ex. Civil Rights Act, Fair Labor Standards Act, Equal employment opportunity, American Disability Act, etc.)
 - Employer qualifications under each
 - Posting requirements NOTE: Prepare for situational-based questions
 - Federal law compliance
 - Department of Transportation, Drug Enforcement Agency, Federal Select Agent Program, Occupational Safety and Health Administration (OSHA), Clinical Laboratory Improvement Amendments (CLIA), etc.
 - State and local law compliance
- Record and specimen use and retention requirements
 - $\circ~$ Safety, QA, vaccinations, incident reports, etc.
 - Legal records
 - Chain of custody samples/records
 - Institutional Review Board requirements
 - Common Rule regarding use of residual specimens

- Fiscal Management and Budgeting
 - Types of laboratory budgets (ex. Zero-base budget, appropriation budget, internal service fund budget, etc.)
 - Understanding of each budget type
 - Why different budget types are used
 - $\circ~$ Advantages and disadvantages of each type of budget
 - Knowledge of the types of test costing strategies used by laboratories (ex. loss leader)
 - Understanding of each type of costing strategy
 - Why/when each is used
 - Advantages/disadvantages of each
- Difference between CPT and ICD-10 codes

4. Communication

- Approaches to build, maintain, and enhance the State Laboratory System
 - Collaboration and interaction with hospital and private laboratories
 - Ongoing communication and interaction with local public health, agriculture and environmental health agencies
 - Foster and enhance partnerships with state and federal public health programs
- Surveying customers for performance feedback
- Surveying lab staff for job satisfaction
- Establishing oral and written communication protocols and guidelines for staff and management
- Insure an environment of cultural, racial, gender sensitivity
- Define appropriate types of dialogs and exchanges with customers, the press, legislature, etc.
- Risk communication planning
- Health Insurance Portability and Accountability Act (HIPAA)
 - Purpose of Act
 - What is covered under HIPAA?
 - Examples of HIPAA violations
 - Category, types and fines for violations?

5. Security

- Facility access and requirements for different testing areas
- Staff access and background requirements
- Federal Select Agent Program Requirements
 - Definition of select agents
 - Security requirements for staff, facility, etc.
 - Roles and responsibilities of Responsible Official (RO), Alternate RO, and Principal Investigator (PI)
 - Federal Select Agent Program (FSAP) forms and reporting timelines
 - Requirements of Tier-1 and non-Tier-1 laboratories

6. Emergency Management and Response

- After-hours security requirements
- Continuity of Operations Planning (COOP)
- Incident Command Structure and required training
- Protocols to handle possible threats to laboratory or personnel
 Bomb, active shooter, unauthorized person in building, etc.
- Surge Planning

7. Workforce Training

- Continuing education (CE) and professional development
- State-specific certifications
- Annual Required Trainings
 - Safety
 - Security
 - Ethics
 - \circ Bloodborne pathogens
 - Chemical Hygiene and Hazardous Materials

8. General Laboratory Practice

- Laboratory concepts and terminology
- Understanding of different laboratory technologies and instrumentation
- Requirements for preventative maintenance, calibration, etc.
- Turnaround time requirements and notifications
- Regulatory requirements

9. Safety

- Requirements for Laboratory Facility design physical and environmental
- Components of a Biosafety Plan/Program
- Components of a Biosecurity Plan/Program
- Components of an Incident Response Plan/Program
- Employee safety
 - Bloodborne Pathogen Training
 - Occupational Health Program requirements for laboratory workers
 - o Hazardous response for biological, chemical and radiological agents
 - Chemical Hygiene Plan
 - o Safety Data Sheets (SDS), safety placards and posted warning requirements
 - Risk Assessment Process
 - for novel pathogen use
 - for newly developed procedures
 - Required Immunizations and time frames for administration
 - Global Harmonization System (GHS) Requirements
 - National Fire Protection Association (NFPA) versus GHS (labels, pictograms, meanings)
 - Containment levels and requirements
 - 1. Biological, chemical, radiological
 - 2. Personal Protective Equipment
 - 3. Facility controls
 - 4. Waste disposal
 - o International Air Transport Association (IATA) Packaging and Shipping Rules and Regulations
 - Category A
 - Category B
 - Category A, Risk Group 4
 - Sterilization/disinfection methods
 - o Animal research

10. Surveillance

Notification policies and procedures

- Appropriate data dissemination
- · Policies surrounding public health surveillance activities and reporting requirements
- · Software and tracking systems available or employed

11. Informatics

- Electronic lab test ordering and result reporting
- HIPAA rules and regulations
- Protected health information (PHI)
- Laboratory Information Management Systems
- · Regulations regarding test result reporting and referrals
- Familiarity with Health Information Exchange (HIE)
- Cloud computing-associated issues
- Knowledge of HL7, LOINC and SNOMED codes

12. Microbiology (and Molecular Diagnostics)

- Bacteriology, Parasitology, Mycology, Virology
 - Tests used to distinguish the different agents within and between types
 - Disease Epidemiology
 - Unique or distinguishing features of different agents
 - Clinical symptoms associated with disease causing agents
 - Modes of infection/transmission
 - \circ $\,$ Tests used to distinguish different agents (within and between types)
 - Biosafety considerations or categorizations of different agents
 - What do the agents look like under standard or electron microscope?
 - $\circ~$ Case studies what is the agent
 - Emerging pathogens
 - o Interpretation of antimicrobial susceptibility tests
 - Zoonotic diseases of public health significance
- Molecular Diagnostics
 - Basic Info
 - Genomic/Genetic DNA
 - Nucleic Acid types, structure and functions (ex. Mitochondrial DNA, RNA, messenger RNA)
 - Gene regulation
 - DNA replication
 - Mutation types, mutation effects and examples
 - Pathogen DNA, RNA
 - Structure and function
 - Central Dogma
 - Inheritance of traits and types
 - ♦ Autosomal single-gene inheritance
 - Autosomal dominant/recessive inheritance
 - X-linked recessive/dominant inheritance
 - ♦ Y-linked inheritance
 - Mosaicism
 - o Multifactorial disorders, somatic cell genetic disorders, mitochondrial disorders
 - $\circ~$ Chromosome structure, analysis, mitosis, aberrations
 - Hematology/Oncology/Solid Tumors
 - Identity/Human Leukocyte Antigen
 - Pharmacogenomics

- \circ QA/QC
 - Test validation and performance verification
- Laboratory Technologies
 - ♦ Culture
 - · Primary, selective and differential media types and for which bacterial agents
 - Types of cell lines for specific viral agents
 - Growth requirements for fungal agents
 - Microscopy (bright field, dark field, fluorescent, polarized light)
 - Immunologic / serologic testing
 - Direct Fluorescent Antibody (DFA)
 - Indirect Fluorescent Antibody (IFA)
 - Slide and tube agglutination
 - ELISAs
 - Plaque Reduction Neutralization Testing (PRNT)
 - Luminex based assays
 - Molecular Testing
 - Types of detection methods (DNA vs RNA targets)
 - Amplification-based
 - Probe hybridization
 - Sequencing
 - Multi-gene analysis
 - · Characterization and/or subtyping methods
 - Pulsed Field Gel Electrophoresis
 - Fragment Analysis
 - DNA Sequencing
 - Pyro-sequencing
 - Whole genome sequencing

13. Chemistry

- General laboratory methods
 - \circ Centrifugation
 - Pipette qualification and verification
 - Dilutions
 - Calculations and Statistics
- Enzymes
- Protein chemistry and biochemistry; amino acids
- Non-protein nitrogen
- Acyl carnitine, organic acids analysis
- Carbohydrates
- Acid Base chemistry; Henderson Hasselbalch; Blood Gas
- Metabolic/Respiratory Alkalosis/Acidosis
- Electrolytes
- Nutrition, minerals and vitamins
- Markers and/or Biomarkers of
 - Acute or chronic inflammation
 - Pregnancy
 - Tumor presence
 - Cardiac function

- Endocrinology
- Hormones
- Kidney and liver function analyses
- Urinalysis
- Lipids
- Allergy, acute infection, chronic infection monitors
- Diabetes testing
- Toxicology
- Therapeutic Drug Monitoring
- Instrumentation
 - Photometric techniques, Beer's Law, Stoichiometry
 - Immunoassay ELISA, EIA, FIA, etc.
 - Mass spectrometry
 - Liquid chromatography
 - Radiochemistry

14. Bioinformatics

- Next Generation Sequencing (NGS) technologies and data analysis tools
- Application of different NGS technologies
- Cloud Requirements and Restrictions
- · Bioinformatics requirements for whole genome sequencing
- Technology and resource requirement
- State and federal programs involved with bioinformatics

15. Other Testing Areas

- Newborn Screening
 - Metabolic and hereditary disorders
 - Recommended uniform screening panel (RUSP)
 - Confirmatory testing
 - Timeliness initiatives
 - $\circ \ \ \, {\rm Cutoff\ values}$
 - Population prevalence studies
- Drugs of Abuse Testing
 - Screening and confirmatory testing
 - Typical analytes targeted in screening
 - \circ Chain of custody
- Biomonitoring
 - NHANES

16. Research

- National Institutes of Health (NIH) Requirements
 - Human Subjects and Clinical Trials
- Funding and resource management
- Regulatory requirements
- Purpose of Institutional Review Boards (IRB) ((also known as independent ethics committee, ethical review boards or research ethics board)

- Patents
- Statistics
- · Policies and procedures relating to publication and peer review of laboratory information
- · Appropriateness of university and external agency collaborations

Laboratory Director Certification Programs (CLIA-approved)

The qualification for a laboratory director of high complexity testing [as defined by reference 42 CFR 493.1443(b)(3) (i)] is that the laboratory director must hold an **earned doctoral degree**** in a chemical, physical, biological or clinical laboratory science from an accredited institution and be certified and continue to be certified by a board approved by the US Department of Health and Human Services. As of 2/18/2015 the following is a listing of approved Certification Boards. The Certification Boards highlighted in red will be reviewed in detail in this resource guide.

American Board of Bioanalysis (ABB) (Website)

Certification Disciplines: Microbiology, Public Health Microbiology, Diagnostic Immunology, Hematology, Chemistry, Molecular Diagnostics

American Board of Medical Microbiology (ABMM) (Website)

American Board of Clinical Chemistry (ABCC) (Website)

• Certification Disciplines: Clinical Chemistry, Toxicology, Molecular Diagnostics

National Registry of Certified Chemists (NRCC) (Website)

American Board of Forensic Toxicology (ABFT) (Website)

American Board of Histocompatibility and Immunogenetics (ABHI) (Website)

American Board of Medical Genetics and Genomics (ABMGG)

(formerly known as American Board of Medical Genetics (ABMG)) (Website)

American Board of Medical Laboratory Immunology (ABMLI) (Website)

** It is important to highlight that CLIA personnel qualification and responsibility requirements stated in 42CFR, Part 493, Subpart M specifies that "The laboratory director must hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution, AND be certified and continue to be certified by a board approved by HHS" [§.493.1443(b)(3)].

The Centers for Medicaid and Medicaid Services (CMS) further interpreted or clarified the "earned doctoral degree" requirement for a laboratory director, by specifying that "an acceptable doctoral degree is a Doctor of Philosophy (PhD) or Doctor of Science (DSc) [CLIA State Operations Manual – Appendix C – "Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services," (Rev. 166, 02-03-17)]

Compliance or acceptability of alternate doctoral degrees including (1) Doctor of Dental Surgery (DDS), (2) Doctor of Veterinary Medicine (DVM) or (3) Doctor of Public Health (DrPH) with respect to fulfilling the CLIA educational requirements for a laboratory director of a high complexity testing laboratory has not been specifically determined. Instead, compliance determinations are at the discretion of each CMS CLIA Surveyor. As of January 2018, CMS and the American Board of Bioanalyst (ABB) have declined to officially pre-approve doctoral degrees as acceptable and instead both entities indicate that they will evaluate applicants on a case-by-case basis; ABB prior to the examination and CLIA (CMS) upon their first visit to the laboratory.

Board Examination Comparison Table

Question	АВВ	АВММ	NRCC	ABCC
General Exam Description/ Overview	ABB certifies clinical laboratory professionals who meet the education, experience, and knowledge of the laboratory field in which certification is granted. ABB is recognized by CLIA as a certifying agency for laboratory directors and clinical consultants with designations established for High-complexity Clinical Laboratory Directors (HCLD) and Public Health Laboratory Directors (PHLD).	ABMM certifies doctoral-level microbiologists to direct medical and public health microbiology laboratories. ABMM certification is recognized by federal and state governmental agencies as meeting the licensure requirements to direct lab engaged in the microbiological diagnosis of human disease and is recognized by CLIA and all 12 states that require licensure: California, Florida, Georgia, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Rhode Island, Tennessee and West Virginia.	NRCC provides certifications for Chemical Hygiene Officers, Clinical Chemists, Clinical Chemistry Technologists, Environmental Analytical Technologists, Toxicological Chemists, and Toxicological Technologists.	ABCC certifies individuals with doctoral degrees in clinical chemistry, toxicological chemistry, and other clinical laboratory medicine disciplines. In purpose, function, and organization the ABCC is analogous to the certifying boards in various medical specialties with the aim of certifying as Diplomats, qualified specialists who comply with the requirements of the Board.
Website	https://www.aab.org/aab/About_ABB.asp https://www.aab.org/aab/FAQs1.asp	https://www.asm.org/index.php/abmm-about	http://www.nrcc6.org/	http://www.abclinchem.org/Pages/default.html
When is the exam offered?	Typically, twice a year; in the spring and fall	Once a year, from June 1 to June 30	Any time. Requires the use of a local proctor to receive and administer the exam.	Twice a year; typically in February and July
Exam locations	Various locations in the U.S.	Online at testing centers around the country	Examinations can be taken in the local or state library or a formal learning center (ex. Sylvan). Some locations may charge a fee.	Online at various testing centers in the US, Canada and other locations
Exam costs	Application Fee = \$295 General Knowledge (GK) Exam Fee = \$225 One Technical Discipline (TD) Exam Fee = \$225 Additional technical discipline exams taken the same day = \$130 each GK + 1 TD same day = \$355 GK + 2 TD same day = \$485 Applications fees are non-refundable. Examinations canceled within thirty (30) days of examination date will be subject to a \$100 cancellation fee.	Exam cost = \$400, but application fee also applies: \$450 for ASM members, \$575 for non-ASM members.	\$185.00 each time up to three times	Exam sitting fee (clinical chemistry, toxicology) = \$200 per attempt Exam sitting fee (molecular diagnostics) = \$400 per attempt
Application requirements	The application for certification MUST be completed online and include: Education information: institutions attended, locations, dates, and degrees obtained. Employment history: institutions, addresses and telephone numbers, positions held and duties performed, and dates. License or certification: include Medicare, CLIA, state, etc. References: Names, addresses, and affiliations of two qualified laboratory directors or physician clients. Curriculum vitae, list of scientific publications and awards received. Official academic transcripts: Must be directly forwarded to ABB and contain the institution seal. Degrees from institutions outside the US must be evaluated for equivalency by an agency acceptable to ABB. ABB requires copies of transcript release forms sent to the educational institutions.	Creation of a Web assessor account Application fee payment Official graduate transcripts	Application fee payment, completed application, Applicant photograph and academic transcripts	\$500 application fee

Degree requirements to sit for the examination?	Meet the qualifications of HCLD under the CLIA '88, Subpart M, Section 493.1443. OR Hold an earned doctoral degree from an accredited institution in a chemical, physical, biological, or clinical laboratory science as the major subject AND successfully completed 32 semester hours (minimum) in chemistry or the biological sciences acceptable to ABB	Doctoral degree* + 3 years of experience OR Doctoral degree* + CPEP approved program *doctoral degree = PhD in microbiology or equivalent OR DrPH, MD, DO, DVM, DDS, DMD if special training and experience is approved by ABMM board.	Earned Doctoral degree with at least the equivalence of 24 semester hours (36 quarter hours) in chemistry and 8 semester hours (12 quarter hours) of additional natural science courses from an institution acceptable to the Board AND A minimum of 2 years full-time (or part-time equivalent) of toxicology experience with human specimens which may include interpretation of data. **LRN-C testing qualifies as toxicology experience	Earned doctoral degree in a chemical, physical, biological or clinical laboratory science OR A MD, DO, DPM or DMD degree from an accredited university or college acceptable to the Board. Applicants must have completed a minimum of 30 semester hours (or equivalent) of undergraduate and/or graduate courses taken at institutions acceptable to the Board that meet the combined criteria established by each of the <u>ABCC certification</u> <u>disciplines</u> Prior to admission to examination, applicants must demonstrate five (5) years' full-time (or equivalent part-time) diverse professional experience in the relevant discipline area (clinical chemistry, toxicological chemistry or molecular diagnostics). Experience must be obtained subsequent to conferral of the doctoral degree and in laboratories or institutions with standards acceptable to the Board. Experience may be gained as part of or outside of a formal training program. A laboratory director who is qualified to serve as a director of a CLIA-certified laboratory must attest as to the candidate's experience. Exceptions are listed at http://www.abclinchem.org/ geninfo/Pages/rules_abcc_cert.html
--	--	---	--	---

Pre-examination requirements	Candidates must have a minimum of four (4) years** of clinical lab training or experience on human specimens within the ten (10) years immediately prior to the application date or both, including at least two (2) years of experience within the ten (10) years immediately prior to the application date directing or supervising high complexity testing in a clinical setting **Effective January 1, 2012, ABB will accept up to two (2) years of alternative experience toward the four-year experience requirement for HCLD certification. An additional two (2) years of clinical supervising or directing experience is still required in addition to the two years of "alternative" experience. (see General Regulations, rule 18).	Experience is defined as full-time postdoctoral training or director- level lab experience directly relevant to the practice of medical and PH microbiology and its subspecialties. Experience requires an ongoing relationship with a medical and PH microbiology, reference or other microbiology lab that includes a diagnostic service component such that the applicant has devoted at least 75% of time to management, medical and administrative activities during the three years of experience. The cumulative training/experience must include percentages of time devoted to each of the listed areas: Responsibilities and skills in the medical and public health microbiology laboratory (50-65%) Ex. Assisting medical and PH microbiology technologists in interpreting the medical significance of lab findings, oversight of QA/QC, technical troubleshooting & problem solving. Interaction with healthcare providers (15-30%) Ex. Consultation with healthcare providers regarding selection and interpretation of medical and PH microbiology tests/results, consultation with clients, participation in hospital/institution committees (infection control, antibiotic subcommittee, etc.) Interaction with healthcare providers (15-30 Ex. Consultation with local and state PH health officials, Reference lab consultation with local and state PH health officials, Reference lab consultation with clients, participation in hospital/institution committees (infection control, antibiotic subcommittee, etc.) Research (0-25%) Ex. Development/evaluation of new test methods/techniques/ instrumentation, collaboration with medical and PH microbiology/ basic research colleagues. Teaching (0-25%) Ex. Didactic lectures and rounds, Resident/fellow/student training. The minimum percentages in each area must be met. Research and teaching experience are not required, but applicants may have up to 25% of their time devoted to either, or a combination, of those areas provided the combination does not exceed 25%. Experience in which more than 25% of time is spent or research,	Select the appropriate certification and download and complete the application, including photo and notarization, and submit with the application fee electronically or by mail. Submit academic transcripts to NRCC by mail or electronically. Credits to meet the educational requirements of NRCC which are from outside the US or Canada require transcript review by a NRCC approved evaluation agencies and must be submitted to NRCC. Completed application files (including transcripts & references), are submitted to a credentials committee for final review and approval prior to scheduling the exam (allow at least a 2-weeks before your exam date)	Applications must be submitted online in compliance with the instructions and be accompanied by the application fee (half of the fee will be refunded if the applicant is not eligible for examination). Applicants must provide official documentation of degrees awarded, academic transcripts or equivalent documentation of all courses taken and grades and all must be submitted directly to ABCC by the university registrar. A course-by-course evaluation must be submitted from a credentials evaluation agency directly to the ABCC office for education obtained at an institution outside the U.S. or Canada. For post-doctoral training programs, the Program Director must submit a letter describing the nature of the training and attesting to its satisfactory completion by the applicant. Applicants must arrange for three (3) letters of reference to be submitted directly to ABCC and these must be current to the time the application is submitted and attest to familiarity with the applicant's professional expertise, the length of acquaintance, and the good character of the applicant insofar as pertinent to the Board. Current ABCC Credential Committee members may not serve as references. All parts of the exam must be passed within 3 years after the date of the first exam. Failure to take/pass the exam within this time will result in termination of the application and forfeiture of all fees.
advance do you need to register for the exam to allow sufficient time for acceptance?	at least 6 to 8 weeks to process if all documentation (e.g. transcripts, employment verifications) is received promptly. The Board's decision regarding certification applications should be sent within 2 months of applying, however if documentation is not received promptly, this can be longer.			anticipated examination date. The Board takes no action on incomplete applications (lacking, for example, a transcript or letter of recommendation). When the Board or its committees are satisfied that the requirements for admission for examination have been met, the applicant is designated as a Candidate for examination and will be notified at least 45 days prior to an assigned examination date

How many	General Knowledge exam = 70 questions	200	150 from a pool of questions	Clinical Chemistry:
questions?	Subject Discipline exams = 70 questions each (typically)			Part A - Calculations and problem solving
				Part B, Analytical and clinical issues
				Toxicology:
				Part A Calculations and problem solving
				Part B – Analytical, toxicological and therapeutic drug monitoring issues
				Molecular Diagnostics:
				120 questions
				All questions are in multiple-choice format with one best/correct answer. All choices are A-E.
Examination Testing Time	2 hours for each exam	6 hours	3 hours	Clinical Chemistry Exam has two parts: Part A (3 hours); Part B (3.5 hours)
				Toxicology has two parts to the exam: Part A (3 hours); Part B (3 hours)
				Molecular Diagnostics exam is only one part lasting 3 hours
Does the exam	The exam reflects the information that a laboratory director	Some to a degree. Much of the exam is clinical microbiology	No, it more clinical testing based	Yes.
reflect the actual duties that a Lab Director performs?	should be knowledgeable of.	based so not as relevant for a PHLD.		The Molecular exam has been revised in recent years to provide
	Many of the technical subject discipline questions are very detailed and reflect info that a lab director should know but	Some of the management, QA, and infection control questions		a better balance between technical, clinical and administrative
	typically not at the level of detail of the question because there	are pertinent.		aspects of the job duties of a laboratory director
	are other lab staff that are typically knowledgeable of the details (ie. QA staff, safety officers, HR team)			

What are the sections/topics covered by the exam?	 ABB's examinations cover general laboratory knowledge and a minimum of one (1) of the following clinical laboratory disciplines and specialties: Andrology Chemistry (including urinalysis, endocrinology and toxicology) Diagnostic Immunology Embryology Hematology (includes bacteriology, parasitology, virology, and mycology. Molecular Diagnostics Public Health Microbiology BCLD applicants must pass ABB examinations covering general laboratory knowledge plus a minimum of three (3) of the five (5) following clinical laboratory disciplines: Chemistry; Diagnostic Immunology; Hematology or Public Health Microbiology; Microbiology or Public Health Microbiology; Molecular Diagnostics Chemistry; Diagnostic Immunology; Hematology; Microbiology or Public Health Microbiology; Molecular Diagnostics General knowledge exam covers: Administration/management Accreditation Regulatory Laws Patient test management, reporting Personnel, Employment/HR Laws Lab billing Facility design/requirements QA/QC, CLIA Laboratory Safety Fiscal/budgeting HCLD applicants must pass an ABB examination covering general laboratory knowledge plus an ABB examination in a minimum of one (1) of the eight (8) clinical laboratory disciplines listed above.	https://www.asm.org/images/PPC/College/ABMM_Exam_ Content_11182016.pdf	General toxicology but with a clinical focus. Majority of questions are regarding drugs of abuse, specimen type testing, adulteration, instrumentation theory and use for testing and calculations	Clinical Chemistry and Toxicology: Part A: Calculations and problem solving Part B: Analytical and certification topic specific Exam domains for Toxicology include: • Analytical techniques • Physiology • Pathophysiology • Management Exam domains for Clinical Chemistry include: • Clinical chemistry interpretation • Clinical case approach • Analytical • Instrumentations • Methodology • Statistical analysis • QA • Regulatory/management • Molecular/genetics The Molecular Diagnostics exam is a single exam. Exam domains for Molecular Diagnostics include: • Genetics • Molecular Biology • Hematology • Microbiology • Identity/HLA • Pharmacogenetics • Biomarkers • Solid Tumors • Techniques • Management
Exam scoring criteria	Based on the number of correct questions answered. However, ABB may exclude questions based on the analysis of examinee responses or if the majority of examinees miss a question	The certification boards of the American College of Microbiology use a <u>criterion-referenced scoring system</u> . You are not graded on a curve and do not compete against each other. The exam committee may remove some questions that the majority of examinees miss to form the new denominator. The new numerator is the remaining questions	Multiple choice	Based on the number of correct questions answered. The exam committee may remove questions that the majority of examinees miss or other problems with the question are revealed
What score is considered passing?	Generally, 70% Cut score is determined independently for each exam based on the mean +/- 2SE	70%	60% (90 of 150)	This information is not shared outside of the board
How long does it take to get your exam score?	Typically 4–6 weeks from the date of your examination. Results are forwarded via email and certified mail.	About two months	A couple of days	About one month

Does your score indicate what questions you missed?	No, you are provided with a score indicating the number of questions you answered correctly for each section, but not the specific questions missed.	You are provided with a raw score of the number that you missed, but not the specific questions.	Νο	No
Exam passing rate	ABB does not publish this information but from info gathered from recent exam takers (less than ~40%; higher if the General Knowledge and Subject exams are taken separately)	In 2016: 51% Passing percentages were 39%, 31%, 33%, 30%, 30% from 2015 to 2011, respectively	N/A	
What are the options for a non-passing exam score?	The exam can be retaken two (2) times after receiving a failing score but to avoid additional application fees, the exam must be retaken at least one time within the next two examination administrations or within one year, whichever is longer. After a second failure, you have an additional year (or two examination administrations) to retake. After three failed exams, candidates must wait two years after the date of the last failed examination and begin the certification process again including submission of a new application form and fee. In addition, the Board requires that you provide evidence that you have gained additional education or training in the discipline that you are applying for. Documents, such as transcripts and employment verification letters that are in your original application should be documented with your original application.	Candidates have three (3) chances to pass the exam. After three (3) failing scores, the exam cannot be re-taken.	The exam can be retaken two (2) times after receiving a failing score.	All parts of the examination must be passed within three (3) years after the date of the first examination. Failure to take or pass the examination within this time will result in termination of the application and forfeiture of all fees. An individual may reapply for certification only once per specialty. The applicant's reapplication must allow at least one exam sitting to lapse between eligibility periods. If necessary, all or part of the examination may be repeated one time (only) without reapplication during the three-year eligibility period by notifying the ABCC office of such intent at least 45 days prior to any scheduled examination. If unable to successfully complete the examination under the conditions above, the applicant may reapply one additional time. The applicant will be required to sit for all parts of the examination regardless of past performance on any one portion. Applicants may not have more than one ABCC examination application open concurrently. Before being allowed to apply for ABCC examination in Clinical Chemistry, Toxicological Chemistry, or Molecular Diagnostics, an applicant must bring any current application process to a close by obtaining a certificate, failing two iterations of the examination, or by allowing the 3-year limit to expire before opening another ABCC examination application in the same or different specialty. If unable to successfully complete the examination under the conditions above, the applicant may reapply one additional time. The applicant will be required to sit for all parts of the examination regardless of past performance on any one portion Applicants may not have more than one ABCC examination application open concurrently. Before being allowed to apply for ABCC examination in Clinical Chemistry, Toxicological Chemistry, or Molecular Diagnostics, an applicant must bring any current application process to a close by obtaining a certificate, failing two iterations of the examination, or by allowing the 3-year limit to expire before opening another ABCC exa
Preparation	VEC	VEC	VEC	VEC
If you have been working in a PHL is it necessary to study?	YES	YES	YES	YES

How long should individuals expect to prepare/study for the exam?	Typically 6 months to a year, with 2-3 hours dedicated each day. This will also depend on whether the General Knowledge exam is taken at the same time as the Subject Discipline exam.	6 months to 1 year, depending on how much time is committed to studying.	Depends on previous scientific and laboratory knowledge	Very much candidate specific. If a candidate has been working in a specific field, say cancer genetics, and is anticipating sitting for the Molecular Diagnostics exam, time should be devoted to reviewing resources that cover domains of the exam that the candidate is less familiar, say Microbiology, Identity/HLA, PGx and Lab Management
What is the level of detail of the exam questions?	Many questions are very detailed while others are general knowledge and can be answered from practical experience. There are highly specific and detailed questions, more than you would expect to have to commit to memory as a laboratory director	Very detailed. Many questions are vignettes of clinical cases that require you to know the offending organism, then figure out what step to take next. Bacteriology, virology, parasitology, mycology, infection control, quality assurance, and laboratory management are all topics on the exam.	The exam questions are straight forward multiple choice type questions.	Some questions are detailed and require the candidate to perform calculations and problem solving while many questions are recall of facts.
What is the best way to prepare for the exam?	The ABB study guides are a great resource, but need to be supplemented with other reference materials. Many folks recommend use of flashcards for memorization of specific details or study groups. Participation in a formal study course is also beneficial if able to. Study daily and consistently - even for one hour, and have an extensive review the week of the exam.	There is no study guide available, so you have to assemble a group of materials yourself. Pathology Question of the Day (online) is a great way to prepare as the questions are very similar.	http://www.nrcc6.org/studyresources.pdf AACC Clinical Toxicology certificate course was very helpful	
What are the pros and cons of this exam?	 Pros: ABB allows applicants to test in specific scientific disciplines; offers a PHLD certification which is more geared toward PH related Microbiology questions as opposed to Clinical/Hospital laboratory microbiology questions. Cons: Pass rate is not high when both exams are taken together; much of the info is very detailed and in the weeds and requires straight memorization. Questions are geared to challenge the applicant so many of the available multiple choice answers require interpretation or choosing the best answer from a selection that does not include the "correct" answer. 	Pro: Exam is accepted by CLIA as one of the board exams required to be a PHLD. Cons: Expensive to apply and register. Many questions are clinical microbiology related, so difficult at times for someone who has not been in that environment in a long time (or ever) to be able to grasp easily; multiple choice questions for laboratory management questions is not practical		
Renewal Fee	N/A	N/A	\$85.00/1year or \$230.00/3 years	\$250.00 for two years
Continuing education requirements	All ABB Diplomats (Directors) and Certificants (Managers, Consultants, and Supervisors) are required to participate in the PEER program as a condition for maintaining their American Board of Bioanalysis certification. Under the PEER program, ABB required a documented 2.4 CEUs (24 contact hours) of acceptable continuing education every two years.	The ABMM requires its certified individuals, Diplomats, to recertify every three years. Diplomats need to complete an application form and must accumulate 150 contact hours of continuing education over three years. The recertification fee per specialty is \$300 for ASM contributing and premium members and \$350 for ASM supporting and non-members. The deadline is January 31. For applications not postmarked by January 31, a late fee of \$300 for ASM contributing and premium members and \$350 for ASM supporting and non-members will be applied.		http://www.abclinchem.org/geninfo/Pages/new_abcc_cert.html Diplomats will be notified every two years of the CE requirement. CE activities must be obtained during the two-year period, January 1—December 31, immediately prior to submitting documentation and must total at least 50 hours for the preceding 2 years. In addition to attesting to completion of the required CE, Diplomats must submit the current CE renewal fee by February 1 of the appropriate year in order to remain in the directory of active Diplomats.
Frequently Asked	https://www.aab.org/aab/FAQs1.asp	https://www.asm.org/ccLibraryFiles/FILENAME/00000001137/ ABMM%20Examination%20Guide.pdf		
Program Contact	Contact the AAB office by telephone at 314-241-1445 or email at aab@aab.org, for assistance and answers to questions.	American College of Microbiology American Society for Microbiology 1752 N Street, N.W. Washington, D.C. 20036 Phone: 202.942.9257 Fax: 202.942.9353 certification@asmusa.org	Russ Phifer, Executive Director National Registry of Certified Chemists 125 Rose Ann Lane West Grove, PA 19390 Phone: 610.322.0657 rphifer@nrcc6.org	Ms. Erin Grady, Education Coordinator American Board of Clinical Chemistry 900 Seventh Street, NW, Suite 400 Washington, DC 20001 Phone: 202.835.8717 Fax: 202.887.5093 EGrady@aacc.org

Free Web-based Laboratory Trainings and Educational Resources

General Resources

- <u>American Society for Clinical Pathology (ASCP)</u>
- Lab Management University
- <u>Clinical Laboratory Management Association (CLMA)</u>
- <u>Commission on Office Laboratory Accreditation (COLA)</u>
- Health Information Technology
- The Joint Commission
- <u>Competency Guidelines for Public Health Laboratory Professionals: CDC and APHL</u>. Morbidity and Mortality Weekly, Supplements May 15th, 2015/ 64(01); 1-81.
- US Centers for Disease Control and Prevention (CDC)
- Intro to Public Health Laboratories (CDC 101 Course)

Quality Management Systems (1)

- Centers for Medicare and Medicaid Services (CMS)
- <u>Clinical Laboratory Improvement Amendments (CLIA) Regulation Requirements</u>
 - Brochure #1 How do they affect my laboratory? Summary of the updated requirements from the CLIA regulations (1/24/2003)
 - Brochure #2 Verification of Performance Specifications
 - Brochure #3 Calibration and Calibration Verification
 - Brochure #4 discontinued 12/31/2015
 - Brochure #5 How to Obtain a CLIA Certificate
 - Brochure #6 How to Obtain a CLIA Certificate of Waiver
 - Brochure #7 Laboratory Director Responsibilities
 - Brochure #8 Proficiency Testing
 - Brochure #9 Complaints, Do You Have a Concern About a Laboratory's Operation?
 - Brochure #10 What Do I Need to Do to Assess Personnel Competency?
 - Brochure #11 CLIA Individualized Quality Control Plan Introduction (IQCP)
 - $\circ~$ Brochure #12 CLIA IQCP, Considerations When Deciding to Develop an IQCP
 - Brochure #13 CLIA IQCP, what is an IQCP?
- <u>Clinical Laboratory Standards Institute (CLSI) Guidelines and Quality Management Systems</u>
- <u>College of American Pathologists (CAP) Laboratory Accreditation Checklists</u>
- Prudent Practices in the Laboratory; Handling and Management of Clinical Hazards (2001) National Academies of Science Engineering and Medicine.
- <u>CLIA Overview and Personnel Competency</u>
- Employee Competency Assessment Program
- Testing Validation and Verification
 - Presentation by Eileen Burd at 2011 APHL TB Conference
 - Verification of FDA-cleared tests reference Cumitech 31A, CLIA brochure #2 or CLSI M52
 - Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems reference CLSI M52
 - Validation to establish performance claims (tests that are not FDA-cleared) reference Cumitech 31A

Management and Leadership (3)

- <u>Americans with Disabilities Act</u>
- Major Laws of the US Department of Labor

- <u>Federal Employment and Labor Laws</u> (for informational purposes; should not be used for legal advice. Please consult a lawyer for legal advice)
- Federal Policy for the Protection of Human Subjects (Common Rule) (HHS)
- Proposed Revised Common Rule (HHS)
- Institutional Review Boards (US Food and Drug Administration)
- Budgets (National Conference of State Legislatures)
- <u>Veterans Preference in Hiring</u> (US Office of Personnel Management)

Ethics (2) and Research (15) and Communications

- Human subjects and clinical trials (NIH)
- <u>HIPAA</u>
- American Society for Clinical Laboratory Science Code of Ethics
- Medical Ethics
- <u>Freedom of Information Act</u> (FOIA)
- Federal Subpoena Info

Safety (9) and Security (5)

- OSHA Laboratory Standards
- Federal Select Agent Program
- American Society for Microbiology (ASM)/<u>ABMM Laboratory Biosafety</u>
- Biosafety in Microbiology and Biomedical Laboratories (BMBL) (website) (PDF)
- Biosafety in the Laboratory: Prudent Practices for Handling and Disposal of Infectious Materials (1989); National Academies of Science Engineering and Medicine.

Emergency Management and Response (6)

- <u>Continuity of Operations Planning (COOP)</u> (FEMA)
- <u>Continuity Programs Policies</u>, Plans and Evaluation Division (PPED) (FEMA)
- Incident Command System (ICS)
- ICS Training
- ICS Resources

Workforce Training (7)

- <u>American Society for Clinical Pathology</u>
- Lab Management University
- <u>Clinical Laboratory Management Association</u>
- <u>Competency Guidelines for Public Health Laboratory Professionals: CDC and APHL</u>. Morbidity and Mortality Weekly, Supplements May 15th, 2015/ 64(01); 1-81.
- Intro to Public Health Laboratories (CDC 101 Course)
- <u>Centers for Medicare and Medicaid Services</u> (CMS)
- <u>CLIA</u>

Surveillance (10)

<u>US Centers for Disease Control and Prevention</u> (CDC)

- Public Health Surveillance CH53
- Intro to PH Surveillance (CDC 101 Course)
- Intro to Epidemiology (CDC 101 Course)
- World Health Organization
- Public Health Surveillance Purpose and Characteristics (Self study course)
- Intro to Public Health Surveillance 101 (Slides and free webinar course)

Informatics (11)

- <u>HIPAA</u>
- What is Protected Health Information?
- What does Protected Health Information include?
- Health Information Exchange
- HL7 Data Transmission (Using LOINC and SNOMED) Example and Explanation
- Coding Standards: What the difference between ICD, CPT, LOINC and SNOMED CT?
- SNOMED CT and HL7 Bringing Standards Together
- Bioinformatics
- Introduction to Public Health Informatics (CDC 101 Course)

Scientific Discipline Specific Topics - Microbiology, Molecular Diagnostics, Toxicology, Chemistry (12, 13)

- <u>American College of Medical Genetics and Genomics</u>. Standards and Guidelines for Clinical Genetics Laboratories (General laboratory and Subject based materials)
- Gene Tests and Gene Reviews
- National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology
- <u>Catalogue of Somatic Mutations in Cancer</u> (COSMIC)
- Clinical case studies, reports and reviews published in scientific journals specializing in molecular genetics, molecular diagnostics, microbiology, and oncology are a good source of information.
- Journal of Analytical Toxicology
- Therapeutic Drug Monitoring Journal
- Morbidity and Mortality Weekly Report
- <u>Topic Specific Powerpoint Lectures</u> by Dr. Roger L. Bertholf -
 - Introduction to Laboratory Medicine (33 slides)
 - Statistics for Laboratorians (220 slides)
 - Review of Analytical Methods--Spectrophotometry (74 slides)
 - Review of Analytical Methods--Electrochemistry (40 slides)
 - Immunochemical Methods (93 slides)
 - Proteins and Electrophoresis (47 slides)
 - Fertility and Tumor Markers (72 slides)
 - Clinical and Forensic Toxicology (77 slides)
 - Therapeutic Drug Monitoring (43 slides)
 - Forensic Toxicology: Screening (48 slides)
 - Forensic Toxicology: Confirmation (59 slides)
 - Molecular-Imprinted Polymers (13 slides)
 - GI Tumor Markers (22 slides)
 - Human Subjects Protection (23 slides)
 - Research Ethics (41 slides)
 - Medical Errors: Causes and Prevention (66 slides)

Free TRAIN Learning Network Trainings

Trainings can be found on the website. If you do not already have a TRAIN account you can set up an account free. All you need to do once you have site access is to enter in the Course ID # and the course will be located.

We will continue to expand this section as more courses are developed or identified.

Course Title and	Time	Sponsor	Additional Training Course Details
TRAIN ID Number			
Biosecurity and Biosafety ID:1056335		EU CBRN CoE Initiative	In this module we investigate the standards and procedures in place for biosafety-that is, reducing the risk that a disease-causing agent infects a laboratory worker or escapes the laboratory and infects the community outside the lab and biosecurity-that is, defense against the deliberate release of infectious agents from the confines of the laboratory for malicious purposes. We will look carefully at the application of special equipment, physical protection, best practices, and techniques for achieving a safe and secure laboratory environment. Lesson 4-1: Biosafety and Biosecurity Lesson 4-2: Acquiring Bio-Weapon Capability Lesson 4-3: Terrorist Biosecurity Violations Lesson 4-4: Preventing Biosecurity Breaches After completing this module, you will be able to: • Compare and contrast biosafety and biosecurity concepts, goals, and measures • Assess acceptable risk inside and outside of the laboratory • Understand levels of risk posed by different biological agents • Understand and apply knowledge of risk groups and biosafety levels • Assess the risks and consequences of terrorist use of biological agents • Apply methods for preventing breaches in biosecurity and biosafety • Analyze a qualitative risk and threat assessment • Understand national legislation and international regimes for criminalizing and punishing attempts to acquire, develop, produce, and possess biological agents for offensive purposes
Bloodborne Pathogens Update (OSHA) Training ID 1030583	20 min	Virginia Department of Health	This training is provided to you in compliance with the Occupational Safety & Health Administration's (OSHA's) requirement to provide training on this topic. The information in this course will help reduce your risks for occupational exposure to disease and tell you what to do in the event that you are exposed while on the job. There is a test at the end of this course, which will require a score of at least 80% to successfully complete this course. Learning Objectives Define "bloodborne pathogens" (BBP) Recognize how these diseases are transmitted Determine your risk of exposure Protect yourself from exposure Respond appropriately if exposed Describe your right to medical evaluations
Core Competencies for PH Officials ID: 1058507	60 min		This archived webinar presented by the Association of Public Health Nurses (APHN), a member of the Quad Council of Public Health Nursing Organizations, and the Public Health Foundation (PHF) focuses on the revised Core Competencies for Public Health Professionals (Core Competencies) released by the Council on Linkages Between Academia and Public Health Practice in June 2014. Originally presented in June 2015, this provides an overview of the 2014 version of the Core Competencies, changes made in this version and how these changes address feedback from the public health community, and tools and resources available to support use of the Core Competencies. Learning Objectives Describe the Core Competencies Describe the revisions made to the Core Competencies Describe the revisions made to the Core Competencies Describe the revisions and resources that can assist public health professionals or organizations with using the Core Competencies

Core Microbiology Skills ID 1035332	30-40 min	CDC	In this series of short videos you will learn several core microbiological skills that are used in public health, clinical and research laboratories. Use these videos as an adjunct to training given in your laboratory. The skills we will cover are: how to make a smear, how to do a gram stain, how to perform a wet and tube motility, how to perform a slide and tube catalase test and finally how to do an oxidase test
Disability Rights Course ID: 1026940	2 hours	DBTAC – New England ADA Center	 The Disability Rights Course is a free, self-paced webcourse available 24/7 that provides an overview of disability rights laws. The course takes approximately 2 hours and includes real life scenarios, quizzes and a final exam. Upon completion of this course, you will: Have a general understanding of the major federal disability rights laws (the Americans with Disabilities Act, the Fair Housing Act, Section 504 of the Rehabilitation Act and the Air Carrier Access Act) Be able to assess what laws apply in different discrimination scenarios Have resources for help and information about disability rights laws Note: it prompts you in TRAIN to go to second level of registration which indicates a cost is necessary but the next screen doesn't require payment – course is FREE.
Federal Regulations and Agencies ID: 1029954	25 min	UNC Gillings School of Global Public Health	 This training offered by the UNC Gillings School of Global Public Health provides an overview of federal agencies as regulators and advisors when it comes to public health. Learning Objectives Provide insight into jurisdictional issues that arise in public health Define certain federal agencies and distinguish between their regulatory power and advisory roles Discuss the HIPAA and its implications on public health PH Competencies; 7A1; 7A2; 7B1; 7B2; PHP Capability 6 fxn 2; 1.3 and 1.6
Grant Writing and Budgeting for PH Programs ID: 1029853	25 min	UNC Gillings School of Global Public Health	 This training offered by the UNC Gillings School of Global Public Health gives an introduction to funding for public health in America since September 11, 2001 and gives an overview of grant writing as a way to secure funding for public health programs. Learning Objectives Describe the history of and the current environment for public health funding Define federal, state, and local government funding priorities and mechanisms, as well as private foundations and other potential funders Recognize the major content areas of a grant proposal and describe how they are developed, including budgets, workplans, technical approaches, and evaluation plans 7A6 - Tier One - Core Competencies for PHP
Good Laboratory Practices for Molecular Genetics Testing (PACE) ID: 1044041	90 min	PACE	 This on-line learning module is presented in first person. This means the learner is actually depicted as getting an assignment and doing the work throughout the course. This training is not meant to be prescriptive. There are several different ways to obtain information and perform the tasks described in the training. Examples are provided as potential options. The characters and scenarios in this training are fictitious and are based on possible real-life situations. For the purposes of this training module, the manufacturer details are fictional and do not indicate CDC's support for any commercially available product or service. Although some of the recommendations in this training exceed CLIA and other requirements that pertain to molecular genetic testing, following these good laboratory practices will likely lead to improvements in the quality and use of genetic laboratory services and should improve health outcomes for the public. Upon completion of this course you will be able to: Describe the application of the CLIA requirements to molecular genetic testing. Select quality assurance measures for molecular genetic testing which are consistent with good laboratory practices. Develop procedures and processes for a molecular genetic test which are consistent with regulatory requirements and good laboratory practices

Health and Safety Essentials for Workers ID: 1069167	2 hours	CDC	 This level of training will delve deeper into the content of infectious diseases of public health significance to develop the skills to recognize hazards and mitigate them. The purpose of this course is to prevent and reduce the work exposures to the Ebola virus and other infectious diseases using direct training and the train-the-trainer method. Course Objectives Explain the importance of awareness and site-specific level training Describe the association of infectious agents to the disease Describe means of transmission for Ebola virus disease and other high consequence pathogens Explain the importance of conducting risk assessments in identifying potentially infectious material, chemical and safety hazards Describe what is meant by contact, droplet, and airborne transmissions in infection control Describe how personal hygiene practices can reduce the risk for exposure Describe appropriate selection of personal protective equipment (PPE) for use with potentially infectious materials. Describe limitations of PPE
HIPAA ID: 1041019	25 min	UNC Gillings School of Global Public Health	 This training provides public health professionals with a summary of the Health Insurance Portability and Accountability Act (HIPAA). Learning Objectives Describe the Health Insurance Portability and Accountability Act of 1996; Discuss the Privacy Rule and its purpose; Determine when private information can or cannot be disclosed; and Explain how HIPAA and the Privacy Rule affect public health practice and research
Incident Command System ID:	150 min	UNC Gillings School of Global Public Health	This training is designed to help public health professionals at the local level integrate use of the Incident Command System (ICS) into a common public health department activity: investigating a disease outbreak. This training has accompanying activities which are an integral part of the training content. All activities will be provided as you progress through the training. Please note: prerequisites for this training are completion of ICS trainings 100, 200, and 700 and training or experience in disease outbreak investigation. In addition, completion of ICS 300 is strongly recommended for persons who might serve as Command Staff or General Staff. These trainings can be accessed from the FEMA Web site. Learning Objectives • Describe how ICS can benefit disease outbreak investigations undertaken by local public health department staff • Use appropriate ICS terminology to describe the roles and tasks that public health staff assume in an outbreak investigation • Give examples of the ICS steps taken in outbreak investigations For a hypothetical disease outbreak: Demonstrate the ability to develop an Incident Action Plan, carry out an operational briefing, and formulate positions and an organizational chart for how an outbreak response might be organized

Introduction to PH Laboratories ID: 1059672		CDC	Public health laboratories focus on diseases and the health status of population groups. They perform limited diagnostic testing, reference testing, and disease surveillance. They also provide emergency response support, perform applied research, and provide training for laboratory personnel. This course covers the public health laboratory infrastructure and core functions of state public health laboratories. The course introduces learners to laboratory safety, procedures for collecting and submitting samples for testing in public health laboratories, and how lab results are used in public health practice.
			Learning Objectives 1. describe the role of public health laboratories 2. summarize the core functions of state public health laboratories 3. describe the parts that are common to all public health laboratory system infrastructures 4. recognize the need for different laboratory levels and safety practices 5. explain the necessity for communicating with a laboratory when collecting and submitting samples for testing 6. describe how laboratory results are used to affect public health
			This course is part of the Public Health 101 Series - a set of courses that introduces learners to public health and the core sciences of public health practice. The core scientific components span topics in epidemiology, public health informatics and surveillance, prevention effectiveness, and public health laboratories. Each course includes the four-step approach to solving public health problems.
			The Public Health 101 Series can benefit the following groups:
			 Those who work in PH but who have not had formal training in a particular core area Those who have had public health education and would like a refresher Students or others interested in pursuing careers in public health Health educators and instructors responsible for the training and professional development of the public health workforce
			To locate other courses in this series, search by keyword "Public Health 101."
Intro to Policy Evaluation in Public Health ID: 1064948	2 hours	CDC Office of the Associate Director for Policy	The two-hour online course, designed for public health practitioners, introduces the learner to the use of policy evaluation in public health and provides specific instruction on applying evaluation methods throughout a policy process. Instructional content describes what "policy evaluation" is and will enable the learner to have a better understanding of how to apply the Centers for Disease Control and Prevention (CDC) Evaluation Framework to conduct an evaluation of adopted policies that may impact public health.
Introduction to Management in PH ID: 1019168		CDC	None provided
Introduction to PH Surveillance ID: 1030016	40 min	UNC Gillings School of Global Public Health	 This issue of FOCUS describes the process and reasoning behind the surveillance methods and interpretation used to inform public health practice. Learning Objectives Define surveillance and explain surveillance systems. Describe basic surveillance techniques by person, place, and time. Touch on the importance of standardization when comparing surveillance data. Provide an overview of how to present surveillance data
Laboratory Biosafety	20 -30	The NC Institute for	This issue of FOCUS describes some of the differences between the biosafety levels, with examples of organisms studied and the precautions that
ID 1030020			 Learning Objectives Define barriers and procedures used by laboratories to protect workers and others from infection Describe the four biosafety levels and the protective measures used by each type of laboratory when handling infectious materials Provide examples of the types of biological agents handled in each type of laboratory Describe typical places where each type of laboratory can be found in the US 6A3; 6B3; 4.2 - Tier One - Core Competencies for PHP

Legal Aspects of Public Health and Food Safety ID: 1048259	1 hour	CDC	Food safety is a unique and critical role filled by public health agencies. In the event of a foodborne illness outbreak investigation, you may wonder what personal information is protected by privacy laws and what may be shared. You may also wonder about the source and scope of your public health authority to keep the public safe from foodborne illnesses.
			This 1-hour course is an introduction to legal issues that arise in public health food safety, from surveillance and outbreak investigation through restaurant inspections and detention of food. The content for the course was developed in partnership with the Network for Public Health Law, whose Eastern Region Office contributed invaluable practical experience and knowledge.
			 Learning Objectives Identify federal privacy requirements related to food safety surveillance and foodborne illness outbreak response. Describe the source and scope of state and local authority related to food safety. Explain the administrative process for developing food safety regulations. Identify the food safety control measures available to state and local authorities. List common legal issues encountered during the enforcement of state and local food safety provisions
Routine Microscopy Procedures: Basic Microbiology Curriculum	90 min	CDC	Course Description: This eLearning course is designed to familiarize laboratorians with routine microscopy procedures used in the microbiology laboratory. Laboratorians will explore the required steps for a smear preparation as well as the requirements for preparing and interpreting the results of Gram stains, wet mounts, potassium hydroxide (KOH), and India Ink procedures.
ID: 1046095			The Routine Microscopy eLearning course is the second of six courses in a Basic Microbiology Curriculum. Additional courses include:
			 Basic Microscopy (ID1044412) Basic Culture Media and Isolation Techniques (ID: 1048274) Biochemicals & Gram Positive Organism ID (ID: 1051106) Biochemicals & Gram Negative Organism ID (ID: 1051413) Antimicrobial Susceptibility Testing (AST) (ID: 1050165)
			Each of these courses contains laboratory exercises for the participant to complete with their mentor or supervisor to demonstrate understanding of the content. A facilitator guide was also created to assist the mentor or supervisor with administering the laboratory exercises.
Mycology Review: Identification of Common Dermatophytes		MDCH	Course Description: This self-paced training tool will review the colony and microscopic morphology of nine fungi commonly isolated from human clinical specimens. Photomicrographs and key characteristics for differentiation of these nine dermatophytes are included, along with six photomicrographic unknowns to test your knowledge. This tool is also suitable for use as a competency assessment exercise.
ID: 1001959			It was designed and produced by the Mycobacteriology/Mycology Unit at Michigan Department of Community Health (MDCH), Bureau of Laboratories, Lansing, MI. Users may use the photographs for educational purposes. We would ask that credit be given to MDCH if the photographs are used in presentations.
Practical Law for Public health officials ID: 1028438	90 min	CDC	Course Description: Do you know how the law contributed to motor vehicle safety, vaccination, or safer workplaces? Law reform or litigation has played a part in most of the greatest public health achievements in the 20th century. As public health professionals and leaders, understanding public health law and how to use it is essential to protecting the public's health. In this module, you will learn how to assess when to involve legal coursel, how to get effective legal advice, and what laws will affect your decision-making ability when facing public health threats. By the end, you will be able to use core concepts of public health law to more effectively protect the public's health while avoiding legal trouble.
			After completing this module, participants should be able to:
			 Recognize legal issues. Formulate legal questions. Implement effective strategies for working with legal counsel. Describe key principles of public health law. Identify key public health laws that govern leadership's responsibilities, authority, and limitations.

Public Health Law		CDC	This course has Continuing Education available.
ID: 1065624			The U.S. Constitution plays a central role in the daily practice of public health today. Traditionally, the Constitution has been interpreted as granting the government broad authority to protect the public health. In the past 25 years, however, judicial decisions have placed substantial limits on this power. It is more important than ever for public health officials to understand the power and limits of their authority. Having a legal background or understanding of the constitutional power and limits of this authority equips public health leaders with the tools necessary to ensure their policies are constitutionally permissible, and capable of withstanding legal challenge. This online training teaches public health officials how to most effectively use the tools of law and policy—within the parameters of the U.S. Constitution—to achieve their public health goals. At the conclusion of the session, the participant will be able to: Name two historical events that helped shape the practice of public health law today. Identify an example that illustrates how history shapes government's modern day authority. Identify two constitutional limitations on the ability of the government to enact PH regulations. Name the two things that the government must balance when creating PH laws and policies.
Public Health Essentials on Line ID: 1051672	45 min	AZ PH Training Center	 This multimedia training will provide a dynamic look at the some of the most fundamental aspects of public health from the unique points of view of members of the workforce and of community members as well. Learners will gain a grounded understanding of the Three Core Public Health Functions and the Ten Essential Public Health Services. Learners are asked to develop an action plan detailing immediate, short term, and long term goals that they will strive towards in building a capacity to better serve their public health community. The goals in the action plan relate to the learner's role in the delivery of services as they relate to the systems management section of the Public Health essentials continuum. Outcomes Describe and define public health. Identify the role your work plays in public health. Define three social determinants of health. Recognize the three Public Health Core Functions. Relate examples of each of the Ten Essential PH Services. Discuss the role individuals/ teams in the workplace in good health outcomes for the community
Public Health Surveillance ID: 1030076	40 min	UNC Gillings School of Global Public Health	This presentation gives an overview of public health surveillance. Learning Objectives • Define public health surveillance • Identify uses of public health surveillance • List sources of public health surveillance data
Public Health and the Incident Command System ID: 1046620	42 min	CDC	This course provides an overview of applying Incident Command System to Public Health to plan for and respond to disasters. The goal of the course is to build skills so that the public health worker can play an integral role in the Incident Command organization and structure. Learning objectives focus on 'participating in improving the organization's capacities' which is competency 3.3 under 'Plan and Improve Practice'. Learning Objectives Recognize the key concepts of the disaster cycle Understand the relationship between Public Health and response partners using the Incident Command System Identify the various Incident Command roles of Public Health during a disaster Describe the importance of pre-incident planning and training of Public Health personnel
PH Code of Ethics ID: 1050890	35 min	UNC Gillings School of Global Public Health	This training presents the 12 principles for the ethical practice of public health; explanations and a practical application of each principle; and suggestions of how to use the Public Health Code of Ethics. It begins with a brief description of what a Code can and can't do, and the process by which the Public Health Code of Ethics was written. Learning Objectives Describe how an aspirational code can guide an ethical discussion Describe a situation where a given ethical principle applies in public health Identify means of creating an ethical environment within public health organizations

Public Health Confidential: Federal Overview ID: 1064343		CDC	Public Health 101: • A short course • Introduction to PH Surveillance • Introduction to PH Informatics • Introduction to PH • Introduction to PH Laboratories • Training Plan • Introduction to Prevention Effectiveness
PH Financial Management ID: 1012722	7 hours	CDC	This course provides an overview of the principles of finance, discussions regarding finance issues related to public health, and understanding of financial management of public health programs and activities. Module I will focus on basic concepts of budgeting in public health organizations. The second unit in this course examines issues primarily related to managerial or cost accounting. The primary focus of managerial accounting is the use of financial data in administrative decision making. Module III focuses specifically on capital budgeting decisions. The final module determines the importance of integrating strategic and financial planning. Financial plans ensure that resources are allocated in a way that is consistent with the strategic direction of the agency.
PH Laboratory Diagnosis ID:1030022	40 min	UNC Gillings School of Global Public Health	 Provides an overview of the pathogens tested in public health laboratories and describes some commonly used lab tests. Learning Objectives Provide an overview of pathogens tested in public health laboratories Describe laboratory tests commonly used in outbreak investigations
Recognition and management of Bioterrorist Agents: An Overview ID 1030369	30 min	UNC Gillings School of Global Public Health	 This presentation discusses biological agents that could be used by terrorists, the potential for their use and the epidemiology and recognition of these agents. Learning Objectives Understand the risks posed by bioterrorism in the USA Be aware of potential bioterrorist agents Understand the epidemiology and recognition of bioterrorist agents
Responding to Unethical Events in PH ID: 1050904	10 min	UNC Gillings School of Global Public Health	This training provides an overview of possible responses to behaviors or decisions that are clearly unethical. It is part of the "Public Health Ethics" training series developed to promote the ethical practice of public health by teaching about the ethical principles of public health and by providing resources for creating an ethical climate in public health agencies and schools of public health. Learning Objective Describe the range of possible responses to an event that is clearly unethical
Recognizing Biosafety Level ID: 1046752	10 min	CDC	Quick-Learn lessons help you develop basic public health knowledge and skills in specific areas through interactivity and practice. Learn how to recognize characteristics of the four biological safety levels.

National STD Curriculum ID: 3489	The new National STD Curriculum website addresses the epidemiology, pathogenesis, clinical manifestations, diagnosis, management and prevention of STDs. The curriculum is free, up-to-date, and integrates the most recent CDC STD Treatment Guidelines. Funded by a grant from the CDC and developed by the University of Washington STD Prevention Training Center and the University of Washington, this website replaces the former CDC STD Self Study Modules for Clinicians.
	Free CME and CNE credit is available from the seven self-study/quick reference modules and the Question Bank section which features 100+ interactive board-review style questions. Each module can be completed within 60 minutes and 1 CME and CNE credit is available through the National STD Curriculum website. Time needed to complete a Question Bank topic varies by STD but ranges from 30 minutes to 1.75 hours so available CE varies from .5 to 1.75.
	The 7 modules available through TRAIN:
	Chlamydia, Gonorrhea, Herpes Simplex Virus (HSV)–Genital, Human Papillomavirus (HPV), Pelvic Inflammatory Disease (PID), Syphilis and Vaginitis
	The 12 Question Bank topics through TRAIN:
	Bacterial Vaginosis, Candidiasis–Vulvovaginal, Chancroid, Chlamydia, Epididymitis, Gonorrhea, Granuloma Inguinale, Herpes Simplex Virus– Genital, Lymphogranuloma venereum, Mycoplasma genitalium, Proctitis, Proctocolitis, Enteritis and Trichomoniasis
	For each STD, the learning objectives for the modules and/or the Question Bank usually include some of the following:
	1. Summarize the epidemiology in the United States.
	2. Describe the microbiology, life cycle, and transmission.
	3. Discuss the clinical manifestations in men, women, and children.
	4. Compare laboratory diagnostic methods used to diagnosis.
	5. Discuss serologic screening in asymptomatic persons.
	6. List the CDC-recommended treatment regimens.
	7. Summarize counseling and education messages for individuals with that STD
Speaking with the Public5 online coursesCDCID: 1066814courses	CDC offers five online health literacy courses for health professionals. Speaking with the Public Online Training is part of health literacy training available to the public.

Fee-based Trainings, Educational Programs and Courses

- APHL's Emerging Leader Program
- CLSI Quality Laboratory Management System (LQMS) On-line Certificate Program -
- Laboratory Safety and Compliance Programs (CAP)
- Short presentations (CAP members only) on emerging topics (Free for CAP members only)-
 - American Board of Bioanalysts (AAB) Molecular Diagnostics Seminar Full day seminar "Clinical Genomics: A Review of Technology and Clinical Applications" by Gregory Tsongalis
 - ♦ AAB On Line Courses
 - Immunohematology
 - Immunology and Serology
 - Microbiology
 - Molecular Diagnostics
 - PER Basic Laboratory Knowledge
 - ◆ PER Chemistry Review
 - Direct Patient Access to Laboratory Test Results Webinar
 - AAB Hematology, Microbiology and Serology Course In-person seminar and on-line course available
 - American Association of Clinical Chemistry (AACC) Professional Practice in Clinical Chemistry week-long intensive training course for laboratory medicine
 - American Society of Criminology (ASC) Toxicology for chemists Online (8)-week course with live lectures and notes
 - Association for Molecular Pathology (AMP) Course In person course prior to AMP meeting
 - Forensic ED On-line Trainings
 - Relevant Topics: Standard Operating Procedures, Ethics of Laboratory Leadership, Clinical Chemistry, Molecular/DNA, Mass Spectrometry
 - o <u>Safety</u>

Board-Sponsored Resource Guides

American Board of Clinical Chemistry

ABCC Molecular Diagnostics Certification Examination Study Resource Guide

American Association of Bioanalysts (AAB)

- General Knowledge for the Clinical Laboratory Director
- PER Basic Knowledge Manual
- PER Handbook
- PER Q & A Book
- <u>Review Manual for Public Health Microbiology</u>
- Total Quality Management (TQM) in the Clinical Laboratory

American Society for Clinical Pathology (ASCP)

 <u>Board of Certification (BOC) Study Guide: Clinical Laboratory Certification Examinations 5th Edition</u>, ISBN:9780891895879 by Patricia A. Tanabe, MPA, MLS(ASCP) E. Blair Holladay, PhD, SCT(ASCP), ASCP Board of Certification Staff

American Board of Medical Microbiology (ABMM)

<u>ABMM Examination Content</u>

American Society for Microbiology Committee on Post Graduate Educational Programs (CPEP)

- <u>CPEP Fellowship Essential Medical Microbiology</u>
- <u>CPEP Fellowship Essentials in Medical Immunology</u>

Recommended Reference Books or Journals

A survey conducted of board certified individuals recommended the books highlighted in red as most useful when preparing for the board examination.

General Laboratory and Quality Management

ISBN Number	Name	Estimated Cost
N/A	Competency Guidelines for Public Health Laboratory Professionals: CDC and the Association of Public Health Laboratories. (2015). MMWR 64(01); 1-81. https://www.cdc.gov/ mmwr/preview/ind2015_su.html	\$0
ISBN-13: 978-1555816209 ISBN-10: 1555816207	Biological Safety: Principles and Practices, 5th ed., Editors: Dawn P. Wooley, Karen B. Byers (2017)	\$150
ISBN-13: 978-0160850424 ISBN-10: 0160850428	Biosafety in Microbiology and Biomedical Laboratories (BMBL), 5th Edition (2009)	\$20
ISBN-13: 978-1555817275 ISBN-10: 1555817270	Garcia, L.S. (2013). Clinical Laboratory Management. (2nd ed.) Washington D.C.: ASM Press.	\$50 - \$130
ISBN-13: 978-0943903125 ISBN-10: 0943903122	Harmening, D.M. (2012). Laboratory Management: Principles and Processes (3rd ed.). St. Petersburg, FL: D.H. Publishing & Consulting Inc.	\$30-60
ISBN-13: 978-1416002871 ISBN-10: 1416002871	McPherson, R.A. & Pincus, M.R. (2011). Henry's Clinical Diagnosis and Management by Laboratory Methods (22nd ed.). Philadelphia: W. B. Saunders Company. (Part 1 ONLY)	\$30
ISBN-13: 978-0397551491 ISBN-10: 0397551495	Snyder, J.R., & Wilkinson, D.S. (1998). Management in Laboratory Medicine (3rd ed.). Philadelphia: Lippincott, Williams, & Wilkins.	\$20
ISBN-13: 978-1511695039 ISBN-10: 151169503X	How To Be A Lab Director 2017 edition – May 3, 2016, Philip A. Dauterman MD	\$20
ISBN-13: 978-1605855479 ISBN-10: 1605855472	Varnadoe, L.A. (2008). Medical Laboratory Management and Supervision. (2nd ed.). Florida: Priority ed.	\$80
https://clsi.org/	Clinical and Laboratory Standards Institute (2013). Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline QMS 14-A. Wayne, PA: CLSI.	
https://clsi.org/	Clinical and Laboratory Standards Institute (2011). Quality Management System: A Model for Laboratory Services; Approved Guideline - Fourth Edition QMS 01-A4. Wayne, PA: CLSI.	
https://clsi.org/	Clinical and Laboratory Standards Institute (2011). Quality Management System: Continual Improvement; Approved Guideline - Third Edition QMS 06-A3. Wayne, PA: CLSI.	
ISBN-13: 978-1555817275 ISBN-10: 1555817270	Clinical Laboratory Management. by Lynne S. Garcia, 2nd Edition. ASM Press, Washington D.C.	\$130

Clinical Chemistry and Toxicology

ISBN Number	Name	Estimated Cost
9781594250873	Self-Assessment in Clinical Laboratory Science II. Published by	\$24
	AACC.	

ISBN Number	Name	Estimated Cost
ISBN-13: 978-1594251023 ISBN-10: 1594251029	Contemporary Practice in Clinical Chemistry, by William Clarke, 2nd Ed. AACC Press; Washington, DC, 2011	\$124
ISBN-13: 978-0323036580 ISBN-10: 9780323036580	Clinical Chemistry: Theory, Analysis, Correlation, Kaplan & Pesce, 5th Ed	\$45-110
9781451118698	Clinical Chemistry, by Bishop, 6th Ed, particularly the "Enzymology" chapter	\$45
9780721601892 0721601898	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Carl A. Burtis, Edward R. Ashwood, David Bruns (eds), WB Saunders, Saint Louis, MO.	\$180-250
ISBN-13: 978-0781728454 ISBN-10: 0781728452	Medical Toxicology by Richard C. Dart	\$60
ISBN-13: 978-0071354691 ISBN-10: 0071354697	The Pharmacological Basis of Therapeutics by Alfred G. Gilman, Louis S. Goodman, Theodore W. Rall, Ferid Murad	\$40
ISBN-13: 978-0931890031 ISBN-10: 0931890039	Analytical Procedures for Therapeutic Drug Monitoring and Emergency Toxicology by Randall C. Baselt	\$32
ISBN-13: 978-0931890154 ISBN-10: 0931890152	Advances in Analytical Toxicology by Randall C. Baselt	\$50
ISBN-13: 978-1594251580 ISBN-10: 1594251584	Principles of Forensic Toxicology by Barry Levine	\$60-100
ISBN-13: 978-1890883744 ISBN-10: 1890883743	500 Referenced Review Questions in Toxicology by Robert M. White, Sr.	Out of print; must buy used

Molecular Biology - Molecular Diagnostics

ISBN Number	Name	Estimated Cost
ISBN-13: 978-3642196768 ISBN-10: 3642196764	Diagnostic Molecular Pathology in Practice: A Case-based Approach. Iris Schrijver (ed). Springer, New York NY	\$30
ISBN-13: 978-0128008867 ISBN-10: 0128008865	Diagnostic Molecular Pathology. Gregory Tsongalis.	\$87-120
ISBN-13: 978-0470654477 ISBN-10: 0470654473	Human Genetics and Genomics. Bruce R. Korf and Mira B. Irons. Wiley-Blackwell. Hoboken, NJ	\$12-30
ISBN-13: 978-1588293565 ISBN-10: 1588293564	Molecular Diagnostics: For the Clinical Laboratorian. William B. Coleman and Gregory J. Tsongalis (eds). Springer, New York, NY	\$170-200
ISBN-13: 978-1437706963 ISBN-10: 1437706967	Thompson and Thompson's Genetics in Medicine. Robert Nussbaum, Roderick R. McInnes and Huntington F. Willard (eds), WB Saunders, Philadelphia, PA	\$22-45
ISBN-13: 978-0323359214 ISBN-10: 0323359213	Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Carl A. Burtis, Edward R. Ashwood, David Bruns (eds), WB Saunders, Saint Louis, MO.	\$225
ISBN-13: 978-0070318472 ISBN-10: 0070318476	Appleton and Lange's Outline Review in Clinical Chemistry – Older reference book but still a good reference for fundamentals	\$20-50
ISBN-13: 978-1405169745 ISBN-10: 1405169745	Essential Medical Genetics Fairly high level overview but provides a deep dive of detail.	\$13-40

Microbiology

ISBN Number	Name	Estimated Cost
ISBN-13: 978-1608317332 ISBN-10: 1608317331	Lippincott's Illustrated Reviews: Microbiology; 3rd Edition; Richard A. Harvey et al., 2012 by Lippincott Williams & Wilkins	\$50
Print ISBN: 9781555817374 e-ISBN: 9781555817381	Manual of Clinical Microbiology. 11th edition. Editors: James H. Jorgensen, Michael A. Pfaller, Karen C. Carroll, Guido Funke, Marie Louise Landry, Sandra S. Richter, David W. Warnock (2015) 2 Volumes (\$300 each or \$450 for the set.)	\$225-450
Print ISBN: 9781555818685 e-ISBN: 9781555818678	Cases in Medical Microbiology and Infectious Diseases, 4th edition. Peter H. Gilligan, Daniel S. Shapiro, Melissa B. Miller, (2014)	\$50-90
ISBN-13: 978-1555819088 ISBN-10: 1555819087	Molecular Microbiology: Diagnostic Principles and Practice, 2nd edition. David H. Persing, Fred C. Tenover, Yi-Wei Tang, Frederick S. Nolte, Randall T. Hayden, Alex van Belkum (2011)	\$140
ISBN-13: 978-1581109269 ISBN-10: 1581109261	Red Book 2015: Report of the Committee on Infectious Diseases 30th Edition, by David W. Kimberlin MD FAAP (Editor), Sarah S. Long MD FAAP (Editor), Michael T. Brady MD FAAP (Editor), Mary Anne Jackson MD FAAP (Editor)	\$40-125
ISBN-13: 978-0781730143 ISBN-10: 0781730147	Koneman's Color Atlas and Textbook of Diagnostic Microbiology (2006) 6th Edition, by Elmer W. Koneman.	\$100
ISBN-13: 978-0803644663 ISBN-10: 0803644663	Clinical Immunology and Serology: A Laboratory Perspective; 4th Edition, Christine Dorresteyn Stevens and Linda E. Miller.	\$20-60
ISBN-13: 978-0803625433 ISBN-10: 080362543X	Medical Parasitology, a self-instructional text, 6th Edition, Ruth Leventhal and Russell F. Cheadle.	\$25-50
ISBN-13: 978-0803600362 ISBN-10: 0803600364	Medical Mycology, a self-instructional text (1997) 2nd edition, Martha Kern and Kathleen S. Blevins. 1997.	\$16-50
ISBN-13: 978-1935660156 ISBN-10: 1935660152	Clinical Microbiology Made Ridiculously Simple 6th edition; by Mark Gladwin, William Trattler and C. Scott Mahan.	\$16-50
ISBN-13: 978-1681279886 ISBN-10: 1681279886	100+ eLearning Tips: for Instructional Designers and Teachers, Green, Staci	\$8
ISBN-13: 978-1495215179 ISBN-10: 1495215172	Superb eLearning Using Low-cost Scenarios: A Step-by-Step Guide to eLearning by Doing (Effective E-learning Design) (Volume 2), Pitman PhD, Benjamin	\$25
ISBN-13: 978-1284057027 ISBN-10: 128405702X	Case Studies In Public Health Preparedness And Response To Disasters, Landesman, Linda Y	\$69
ISBN-13: 978-1479396917 ISBN-10: 1479396915	Business Cases for Risk Management: How to write a killer business case that gets your risk treatments funded!, Talbot, Mr Julian	\$30
ISBN-13: 978-1532901065 ISBN-10: 1532901062	How to Write and Teach Case Studies Effectively?, Roy, Kisholoy	\$5.49
ISBN-1-56238-861-4 ISBN 1-56238-862-2 CLSI QMS14-A	Clinical and Laboratory Standards Institute (2013). Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline QMS 14-A. Wayne, PA: CLSI.	\$180 for QMS01-A4, QMS02-A6, QMS05-A2, QMS14-A, and QMS25-Ed1
ISBN-1-56238-761-8 ISBN 1-56238-762-6 CLSI QMS01-A4	Clinical and Laboratory Standards Institute (2011). Quality Management System: A Model for Laboratory Services; Approved Guideline - Fourth Edition QMS 01-A4. Wayne, PA: CLSI.	* See above

ISBN Number	Name	Estimated Cost
ISBN-13: 978-1562387594 ISBN-10: 1562387596	Clinical and Laboratory Standards Institute (2011). Quality Management System: Continual Improvement; Approved Guideline - Third Edition QMS 06-A3. Wayne, PA: CLSI.	\$270
ISBN13: 978-1555812799 ISBN10: 1555812791	Clinical Laboratory Management. by Lynne S. Garcia, 4th Edition. ASM Press, Washington D.C.	\$120

Question Bank Resources

Clinical Chemistry - Molecular

- Question Bank American Association for Clinical Chemistry. Updated questions for laboratory medicine with answers (after testing knowledge) with explanations.
- Lab Tests Online American Association for Clinical Chemistry
- Varsity Tutor

Microbiology

- Varsity Tutor
 - Topics: Biology, Microbiology, Infectious Diseases, Immunology, Molecular
- Value MD 204 Questions on Microbiology
- Clinical Pathology http://www.valuemd.com/usmle-step-1-forum/19357-204-questions-microbiology.html
- ABMM Study Guide
- <u>ABMM and General Microbiology Quizlet</u>
- Microbiology Exam 1 Quizlet
- Medical Microbiology Question of the Day
- Medical Microbiology Question Bank
- ABB Board Vitals Test Bank
- <u>Microbiology Flash Cards Cram.com</u>
- ABMM Practice Questions
- ASM Sample Questions in Microbiology, Author: ASM Editorial Committee on Sample Test Questions, an ad hoc committee of the ASM Education Board (2016)
- ABB PER Q & A Book
- Exam Simulator
- Lippincott's Illustrated Q&A Review of Microbiology and Immunology; 2010; Bonnie A. Buxton, Lauritz A. Jensen, Randal K. Gregg; Lippincott Williams & Wilkins.

Flashcard Study Set and APHL ColLABorate Community

- 1. A flashcard study set using Quizlet with access available upon request. The flashcard sets include over 3,000 flashcards on topics including:
 - General Laboratory
 - Employment Law
 - General CLIA
 - OSHA
 - Safety

- Molecular Diagnostics
- HIPAA
- Healthcare Laws
- Public Health
- Microbiology
- Infectious Disease Diagnosis
- Clinical Microbiology Topics (including Media, Stains, etc)
- Clinical Chemistry
- And more.....
- 2. APHL ColLABorate Community. This community is intended to provide an interactive dialog between individuals considering becoming Board certified or preparing for Board examination. The membership will include APHL member volunteers that are Board certified and willing to provide valuable advice and mentorship regarding board certification, exam preparation, recommended resources, and answers to many other questions of interest.

If you are interested in obtaining access to either of these resources, please contact Pandora Ray (<u>pandora.ray@aphl.</u> <u>org</u>) or Denise Toney (<u>denise.toney@dgs.virginia.gov</u>) for details

Exam Preparation Tips (from Past Examinees)

- Talk with previous examinees about what study tools helped them depending on the specific examination you choose.
- Use the resources in this guide to seek the information you need to know and/or review.
- There are so many free study resources available on the internet to review information or to prepare for answering exam questions; even questions geared toward MLT exams are very helpful.
- Start early in your preparation and begin with the test you feel the least competent so you can keep reviewing.
- Flashcards (creation of these helps study for the exam)
- Set a schedule for how much you want to complete or review each week or month and stick to the schedule.
- Be sure to the memorize and pay attention to the General Knowledge (ABB) Examination content. This is the section that candidates are the least prepared for this exam and many have to retake.
- Begin to study in advance. Typically preparation is 4-6 months for an ABB section; 6 months or more for ABMM.
- Know what study/learning tools work best for you and use them.
- When studying for the molecular diagnostics exam really focus on studying genetic diseases, molecular oncology and tissue typing methods which are the least routinely used in PHLs.
- Eat well and get plenty of rest before the exam day.
- For ABMM, try and find out what the focus of that year's exam will be or what it has been in prior years.
- Study hard and early.
- Study lots of case studies and memorize your CLIA personnel regulations for all levels not just for high complexity laboratories.
- Find the board that best fits you and your experience. NRCC is good for those with toxicology/chemistry experience. There are a lot of options out there for the range of experience required of a PHLD.
- Yes, you are expected to be able to identify parasites from microscopic pictures.
- Know your NFPA or GHS symbols.

- Memorize the Labor Laws, who qualified for what laws and what the laws protect.
- · Have staff and co-workers quiz you on materials once you have studied to truly test your knowledge.
- Make sure to have an extensive review of the material you have summarized in the last few days before the exam.
- If you do not pass the first time, retry now that you know the depth of the exam and you will likely do MUCH better.
- ABMM, assess strengths and weaknesses and focus on your weakest areas and least knowledgeable areas first.
- ABB, don't allow the practice exam to mislead your level of understanding of the material. The actually exam is MUCH harder.
- ABMM, get into a good CPEP to gain knowledge and training. IF you can't, get a job or experience in a clinical or PHL to gain the needed experience and training.
- ABMM, review the study outline material provided and guide studying as suggested by the weighted sections.
- ABB, use the provided testing outline and percentages to determine where to focus your study time.
- Set a study schedule with a set number of times and days to study each section and stick to your schedule.
- If you don't pass, take a breath and just try again; it's not the end of the world and many people do not pass on the first go around.
- Ask to borrow reference books and reviews as opposed to buying them to reduce costs; many reference books only have a few sections that are really relevant for studying

Frequently Asked Questions and Answers

Information to be added at a later time

Contact Information

For more information or to provide feedback:

Pandora Ray Association of Public Health Laboratories pandora.ray@aphl.org

Denise Toney, Ph.D., HCLD(ABB) Commonwealth of Virginia Division of Consolidated Laboratory Services <u>denise.toney@dgs.virginia.gov</u>

Acknowledgments

Committee Members

Robyn Atkinson(UT) Joanne Bartkus (MN) Brent Dixon (SC) Andy Cannons (FL) Jennifer Eastman (AK) Terry Dunn (OK) William Glover (WA) Laura Naught (M)) Jafar Razeq (CT) Tim Southern (SD) Denise Toney (VA) Anthony Tran (DC) Marie-Claire Rowlinson (FL) Katlyn Wainwright (IN) Leslie Wolf (KY)

Association of Public Health Laboratories Pandora Ray Laura Siegel

Centers for Disease Control and Prevention Renee Ned-Sykes John Ridderhof

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

This training was supported by Cooperative Agreement #NU600E000103 funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC or the Department of Health and Human Services. This project was 100% funded with federal funds.



8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 Phone: 240.485.2745 Fax: 240.485.2700 www.aphl.org

© Copyright 2018, Association of Public Health Laboratories. All Rights Reserved.