

Essentials and Guidelines
**Of an Accredited Postgraduate Fellowship Program in
Medical Laboratory Immunology**

ESTABLISHED BY
THE subCOMMITTEE ON POSTGRADUATE EDUCATIONAL PROGRAMS
(CPEP)

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1. PREAMBLE

The *Essentials* of approved postgraduate fellowship programs in medical laboratory immunology have been established by the Committee on Postgraduate Educational Programs (CPEP), to which the American Society for Microbiology has delegated responsibility to perform the duties and make the decisions concerning accreditation of training programs in this field. The *Essentials* represent the minimum requirements for CPEP-accredited educational programs. The present document has been developed and revised after extensive review by medical laboratory immunologists and other health professionals. Advice and suggestions were solicited from a broad range of individuals. The *Essentials* are adopted by the American Society for Microbiology, upon the recommendation of CPEP.

1.1. Purpose

The purpose of CPEP is to promote and encourage excellence in the training of medical laboratory immunologists through the approval of postgraduate programs that can meet these *Essentials*. Ultimately, the goal is to improve the quality of clinical immunology laboratory services (diagnostic, educational, consultative, and investigative) in health-related fields and, thus, contribute to the health and welfare of the public. CPEP assesses each program's compliance with the *Essentials* through review of its application, by on-site evaluations, and by the monitoring of annual reports from approved programs. Copies of these *Essentials* are available to the public and are provided to Fellows who enter CPEP-approved programs.

1.2. Objective

Essentials are a statement of policy and, as such, constitute minimum standards of quality in educational programs that are recognized by CPEP accreditation. These *Essentials* and accompanying guidelines are intended to assist clinical immunology programs in meeting and exceeding minimum standards in the design and conduct of sound educational programs. These *Essentials* represent policies which must be carried out. Strict adherence to the *Essentials* is mandatory. Guidelines present pathways toward fulfilling the *Essentials*. Guidelines usually represent one of many ways to satisfy an *Essential* and, therefore, strict adherence to Guidelines is not mandated.

1.3. Description of Profession

Medical laboratory immunologists are doctoral-level scientists and/or physicians who have developed expertise in immunology, clinical immunology, diagnostic immunology, and related subspecialties and sciences. CPEP graduates are prepared for responsible positions in clinical immunology laboratories, governmental agencies, industry, and in colleges and universities. Specifically, they are trained to be responsible for providing clinical laboratory data, consulting with physicians and health officials, training medical and allied health personnel, laboratory management, and conducting research. More specifically, they are expected to be able to:

1. Develop and manage a fiscally sound diagnostic immunology service that will support, enhance, or establish a clinical diagnosis and/or an epidemiological/public health investigation.
2. Provide, communicate, and interpret immunological data and other relevant information for use in the diagnosis, management, and treatment of patients with infectious, allergic, autoimmune, congenital or acquired immunodeficiency disorders and malignant diseases, and those in need of transplantation, and provide consultation on epidemiological problems.
3. Plan and conduct effective training programs in clinical immunology for technical and professional personnel.
4. Design and conduct immunological research relevant to medical and public health problems.

5. Address and meet local, state, and national regulatory requirements as applicable to the practices of medical and public health in the field of immunology.

2. ESSENTIALS AND GUIDELINES FOR ACCREDITATION

2.1. Sponsorship

2.1.1. Institutions – Essentials

Postgraduate fellowship programs must be established in institutions with complete clinical laboratories or reference laboratories that perform clinical immunology procedures in sufficient volume at an appropriate level of quality, such as:

1. University and other medical centers
2. Public health laboratories
3. Hospitals and clinics
4. Reference clinical laboratories

2.1.2. Affiliates – *Essentials*

In instances where any aspect of the program cannot be provided by a single sponsoring institution, collaborative arrangements with other institutions must be established.

2.1.3. Accreditation – *Essentials*

In programs where the laboratory bench experience, clinical phases, and didactic instruction are provided by two or more institutions, accreditation will be granted to the sponsoring institution that assumes primary responsibility for curriculum planning and mode of instruction; coordination of the various elements of the program and guidance of individual Fellows; selection of the faculty for the program; admission and registration of Fellows; and verification of successful completion of the program. The sponsoring institution must also be responsible for assuring that the activities assigned to Fellows in the clinical laboratories are appropriately educational and not merely service work. The program must be educational, and the Fellows must use their scheduled time for educational experiences. The laboratory diagnostic work performed by the Fellows must be primarily for the purpose of developing competency rather than to provide routine diagnostic services.

The sponsoring and collaborating institutions must not be the subject of an interim action by a recognized institutional accrediting agency or state agency potentially leading to the suspension, revocation or termination of its accreditation, or have been threatened of a suspension, revocation or termination of its accreditation and the due process procedures required by the action have not been completed. The sponsoring and collaborating institutions must be accredited by the Joint Commission of Accreditation of Health Care Organizations, the College of American Pathologists, American Society for Histocompatibility and Immunogenetics (ASHI) and/or the Center for Medicare and Medicaid Services, as appropriate.

2.1.3.1. Guidelines

In providing a postgraduate fellowship program in medical laboratory immunology, it is necessary for one institution to assume the major responsibility for the development and management of the program. Sponsoring institutions, however, may need collaborating institutions to provide certain portions of the

instruction. In such instances, it may be desirable to have an institution that provides a significant portion of the instruction to be listed as a co-sponsor of the program.

Sponsors may recognize the contribution of collaborating institutions by requesting CPEP to issue appropriate certificates recognizing the collaboration.

2.1.4. Certification – *Essentials*

The sponsoring and collaborating institutions must be accredited, certified, or licensed as required by existing laws or accepted practice by recognized agencies or be otherwise acceptable to CPEP.

ASM members shall treat others equitably and respectfully without regard to race, color, ethnicity, religion, national origin, sex, age, marital status, sexual orientation, gender identity or expression, family responsibilities, genetic information, disability, political affiliation, or any other personal characteristic protected from discrimination or harassment by law.

2.1.5. Responsibilities of the Sponsor and Affiliate Institution – *Essentials*

Responsibilities of the sponsor and each affiliate/collaborating institution for program administration, instruction, supervision, and documentation must be clearly described in written documents and made available for distribution and inspection.

2.2. Curriculum

2.2.1. Program Length – *Essentials*

The length of the program is 24 months.

2.2.1.1. Guidelines

Although certification boards may give credit for partial participation in an approved program in the certification of individuals, it is generally agreed that most Fellows need two years to cover the subject matter and develop the desired competencies in medical laboratory immunology. All rotations are mandatory. Most, if not all, individuals will have other training needs that can fill any available time. Therefore, after fulfilling the minimum length of time for training in the scheduled areas, Fellows should be able to extend the length of training time in any rotation in which they feel that they need more education, bench experience or training. However, at the discretion of the Program Director and other training faculty of the program, Fellows may not be required to cover subjects that they have already mastered.

2.2.2. Areas of Training – *Essentials*

The program must provide the necessary education and training in all of the specialty areas of medical laboratory immunology, including:

- Specimen collection, processing, proper handling to maintain stability
- Infectious disease serology
- Autoantibody testing and autoimmune disorders
- Immune deficiency and complement deficiency diseases
- Clinical applications of flow cytometry in hematology and immunology
- Histocompatibility testing and transplantation immunology
- Hypersensitivity and cytokine release analysis

- Immunoglobulin analysis and lymphocyte malignancies
- Soluble markers
- Public health serology
- Molecular diagnostics
- Quality management
- Laboratory safety
- Laboratory management
- Laboratory regulations
- Instrumentation and automation
- Participation in sign-outs, communication, on-call services, and clinical consultation
- Research and teaching methodologies

In order for Fellows to acquire the knowledge and skills of a medical laboratory immunologist, appropriate instruction must be made available through bench training and experience, on-call responsibilities, clinical consultations, clinical conferences, hospital rounds, workshops, organized courses, self-instruction materials, and administrative training. Ample diagnostic material (quantity and variety) must be available, with concomitant opportunity for the Fellow to learn how to correlate laboratory information with patient care and/or public health needs. Emphasis must be placed on laboratory diagnostic practice and clinical experience.

2.2.2.1. Guidelines

While it is CPEP policy that curriculum contents and instructional methods are the prerogative of the sponsoring institutions, CPEP offers the accompanying guidelines to assist the programs in developing sound and appropriate instruction that will enable the Fellow to attain the program objectives.

Major training objectives should be developed and made available for review by the Fellow upon entry to the program to identify the knowledge and skills to be acquired by the end of the two-year fellowship. In preparing objectives, the program directors should consider the *Essentials* and accompanying guidelines in Section 2.2.3.

The first year of the postgraduate training in medical laboratory immunology should be organized on a broad basis to furnish instruction in each of the specialty areas. While instruction may be provided in organized courses and self-instructional materials, practical bench exercises and training and clinical experience should be emphasized. The Fellow should have in-depth knowledge of the clinical aspects of immunodeficiencies, allergies, autoimmune disorders, serology of infectious diseases, transplantation, and hematologic malignancies. Fellows accepted in these programs may have prior training in specific areas. Therefore, the program should be individualized to meet the needs of each Fellow and also complement each Fellow's prior experience while still covering the *Essentials*.

In second year, the fellow will take on the role of an "Acting Assistant Laboratory Director." The second year should continue broad training but at a substantially higher level with emphasis on clinical significance and interpretation of laboratory results, to care for patients and populations and to engage in research. The program must also provide training in laboratory management and experience in dealing with management of interpersonal relationships and supervisory aspects of the laboratory. Program directors should draw Fellows into the management decision-making process and provide increasing responsibility for at least some important aspects of the laboratory services. Fellows' attendance at ward rounds and clinical conferences should increase in frequency and level of participation.

To help the Fellows know whether or not an assignment or segment of the program is being adequately covered, modular or rotation objectives should be prepared for the major components of the program. The program director (or designee) should review objectives with the Fellow at the beginning of each

component. The modular objectives should also help the faculty to organize content, learning experiences, and performance evaluations for various portions of the program.

If the parent institution cannot provide adequate training in certain areas, arrangements must be made for the Fellows to learn the material at other institutions and through supervised independent study.

The Fellows should have the opportunity to become acquainted with “new” immunological problems, epidemics of national or global concern, and major effects or trends in health care and maintenance. Aspects of other laboratory disciplines, such as pathology, molecular pathology, hematology, clinical chemistry, histology, microbiology, and virology, should be an intrinsic component of the basic program in the context of discussions about specific disease processes.

Additional training should be provided in research but should not be so extensive as to preclude or preempt satisfactory completion of other essential rotations and aspects of the program. Although research and publication are encouraged, it should be understood that this is not primarily a research training program.

Opportunity for attendance and presentation at ASM, AMLI or other nationally recognized conferences/meetings in clinical/public health science should be provided/supported unless extenuating circumstances (ex. pandemic, health of the trainee, FMLA, etc) prevent this. Programs should clearly state the availability of conference funds and expectations for conference attendance so that such information can be easily accessible for all trainees. If attendance at national meetings is not feasible, programs should support local and regional conference opportunities for trainees.

2.2.3. Knowledge to be Gained from Specialty Area Training

2.2.3.1. Specimen Collection, Processing, Proper Handling to Maintain Stability – *Essentials*

The Fellows must know and understand the proper collection of specimens for the detection of cells, antibodies, complement, or other components and must be able to discriminate which specimens are appropriate for testing. Universal precautions must be observed in all phases of collection and handling and when packaging and shipping Division 6.2 materials DOT and IATA regulations must be followed.

2.2.3.1.1. Guidelines

The Fellow should be familiar with transport devices and conditions for preserving the quality of the specimen. The Fellow should be familiar with the Department of Transportation (DOT) guidelines for packing and shipping infectious substances.

The Fellow should understand the use and content of the Laboratory Test Catalog/Handbook and be able to assist clinicians in the selection of appropriate tests.

The Fellow should be able to determine if a shipment classifies as a Category A, Category B or Exempt Human Specimen and define the packaging and shipping requirements associated with each shipment type.

2.2.3.2. Infectious Disease Serology – *Essentials*

The Fellow must be familiar with the theory and practice of agglutination, precipitation, enzyme immunoassays, complement fixation, immunofluorescence, immunoblotting, chemiluminescence, rapid

testing methods, and multiplex liquid bead-based assays. The Fellow must know the application and interpretation of antibody and antigen detection tests for common bacterial, fungal, parasitic, and viral infections. The Fellow must understand and be able to articulate the statistical methods needed to evaluate serologic assays including sensitivity, specificity, positive predictive value, negative predictive value, estimations of variance, and accuracy etc.

2.2.3.2.1. Guidelines

1. The Fellow should know the established diagnostic criteria (if established) for both common and emerging infectious diseases.
2. The Fellow should understand the advantages and limitations of the serology of infectious diseases and how the aforementioned statistical parameters can be influenced by disease prevalence and host factors, e.g., age, sex, and immune status, and by co-morbidities, e.g., HIV, HBV, and EBV.
3. The Fellow should be familiar with current testing algorithms as defined by the CDC for commonly tested for STDs and epidemiologically important infections like HIV, Lyme disease, syphilis, etc.
4. The Fellow should understand the methods used to standardize infectious disease serology testing and know the source (CAP, API, ASHI) of available proficiency testing materials.
5. The Fellow should understand the principles involved in the establishment of normal ranges of serologic tests and the influence of age and/or risk factors on the population tested.
6. The Fellow should understand the appropriate methods to be used for the diagnosis of specific infectious diseases, for example when to apply serologic methods, direct antigen detection, point-of-care testing, or molecular diagnostic methods as the best diagnostic tool of choice for a specific pathogen.
7. The Fellow should have direct consultation with infectious disease clinicians to integrate/evaluate laboratory diagnostic tools, clinical diagnosis, and management.

2.2.3.3. Autoantibody Testing and Autoimmune Disorders – *Essentials*

The Fellow must understand the theory and technical aspects of immunofluorescence, Ouchterlony, nephelometry, hemagglutination, hemolytic complement, ELISA, immunoblot, chemiluminescence, and multiplex techniques commonly used to detect autoantibodies and understand the clinical relevance of laboratory testing in the diagnosis and monitoring of autoimmune diseases.

2.2.3.3.1 Guidelines

1. The Fellow should know the established clinical and laboratory diagnostic criteria for all systemic (non-organ-specific) and organ-specific autoimmune diseases.
2. The Fellow should know the autoantibody specificities present in serum or organ-specific tissues from autoimmune disease patients and the methods used for detection of these antibodies.
3. The Fellow should understand methods used to standardize autoantibody testing and be familiar with the use of available standard and proficiency materials and potential sources of these materials.

4. The Fellow should understand the laboratory assays which measure inflammation and must know the role of these tests in the monitoring of autoimmune diseases.
5. The Fellow should know the basis of the theory and application of HLA class I and II serologic and molecular based typing methods, know the associations between individual HLA types and some autoimmune diseases, and understand the theories concerning the role of HLA molecules in the development of autoimmune diseases.
6. The Fellow should understand the principles involved in the establishment of normal ranges of autoimmune disease testing, statistical effects of prevalence and disease incidence, and the influence of sex and age in the population tested.
7. The Fellow should understand the impact of interfering factors on immunoassays.
8. The Fellow should know the assays for complement component quantitation and function and be familiar with the association between complement deficiencies and autoimmune diseases.
9. The Fellow should have direct consultation with rheumatology clinicians to integrate/evaluate laboratory diagnostic tools and clinical diagnosis.
10. The Fellow should be familiar with automated methods for autoantibody detection (eg, automated microscopy systems).

2.2.3.4. Immune Deficiency and Complement Deficiency Diseases – *Essentials*

The Fellow must understand the application of serum proteins (immunoglobulins and complement) analysis (refer to 2.2.3.8), phenotypic (refer to 2.2.3.5) and functional cell analysis, and molecular assays used in the detection and categorization of immunodeficiency disorders.

2.2.3.4.1 Guidelines

1. The Fellow should be familiar with the developmental pathways for lymphocytes, monocytes, and granulocytes, and know lineage-specific markers associated with the cell types. The Fellow should know the disorders associated with blocks in the pathways and molecular defects that have been identified thus far for each.
2. The Fellow should understand the role of screening assays for immunoglobulin or cellular deficiency detection. The Fellow should know the quantitative, functional, and molecular laboratory tests used to characterize the specific defects present in all defined primary immunodeficiency diseases, including newborn screening by using TREC levels.
3. The Fellow should know the clinical features and associated infectious disease risks for immunodeficiency diseases and the strategies used for therapy and disease prevention.
4. The Fellow should be familiar with the variety of secondary immunodeficiencies and their causes. The Fellow should be familiar with the laboratory tests used to evaluate the secondary immunodeficiency diseases caused by infectious diseases, drugs, and nutritional deficiencies.

2.2.3.5. Clinical Applications of Flow Cytometry in Hematology and Immunology. *Essentials*

The Fellow must know the background principles, techniques, and methods of flow cytometry, monoclonal antibodies, and immunofluorescence and their use in the phenotyping of lymphocytes and the white cell elements of the bone marrow, peripheral blood, tissue biopsies such as lymph nodes, and body fluids. The Fellow must be familiar with the surface and intracellular antigen markers which help to categorize hematological malignancies and those which define the developmental stages and functional role of white blood cell and lymphocyte subsets.

2.2.3.5.1. Guidelines

1. The Fellow should know the basic principles of flow cytometry and be familiar with standardized procedures required to correctly analyze and interpret flow cytometry data. The Fellow must understand instrument calibration, compensation, gating, bitmaps, and statistical data analysis.
2. The Fellow must be familiar with flow cytometric assay optimization including FMO and single stain control utilization as well as signal to noise, antibody, and control titration methods
3. The Fellow should understand the requirements for proper collection, transportation, handling, and processing of specimens for flow cytometry testing.
4. The Fellow should be familiar with the variety of CD surface and intracellular antigens that define and are routinely used to categorize and differentiate lymphocytes and bone marrow derived cells.
5. The Fellow should be familiar with the hematological malignancies and their clinical presentations. The Fellow should be able to integrate information from surface and intracellular antigen testing of leukemia and lymphoma cells with clinical and pathological data to arrive at a final diagnostic category of malignancy. This may require that the Fellow work closely with a hematopathologist who has more data and benefits from the morphological aspects of the case.
6. The Fellow should understand the basis for the quantitative assessment of lymphocyte subsets in the peripheral blood. The Fellow should be familiar with the effects that malignancies, infectious diseases, and autoimmune diseases have on the phenotypic and functional characteristics of peripheral blood lymphocytes.
7. The Fellow should be familiar with the guidelines that have been defined by the CLSI and CDC for lymphocyte phenotyping in peripheral blood and by the CLSI for leukemia phenotyping. The Fellow should be familiar with World Health Organization guidelines for characterizing leukemia/lymphoma.
8. The Fellow should understand the guidelines that have been defined for quantitation of CD34+ stem cells in hematopoietic stem cell products.
9. The Fellow should be familiar with flow cytometric assays that evaluate functional properties of neutrophils for diagnosis of neutrophil functional defects.
10. The Fellow should be familiar with biologics which are being used to treat immunologic disorders and the flow cytometric, functional cellular assays and immunoassays used to monitor response.
11. The Fellow should be familiar with requirements for verification/validation of laboratory developed clinical flow cytometry tests.

2.2.3.6. Histocompatibility Testing and Transplantation Immunology – *Essentials*

The Fellow must have a basic knowledge of the Major Histocompatibility Complex genes and proteins and their role in the immune system. In addition, the Fellow must be familiar with non-MHC genes and proteins that affect immune functions such as the Killer Immunoglobulin-Like Receptor (KIR) family of genes and proteins on NK cells and their interaction with MHC proteins. This also includes the role of the major histocompatibility complex class I-related chain A (MICA) gene products and antibodies against these molecules in transplantation and other conditions. The Fellow must be familiar with histocompatibility testing methods including HLA and non-HLA typing by serologic and molecular methods, HLA and non-HLA detection of autoantibodies and identification using serologic, ELISA and flow cytometric based methods, and cellular methods used to assess compatibility and immune responsiveness. The Fellow must be able to assess level of risk for rejection and other immunologic complications based on the results of histocompatibility testing and participate in the decision-making process. The Fellow must be familiar with immunogenetics testing for non-transplant clinical purposes, such as disease associations, vaccine eligibility, pharmacogenetics, and personalized medicine.

2.2.3.6.1. Guidelines

1. The Fellow should have a thorough knowledge of the molecular and serological variations present for Class I and Class II HLA antigens, the genetic organization of the HLA loci, non-HLA genes such as MICA, and the KIR genes and proteins. The Fellow should be familiar with the serologic, cellular, and molecular methods used to determine the HLA type of human samples.
2. The Fellow should be familiar with current WHO nomenclature for naming HLA antigens, including suffixes describing expression status
3. The Fellow should understand the laboratory methods used in hematopoietic stem cells (bone marrow, cord blood, peripheral blood stem cells, and umbilical cord cells) for transplantation (HSCT). Such familiarity should include methods of high-resolution HLA testing and testing for non-HLA determinants. The Fellow should be familiar with methods of bone marrow and peripheral blood stem cell harvesting, cell separation, cell selection, cell preservation, and reinfusion.
4. The Fellow should be familiar with factors considered for donor selection, including donor type (matched, MUD, haploidentical), gender, age, CMV status, etc.
5. The Fellow should be familiar with changes that take place in lymphoid organs and the peripheral blood during bone marrow transplantation. The Fellow should know the stages of re-engraftment as it recapitulates fetal development and know the cell types which are present in the peripheral blood at each stage and methods of chimerism analysis for post-HSCT engraftment monitoring.
6. The Fellow should be familiar with HLA and non-HLA antibody (including autoantibody) screening and identification assays and cross-matching assays to assess pre-sensitization to potential organ donors as well as their use for post-transplant monitoring.
7. The Fellow should be familiar with the clinical and laboratory findings seen during acute and chronic rejection episodes and the therapies used for control of rejection.
8. The Fellow should be familiar with the screening procedures which must be done on donor samples to ensure lack of transmission of infectious diseases through transplanted tissues. The Fellow should know the possible infectious diseases and malignancies which are risks of transplantation.

9. The Fellow should know the immunologic effects of chemotherapeutic and immunosuppressive agents used for transplantation and for control of rejection episodes and possible interference of these agents with test methods.
10. The Fellow should be competent in immunogenetics testing for non-transplant clinical purposes, such as blood/products transfusion support, disease associations, vaccine eligibility, pharmacogenetics, and personalized medicine.

2.2.3.7. Hypersensitivity and Cytokine Release Analysis – *Essentials*

The Fellow must understand the immunologic pathways which lead to type 1 hypersensitivity reactions and cytokine release syndrome. The Fellow must know the available laboratory assays which can be used to monitor the likelihood of allergic reactions to a variety of allergic substances. The Fellow must be familiar with the inflammatory mediators of allergic reactions and the modalities of the clinically available therapies.

2.2.3.7.1. Guidelines

1. The Fellow should know the basis for the IgE mediated allergic response at both the cellular and molecular level. The Fellow should be familiar with the mechanism of IgE crosslinking, intracellular stimulation pathways, and methods of granule release for basophils and mast cells. The Fellow should know the various mediators of inflammation and their pathologic effects.
2. The Fellow should know the *in vivo* skin test methods used by allergists and understand the immunologic response which leads to the positive skin test response in allergic individuals.
3. The Fellow should know the *in vitro* methods for measuring levels of IgE and allergen and component-specific IgE and their interpretation in various clinical conditions. The Fellow should understand the scoring systems, the differences between scoring methods, and their use in the prediction of allergic responses as well as in the normal population.
4. The Fellow should be familiar with the variety of drugs and specific immunotherapies used in allergy and their effects on the allergic immune response.
5. The Fellow should be familiar with the variety of pathological conditions including allergy, asthma, parasitic infections, immunodeficiencies, and malignancies in which high levels of IgE are present.
6. The Fellow should be familiar with other types of hypersensitivity reactions including immune complex-mediated disorders and the associated laboratory testing.
7. The Fellow should know the *in vitro* methods for measuring cytokine levels and understand the mechanism of cytokine release syndrome.
8. The Fellow should have direct consultation with allergists/immunologists to integrate/evaluate laboratory diagnostic tools and clinical diagnosis. It is desirable for a fellow to shadow an allergist/immunologists for 1 week.

2.2.3.8. Immunoglobulin Analysis and Lymphocyte Malignancies – *Essentials*

The Fellow must know the theory and technical methods of protein electrophoresis, nephelometry, immunoelectrophoresis, immunofixation, capillary electrophoresis, and immunosubtraction for quantitation of immunoglobulins and immunoglobulin subclasses and the analysis of light chain clonality. The Fellow must understand the spectrum of clinical lymphoid malignancy diseases where monoclonal immunoglobulins are detected.

2.2.3.8.1. Guidelines

1. The Fellow should be able to integrate immunoglobulin quantitations, electrophoresis, immunoelectrophoresis, and immunofixation testing to determine immunoglobulin clonality for patients' serum, urine, body fluid, and CSF samples.
2. The Fellow should understand the analysis of CSF and serum immunoglobulin and albumin to determine the local oligoclonal synthesis of IgG in the CSF.
3. The Fellow should be familiar with the clinical presentations of the various lymphoid and hematologic malignancies and the clinical and laboratory diagnostic criteria for this group of diseases.

2.2.3.9. Soluble Markers – *Essentials*

The Fellow must understand the common uses of soluble markers such as tumor, cytokine, and chemokine markers, and should know the available laboratory assays and methods which can be used to detect soluble markers.

2.2.3.9.1. Guidelines

1. The Fellow should know why marker results cannot be compared across methods.
2. The Fellow should know what substances can interfere with detecting soluble markers and how they can be evaluated.
3. The Fellow should understand how tumor burden can influence results and how this can be evaluated.
4. The Fellow should understand how cytokine markers change with disease states and which cytokines are important for clinical diagnosis (i.e. IL-1, IL-2 R (CD25) IL-6, IL-6R and TNF- α for cytokine storm from CAR T cell treatment)

2.2.3.10. Public Health Serology– *Essentials*

The Fellow must be familiar with epidemiology and hospital infection prevention.

2.2.3.10.1. Guidelines

1. The Fellow should be familiar with the following principles of epidemiology and hospital infection prevention:
 - Role of the clinical immunology laboratory in hospital infection control
 - Retrospective studies
 - Prospective studies

- Recognition, surveillance and control of healthcare-associated infections.
2. The Fellow should be familiar with transmission risks associated with specific types of healthcare settings (e.g., hospitals and ICU) and transmission risks associated with specific patient populations (e.g., immunocompromised and cystic fibrosis patients).
 3. The Fellow should learn the serologic and molecular methods that help determine the causes of epidemiologically important infections.
 4. The Fellow should be able to provide professional educational assistance to other clinical/diagnostic immunology laboratories throughout the state and where applicable to the general public.
 5. The Fellow should be familiar with the following public health laboratory methods:
 - Sexually transmitted diseases testing
 - Rabies virus detection
 - Public health screening for diagnosis or immune status
 - HIV Testing and confidentiality
 - Vector-borne disease testing such as arboviruses

2.2.3.11. Molecular Diagnostics – *Essentials*

The Fellow must be familiar with the theory, application of, and limitations of molecular techniques such as:

- Nucleic acid extraction
- Use of nucleic acid probes
- Molecular amplification methods; target amplification (PCR-based); signal amplification (non-PCR-based)
- DNA sequencing
- Plasmid isolation and detection; electrophoresis techniques
- Restriction analysis of eukaryotic DNA
- Hybridization and immunoblotting
- Nucleic acid-based array systems such as gene chips and bead-based arrays
- Contemporary sequencing techniques and platforms

2.2.3.11.1 Guidelines

1. The Fellow should have basic knowledge in molecular techniques used in molecular diagnostics such as the hybridization assays, Polymerase Chain Reaction (PCR), Reverse Transcription PCR (RT-PCR), real-time PCR, melt curve analysis, Transcription Medicated Amplification (TMA), Single Nucleotide Polymorphism (SNP) analysis, contemporary sequencing and microarray techniques and platforms, and other newly developed molecular techniques (Next Generation Sequencing, NGS).
2. The Fellow should be aware of the major causes of incorrect molecular diagnostic test results such as cross-sample contamination, sample preparation/extraction efficiencies, and inhibitors of amplification.
3. The Fellow should be knowledgeable in the use of infectious disease molecular tools such as qualitative and quantitative viral load testing or viral genotyping for patient therapy.

4. The Fellow should be aware of the application of gene rearrangement information in the diagnosis of immune deficiency and hematologic malignancies.
5. The Fellow should be familiar with the regulatory requirements associated with the use of IVD, ASR, RUO, EUA, and laboratory-developed tests/products and verification and validation requirements to implement/use such tests/products.
6. The Fellow should be familiar with the regulatory requirements for FDA-approved molecular tests when there is deviation from FDA-approved product insert instructions.

2.2.3.12. Quality Management – *Essentials*

The Fellow must understand and describe the three elements: structure, process and outcome of a comprehensive laboratory quality management program. The Fellow must demonstrate the ability to implement a laboratory quality control, quality assurance, and continuous quality improvement program.

2.2.3.12.1. Guidelines

1. The Fellow should become familiar with laboratory quality control procedures and be given the responsibility to review quality control data. The Fellow should help in the selection of quality assurance indicators and present the results in a written or verbal presentation.
2. The Fellow should know how to use statistical tools for laboratory quality control. If possible, the Fellow should be engaged, if needed, in a statistics course of the parent institution.
3. The Fellow should become familiar with a hospital's continuous quality improvement program.
4. The Fellow should be familiar with root cause analysis and/or quality improvement methods, the steps required for appropriate regulatory response to identified issues, investigation of nonconformances, and required documentation of corrective action.
5. The Fellow should be competent in all aspects of laboratory operations, such as approving the source of all reagents; authorizing staff members to perform different functions in the laboratory; developing procedures, policies and protocols; ensuring that established procedures, policies and protocols are being followed; implementing and monitoring necessary remedial actions; ensuring laboratory compliance with local, state, and federal regulatory agencies as well as accrediting agencies; evaluating equipment, personnel, and space requirements for reliable test performance; and investigating and resolving client complaints. The Fellow must participate in the design or revision of a competency testing program. The Fellow should be aware of the regulatory requirements and consequences related to delegation of duties. Familiarity with approaches to effective management and monitoring of delegated duties is a must.
6. The Fellow should be competent in all aspects of laboratory fiscal management, such as allocating staff and resources; justifying new and existing staff positions; consulting with administrative personnel on laboratory procedures (e.g., accounting, billing, purchasing); developing and monitoring the laboratory budget; developing a fee structure for laboratory services; developing laboratory cost containment measures; and negotiating contracts, laboratory equipment and facilities, and personnel salaries and benefits.

2.2.3.13. Laboratory Safety – *Essentials*

The Fellow must be familiar with the theory and practice of laboratory safety that includes local, state, and federal regulations, and the design and implementation of a program that protects the health and safety of all laboratory employees. The Fellow must be familiar with laboratory and hospital safety committees.

2.2.3.13.1. Guidelines

1. Fellows should attend a hospital, university, or institutional safety orientation course.
2. Fellows should understand modes of transmission and acquisition of relatively common laboratory acquired infections.
3. Fellows should understand the principles and practices of the following safety issues:
 - Composition and use of a laboratory safety manual
 - Universal precautions
 - OSHA requirements
 - Biosafety/laboratory safety (including handling specimens possibly containing highly infectious/pathogenic organisms)
 - Selection and use of appropriate personal protective equipment (PPE)
 - Waste management, including disposal of biohazard material
 - Safe handling of radioactive materials
 - Physical and chemical hazards, including carcinogens
 - Methods of disinfection and sterilization
 - Baseline medical testing (immune status, protective immunization)
 - Laboratory design as it applies to safety
 - Biosafety and chemical hoods
 - Policy for managing laboratory accidents, including managing a safety emergency
 - Occupational exposures
 - Disaster planning/Continuity of Operations Plan (COOP)

2.2.3.14. Laboratory Management – *Essentials*

The Fellow must be competent in aspects of laboratory operations, including the following:

- Developing procedures, policies and protocols
- Ensuring that established procedures, policies and protocols are being followed
- Ensuring laboratory compliance with local, state, and federal regulatory agencies as well as accrediting agencies
- Ensuring conformance to medical ethics
- Ensuring compliance with HIPAA and privacy regulations
- Legal aspects of both human resource (e.g. ADA, FMLA) and information management (e.g. HIPAA)
- Ensuring compliance with IRB approval practices for clinical research
- Evaluating equipment, personnel, and space design requirements for reliable test performance
- Investigating and resolving client complaints

The Fellow must be competent in aspects of laboratory personnel, including:

- Personnel training and continuing education
- Personnel management principles and interpersonal relations
- Developing workload matrices and indicators

- Developing job descriptions
- Developing interviewing skills, and evaluating candidate qualifications
- Evaluating competency of laboratory personnel
- Understanding CE requirements for employee credentialing

The Fellow must be competent in aspects of laboratory fiscal management, including:

- Allocating staff and resources
- Justifying new and existing staff positions
- Reimbursement coding systems
- Developing and monitoring laboratory budget
- Developing fee structure for laboratory services including research testing
- Developing laboratory cost containment measures and cost analysis
- Evaluating existing and new testing procedures considering cost/benefit criteria
- Negotiating contracts for laboratory equipment, service contracts, and facilities

2.2.3.14.1. Guidelines

1. The Fellow should assume responsibility for direction of a section of the laboratory for a 3-6 month period as an acting assistant laboratory director and participate in the on call program for the clinical immunology laboratory.
2. The Fellow should participate in the annual budget planning process, e.g., by preparing a cost analysis of a piece of capital equipment or justification for a new technologist position.
3. The Fellow, whenever possible, should sit in on personnel actions, including interviewing performance appraisals and disciplinary actions. The Fellow should understand the importance of being a good team player.
4. The Fellow should take management training courses that are available. Many institutions provide courses which help develop supervisory skills. Fellows are encouraged to participate. If management courses are not offered at a particular institution, funding should be set aside so that fellows can participate in online courses. Availability of such courses should be shared with fellows.
5. The Fellow should participate in the implementation of internal and external clinical studies to learn the regulatory requirements concerning confidential patient information, limits on laboratory testing, and data reporting limitations.
6. The Fellow should be familiar with reimbursement policies for laboratory services from third party payers such as Medicare, Medicaid, and Private Insurances. The Fellow, whenever possible, should consult or discuss with the Accounting Department the different reimbursement procedures. The Fellow should understand reimbursement principles in an overall assessment of laboratory income potential including the differences between inpatient and outpatient billing.
7. The Fellow should know the different reimbursement coding systems that are used for laboratory services, such as the CPT and the ICD-10-CM. Fellows should understand why accurate coding is important for proper reimbursement.
8. The Fellow should understand and be familiar with the current federal laws that are applicable to all employees. Such laws include, among others, the Civil Rights Act (EEOC), the American with Disabilities Act (ADA), the Age Discrimination Act, the Family and Medical Leave Act and the

wage and hours laws. The Fellow should understand the legal aspects of human resource management (e.g. FMLA and ADA) and information management (e.g. HIPAA and FOIA).

9. The Fellow should be familiar with the provision of clinical immunology services to clients outside of the Fellow's laboratory/setting/hospital (e.g. customer service; bringing in new/outside business; establishing a small or satellite laboratory at another site; how services differ among community hospital, academic, commercial/reference, Veterans Administration, and local/state public health laboratories).

2.2.3.15. Laboratory Regulations – *Essentials*

The Fellow must describe the major requirements of private and governmental (federal and local) agencies that accredit, certify or license clinical laboratories, or that have standards regarding employer/employee relationships. Such agencies include, but are not limited to, CLIA, The Joint Commission, and CAP. Additionally, the Fellow must be familiar with the concepts of healthcare and federal employment laws.

2.2.3.15.1. Guidelines

1. The Fellow should be familiar with the importance of federal agencies, regulations, and acts in clinical immunology (e.g., CLIA, HCA, FDA, Medicare, Medicaid, and appropriate publications in the Federal Register).
2. The fellow should be familiar with the various types of CLIA certifications (waived, PPM, Moderate and High Complexity) as well as the requirements of accrediting agencies such as CAP and CLEP.
3. The fellow should understand the difference between waived tests and nonwaived tests, LDTs and EUAs.
4. The Fellow should be aware of validation requirements from regulatory agencies such as CLIA, CAP, and FDA for laboratory-developed tests.
5. The Fellow is encouraged to meet and discuss regulations with individuals at the State Department of Health laboratory who are responsible for monitoring state and federal laws that affect laboratory testing. The fellow should have a general understanding of how requirements may differ from state to state.
6. The Fellow should complete some or all of the CAP accreditation self-inspection documents and actively participate in a CAP inspection of the laboratory.
7. The Fellow should complete CAP on-line inspector training.
8. If possible, the Fellow should participate with an inspection team in an off-site CAP inspection.
9. The Fellow should participate in an OSHA self-inspection of the laboratory and be familiar with the requirements of CLIA '88.
10. The Fellow should understand the role of proficiency testing in the certification process.

2.2.3.16. Instrumentation and Automation– *Essentials*

The Fellow must understand the application and utilization of:

1. Automated or semi-automated systems for analyte detection
2. Computerized information systems for recording, analyzing and reporting laboratory data
3. Hospital information system and how it communicates with the laboratory information system (LIS)
4. Computers and software which provide management, quality control and safety functions
5. Advantages, disadvantages, and regulations associated with auto -result, -verification, and -release
6. Appropriate test utilization (e.g. cost effectiveness, operations, and clinical benefits)
7. The Fellow must be familiar with at least one contemporary laboratory information system

2.2.3.16.1 Guidelines

1. The Fellow should be familiar with verification and validation requirements for laboratory instrumentation and testing, including LIS/EMR test build and reporting.
2. The Fellow should review literature and manufacturer's specifications which compare different LIS. The Fellow should be familiar with immunology-specific aspects of an LIS (e.g., specimen receipt and entry, preliminary and final reporting of results, test menu, test ordering, and entering results).
3. The Fellow should be able to demonstrate proficiency in generating reports from a LIS (e.g. cost and QC/QA data). Specifically, the Fellow should be able to query a LIS, generate a report, and format the report to a spreadsheet for data base analysis.
4. The fellow should have knowledge of HL7, LOINC and SNOMED codes and familiarity with Health Information Exchange

2.2.3.17. Participation in Sign-outs, Communication, On-call Services, and Clinical Consultation – *Essentials*

The Fellow must demonstrate the communicative skills necessary to consult and advise physicians, instruct technologists, and to justify personnel, equipment requirements and requests for space to the laboratory director and/or institutional administration.

2.2.3.17.1. Guidelines

1. The Fellow should be assigned the responsibility of handling phone calls from physicians regarding specimen collection, and interpretation of laboratory data. The Fellow should participate in the on-call rotations and be responsible for reporting significant results to physicians.
2. The Fellow should be familiar with the basic concepts of Evidence-based Laboratory Medicine and how this can be utilized to aid in the interpretation of laboratory data. The Fellow should be aware of the resources that are used for Evidence-based Medicine.
3. The Fellow should outline the steps involved in making and implementing a policy change.
4. The Fellow should provide/participate in continuing education presentations and/or activities to the laboratory members.

2.2.3.18. Research and Teaching Methodologies – *Essentials*

The Fellow must develop a protocol and describe the research methodology, controls and statistical considerations to test a hypothesis proposed as an answer to a basic or applied research problem in immunology. The research methodology may also be applicable to development and regulatory requirements for laboratory-developed tests.

2.2.3.18.1. Guidelines

1. Fellows should be encouraged to attend and participate in local, regional and national scientific meetings where research data is submitted for presentation. The program should assist Fellows to the extent possible in funding for meeting attendance.
2. The Fellow should learn the use of basic analytical tools for laboratory assays such as ROC curves and basic statistical methods.
3. The Fellow should understand the basic parameters used to establish expected/normal ranges and predictive value analysis.
4. The Fellow should participate in preparing Institutional Review Board (IRB) proposal and take courses in CITI and IRB training.
5. Fellows should be encouraged to interact with other clinical diagnostic trainees to learn about emerging technologies, such as, mass spectrometry or next generation sequencing that are evolving in clinical immunology.

2.2.4. Length of Time Fellows Must Spend in Specialty Training Areas – *Essentials* and Guidelines

The table below lists the amount of time a Fellow spends in each of the major training areas during a two-year program. The minimum *Essential* or requirement times are intended for individuals who enter a program with little or no previous experience in clinical immunology and represent the time needed to achieve the objectives stated in the *Essentials*. The ranges of time or guidelines for each area provide flexibility which may be necessary due to prior experience of the Fellow.

<i>Essentials</i> and Guidelines for Length of Time in Major Training Areas		
Major Training Area	<i>Essentials</i> Minimum Time Spent in Months (Weeks)	Guidelines Range of Time Spent in Months (Weeks)
Infectious Disease Serology	2 (8 weeks)	2-3 (8-12 weeks)
Autoantibody Testing	2 (8 weeks)	2-3 (8-12 weeks)
Histocompatibility Testing and Transplantation Immunology	2 (8 weeks)	2-3 (8-12 weeks)
Cellular and Innate Immunology (Flow cytometry, functional assays etc.) <i>(a)</i>	2 (8 weeks)	2-3 (8-12 weeks)

Hematology (Flow Cytometry) (b)	1(4 weeks)	1 (4 weeks)
Immunodeficiency and other immune system disorders (Immunoglobulin, Complement, other Serum Protein Analyses) (a)	1 (4 weeks)	1-2 (4-8 weeks)
Molecular Biology/ Diagnostics	1 (4 weeks)	1-2 (4-8 weeks)
Public Health Serology	0.5 (2 weeks)	0.5 (2 weeks)
Soluble Markers	0.5 (2 weeks)	0.5 (2 weeks)
Allergy Testing	0.5 (2 weeks)	0.5 (2 weeks)
Laboratory Management) and LIS/Computer Training (c)	2 (8 weeks)	2-3 (8-12 weeks)
On-Call (d)	3 (12 weeks)	>3 (>12 weeks)
Acting Assistant Director of Laboratory Section	3 (12 weeks)	>3 (>12 weeks)
Research	Open	
Teaching	Open	

(a) Immunodeficiency, other immune system disorders, monitoring immune depletion and subsequent repletion, monitoring biologic therapies for immunologic disorders and evaluation of bone marrow transplant engraftment

(b) Diagnosis of hematologic malignancies

(c) Management includes laboratory safety, regulations, quality management, automation, specimen collection, personnel management principles, finance, and laboratory workload assessment

(d) Including clinical consultation and direct communication with providers regarding laboratory results, troubleshooting, problem-solving, and testing issues

2.2.5. Evaluation of Instruction – *Essentials*

Programs must develop and implement means to evaluate all phases of the instruction. Performance and competence must be documented in relation to stated program objectives that are made known upon entering the program. Performance must be documented and reviewed with the Fellow. Documentation of the review must be maintained for at least seven years.

2.2.5.1. Guidelines

A clear definition of program objectives is essential. A program cannot evaluate the knowledge and proficiency which Fellows have acquired unless it has first defined the specific functions and skills that they are expected to learn (see Section 2.2.3). As a consequence, a program should proactively define the objectives for the rotations and didactic instruction in such a way that the Fellows, faculty, and evaluators can recognize the level of proficiency and knowledge Fellows are expected to attain from various segments and from the program. Ideally the objectives and expectations are provided to the Fellow and instructors as

a written document in advance of the rotation, detailing time spent on different activities and learning objectives.

Program directors should develop means for evaluating a Fellow's accomplishments and preparedness for a career as a medical laboratory immunologist (see Preamble). This process should provide evidence that each Fellow has been fully trained and has substantially met all of the program's objectives. This may take the form of written evaluations, assessments (i.e. tests or competencies) and self-evaluations. Periodic review should occur at the completion of each specialty area. Such evidence should be documented and retained in the file of each Fellow.

2.2.6. Program and Performance Records – *Essentials*

The parent institution must maintain a record of the training program and/or performance of each Fellow for at least seven years.

2.2.6.1. Guidelines

Because a standard curriculum for all Fellows is inappropriate, the parent institution should record the bench and clinical rotations, research, organized courses, and individual study that engaged the time of each Fellow. A list of these program components and other information on Fellow activities and performance should be retained by the institution.

2.3. Resources

2.3.1. General Resources – *Essentials*

Resources, as described below, must be adequate to support the number of Fellows admitted to the program.

2.3.1.1. Guidelines

Care should be taken to ensure that the supervisory and instructional staff and other resources are available for all Fellows enrolled in the program and are adequate to provide quality instruction for this advanced, professional level of training.

2.3.2. Program Staff – *Essentials*

The program must have a qualified program director(s) and adequate support staff. The program director must assume overall responsibility. When the program director is changed or is on leave for longer than one month, CPEP must receive immediate notification. The interim/acting director is responsible for all components of the program. The curriculum vitae of the new director, giving details of his/her education, training, and experience, must be submitted to CPEP for inspection and approval by the committee. If the new director's credentials are in order, accreditation of the program will be continued.

2.3.2.1. Guidelines

Primary responsibilities of the program director shall include program development, organization, administration, evaluation, and revision. In some instances, it may be desirable to have an assistant or deputy program director.

Program officials should have time to fulfill the administrative and educational duties of the program. Adequate clerical and other support staff should be available.

2.3.3. Program Director Responsibilities – *Essentials*

The program director must be responsible for the organization, administration, periodic review, continued development, and general effectiveness of the program. In this activity, the program director must cooperate and collaborate fully with the program and instructional officials at the parent and collaborating institutions. The program director shall be responsible for ensuring that appropriate evaluation instruments are developed and applied regularly and consistently and that appropriate records of all Fellows in the program are maintained.

2.3.3.1. Guidelines

The program director shall assume ultimate responsibility for the didactic instruction, laboratory experience, and clinical phase of the program. Although other officials at the sponsoring and collaborating institutions should be delegated specific responsibilities, it is the program director's responsibility that all phases of the program are appropriate and successful in meeting program goals and objectives.

2.3.4. Program Director Qualifications – *Essentials*

The program director must be (a) a medical laboratory immunologist who holds a responsible leadership position in the sponsoring institution and (b) certified (with active status) as a Diplomate by the American Board of Medical Laboratory Immunology (ABMLI) or other CLIA-recognized board that is immunologically focused and acceptable to CPEP. The program director must be engaged full time in immunological work (diagnostic, research, teaching, program administration) at the sponsoring institution.

2.3.5. Assistant or Deputy Program Director Qualifications – *Essentials*

If the program has a designated assistant or deputy program director, they must be certified by a CLIA-recognized board that is immunologically focused and acceptable to CPEP and the certification must be active. The assistant or deputy program director(s) must have appropriate credentials that are acceptable for faculty appointments at the sponsoring and/or collaborating institutions.

2.3.6. Instructional Staff

2.3.6.1. General Qualifications – *Essentials*

All instructional staff must be qualified through academic preparation, experience, and appointment to effectively teach the subjects assigned.

2.3.6.1.1. Guidelines

The breadth or competency of the staff of the sponsoring and/or collaborating institutions should be such that all areas of medical laboratory immunology can be covered satisfactorily to meet the objectives of the program. In addition to physicians and scientists who are immunologists, the staff may include specialists in management and education as well as physicians with interest and expertise in clinical immunology who are specialists in infectious disease, pathology, rheumatology, pediatrics, nephrology, hepatology, hematology, oncology, allergy, histocompatibility, immunodeficiency, and epidemiology.

2.3.6.2. Program Officials – *Essentials*

In addition to the program director, the program officials of the sponsoring and/or collaborating institutions must include at least two doctoral level, full-time staff members with expertise and interest in clinical immunology. These people do not have to be part of the clinical immunology laboratory staff.

2.3.6.2.1. Guidelines

Fields of competence of additional program officials should supplement rather than duplicate those of the program director

2.3.6.3. Technical and Clinical Personnel – *Essentials*

The program director must be assisted by sufficient professional, technical, and clinical personnel to permit the laboratory to carry out all of the responsibilities in service, teaching, consultation and research in an efficient and effective manner.

2.3.6.3.1. Guidelines

The technical personnel should be certified by appropriate agencies (e.g., The National Registry of Certified Microbiologists, Board of Certification [ASCP], National Registry of Clinical Chemistry), or be eligible for such certification.

2.3.7. Financial Resources – *Essentials*

The financial resources of the sponsoring institution must be such that continued operation of the educational program is assured for completion of the program by current and newly accepted Fellows.

2.3.7.1. Guidelines

In addition to adequate budgetary support for the teaching and diagnostic operations of the laboratory, adequate stipend support for Fellows should be provided.

2.3.8. Physical Resources – *Essentials*

Adequate laboratories, classrooms, office space, computer resources, and other facilities must be provided.

2.3.8.1. Guidelines

The laboratories should have sufficient space to accommodate both the staff and Fellows without interfering with the regular activities of the laboratory. A separate office/laboratory area for Fellows is desirable.

2.3.9. Equipment and Supplies – *Essentials*

Appropriate, modern equipment and supplies in sufficient quantity must be provided.

2.3.9.1. Guidelines

Institutions lacking state-of-the-art automated instruments and computer facilities should make Fellows aware of such technology by having them rotate through other institutions and/or attend lectures and workshops dealing with these subject areas. Adequate instructional materials should be available,

including clinical materials that are not available on a regular basis. Programs should provide electronic or internet access to teaching materials as well as maintain collections of digital media, movies, and self-instructional materials to supplement the instruction available in the program.

2.3.10. Library – *Essentials*

A library (including online resources) must be readily accessible and contain an adequate supply of up-to-date books, journals, and reference materials related to the curriculum. Computerized search services must be available, and the Fellow must be trained in their application and use.

2.3.10.1. Guidelines

The sponsoring and collaborating institutions should maintain or have available adequate libraries containing electronic or print authoritative textbooks, monographs, and current journals in the various disciplines related to and associated with clinical laboratory medicines.

2.3.11. Records – *Essentials*

Satisfactory records must be maintained on Fellows' admission, attendance, participation, achievement, and evaluation. Detailed records on each Fellow must be on file at the sponsoring institution for at least seven years. Health records as required by the institution must be maintained in the Fellow's file. A summary record on each Fellow must be permanently kept by the sponsoring institution and sent to the CPEP headquarters office after completion of the training program. The summary should include documentation of time spent on the essentials and other activities. A brief description of research project, presentations, and publications completed during the year is provided in the annual program report.

2.3.12. Advisory Committee – *Essentials*

An advisory committee must be composed of key program officials from the parent and collaborative institutions. The purpose of this committee is to review and establish policy, continuing program development and evaluation, and to help maximize utilization of resources at the sponsoring and collaborating institutions. At least one meeting each year must be held to assess the program. More frequent meetings may be necessary to resolve certain issues that arise during the year. Minutes of these meetings must be prepared and submitted to CPEP with the annual report.

2.3.12.1. Guidelines

The advisory committee should be relatively small, consisting of the program director, one or two associates at the sponsoring institution, and one representative from each collaborating institution. One of the more senior Fellows in the training program may also serve.

2.4. Fellows

2.4.1. Program Description – *Essentials*

Prospective Fellows must be provided with a clear description of the program and its contents, including the program objectives and competencies that the Fellows are expected to attain. There must be no deceptive publicity concerning job placement or income expectations for Fellows. Fellows must be given a copy of the *Essentials* upon entering the program, if not before.

The program must have a printed document that clearly describes the training program that is offered. Additional information on stipend, travel, health insurance, and scheduled time off must be disclosed in writing to each Fellow.

2.4.2. Admission – *Essentials*

The Fellow must have earned a doctoral degree (such as Ph.D., M.D., D.O., Sc.D., Dr. P.H., and D.V.M.) with graduate education in microbiology or molecular biology to qualify for admission to the training program. At this time, Doctor of Clinical Laboratory Sciences (DCLS) and Pharmacy (PharmD) are not acceptable for admission to a CPEP-accredited program. However, Doctor of Philosophy in Health Sciences may be accepted upon review by the Program Director. ASM members shall treat others equitably and respectfully without regard to race, color, ethnicity, religion, national origin, sex, age, marital status, sexual orientation, gender identity or expression, family responsibilities, genetic information, disability, political affiliation, or any other personal characteristic protected from discrimination or harassment by law. Matriculation practices must be consistent with all applicable laws regarding nondiscrimination. The decision for selecting a Fellow must be documented in writing and retained for seven years.

2.4.2.1. Guidelines

Educational prerequisites, other criteria for selection, and the method of selection should be explained to prospective candidates. Desirable prerequisites for the postgraduate training programs include courses in epidemiology, immunology, microbiology, molecular biology, histology, pathogenesis of infection, and statistics. Previous work experience in medical and/or public health diagnostic laboratories may be considered when evaluating candidates for the program.

A fellowship selection committee consisting of two, and preferably three, members should participate in the selection process. It is usually desirable to have members of the advisory committee serve on the selection committee. If possible, all members of the fellowship selection committee should interview candidates. Current Fellows should have the opportunity to meet with prospective candidates and answer their questions on all phases of the program.

Documentation of the selection process and the decision to select a candidate may consist of the minutes from the meeting of the Selection Committee. These written minutes should be retained for a period of seven years.

2.4.3. Salary, Benefits and Scheduled Time Off – *Essentials*

Fellows must have available the following benefits equivalent to those received by other postgraduate residents, Fellows, interns, and employees at the institution:

- The option to participate in health and hospitalization insurance programs
- Customary personal/sick days, vacation, and holidays
- Eligibility for FMLA

2.4.3.1. Guidelines

The participating program is also advised to provide fellows with stipends equivalent to other postgraduate residents (commensurate with years of postgraduate training)

Exceptions to this *Essential* may be necessary to provide emergency services for brief periods. The Fellows may assume other managerial, supervisory, and professional responsibilities as assignments to meet the training objectives of the program.

2.4.4. Health and Safety – *Essentials*

The program director must assure that the Fellows' health and safety is protected by appropriate immunization, PPE, chemical hygiene program, and safe working conditions. The health, safety, and infection prevention and control policies and procedures pertaining to institutional employees and department faculty must also apply to Fellows.

2.4.4.1. Guidelines

A baseline TB screening test and additional immunizations following institutional policy should be encouraged.

2.4.5. Costs to Fellows – *Essentials*

Any costs to the Fellows must be reasonable and accurately stated and published upon acceptance of the Fellow to the program.

2.4.5.1. Guidelines

In most approved programs, the Fellows receive stipends and incur no cost for courses and other educational opportunities. Any expenses that the Fellow might incur with regard to travel and subsistence for any phase of the program or for attendance at meetings, transportation of family and personal effects, health and hospital insurance, should be explained to applicants.

2.4.6. Fellow Guidance – *Essentials*

Program directors (or associates) must be readily available to assist the Fellow in meeting the program's training objectives and addressing the Fellow's career goals. Program directors should meet with Fellows on a regular basis to document feedback on progress.

2.4.6.1. Guidelines - Program Directors (or associates)

Although the program director(s) may see the Fellows in these postgraduate programs almost on a daily basis, regularly scheduled standing appointments to provide formal guidance are strongly recommended. These meetings may be on a monthly basis or coincide with the completion of a rotation. At minimum, formal feedback should occur two times per year to ensure ongoing discussion and that any deficiencies can be addressed. Specific feedback regarding performance is beneficial to the trainee.

2.4.7. Appeal Mechanism – *Essentials*

In the event a Fellow has a grievance with the program, an appropriate appeal mechanism must be available and made known to the Fellow.

2.4.7.1. Guidelines

Every attempt should be made to resolve the Fellows' complaints and concerns within the department or within the institution. A more formal appeal mechanism is available through CPEP. Details of this process are described in the *Operational Procedures* of CPEP which may be obtained from a program director or the ASM website.

2.4.8. Withdrawal or Termination – *Essentials*

Policies and procedures for Fellow withdrawal or termination must be fair, published, and made known to all applicants. Written documentation of any disciplinary action must be included as part of the Fellow's record and included in the permanent record forwarded to CPEP.

2.4.8.1. Guidelines

Policies and procedures for withdrawal and termination should be consistent with those of the sponsoring institution.

2.5. Continuing Program Evaluation

2.5.1. Periodic Program Review – *Essentials*

Periodic and systematic review of the program's effectiveness must be performed and documented. A self-study (analysis, evaluation) conducted by the sponsoring institution must be undertaken for initial program accreditation or reaccreditation. Guidelines for Self-Evaluation are available from CPEP. This documentation must be maintained for seven years. The results of these reviews must be carefully considered and reflected in policies and procedures developed for the program.

2.5.1.1. Guidelines

Less formal program evaluation should be conducted on a continuing basis.

An evaluation of the program by all Fellows should be obtained within the first two years after completion of the program. The information obtained in these evaluations should be considered in the annual review by the advisory committee.

2.6. Maintaining Program Accreditation

2.6.1. Annual Report – *Essentials*

The annual report form provided by CPEP must be completed, signed by the program director, and returned by the established deadline.

2.6.2. Annual Meeting of Program Directors – *Essentials*

Each approved program must have a representative attend the annual meeting of program directors. The program director or designated representative must attend a majority of the meetings and must not be absent two consecutive years.

2.6.3. Replacement of Director or Deputy Director – *Essentials*

If the program director or deputy director of an accredited program leaves the sponsoring institution or a new program director or deputy director is appointed, CPEP must receive notification within one month.

2.6.4. Accreditation Withdrawal – *Essentials*

CPEP must consider withdrawal of accreditation whenever:

1. The educational program is not maintained in substantial compliance with the *Essentials* and the *Operational Procedures* of CPEP.
2. There are no Fellows in the program for two consecutive years.
3. The program director does not submit the annual report within three months of the deadline.

2.6.5. Notification of Withdrawal – *Essentials*

Accreditation will be withdrawn only after notice (with the reasons for withdrawal) has been given to the Chief Executive Officer of the sponsoring institution and after sufficient time has elapsed to permit a considered response. The CPEP *Operational Procedures* must be followed. Program directors are required to notify the Fellows of their withdrawal of CPEP accreditation. Fellows may contact CPEP to ascertain the status of their training to date.