

**NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
CLINICAL LABORATORY EVALUATION PROGRAM
EMPIRE STATE PLAZA, P.O. BOX 509
ALBANY, NEW YORK 12201-0509
Telephone: (518) 485-5378 Fax: (518) 485-5414
E-Mail: CLEP@health.state.ny.us
Web : www.wadsworth.org/labcert**

**APPLICATION INSTRUCTIONS FOR CERTIFICATE OF
QUALIFICATION - CLINICAL LABORATORY DIRECTOR/
ASSISTANT DIRECTOR**

Please read and follow the instructions carefully since submission of incomplete or incorrect applications will delay processing. **NOTE: You must enclose a \$40.00 application fee payment.** Your check or money order should be made payable to the New York State Department of Health. The check or check stub must indicate the applicant's name.

1. PERSONAL INFORMATION: The authority for the New York State Department of Health, Wadsworth Center, Clinical Laboratory Evaluation Program to request personal information from you, including identifying numbers such as Federal Social Security numbers, and the authority to maintain such information is found in Section 5 of the New York State Tax Law. Disclosure of this information by you is mandatory. This information will be used for tax administration purposes and for any other purposes authorized by the Tax Law. The Administrator of the Clinical Laboratory Evaluation Program is responsible for maintaining the records of such information. The administrator can be reached by writing to: Clinical Laboratory Evaluation Program, Wadsworth Center, New York State Department of Health, Empire State Plaza, PO Box 509, Albany, NY 12201-0509.

E-mail addresses may be used to send electronic reminders concerning the status of your application and will not be used for any other purposes.

2. GRADUATE/PROFESSIONAL EDUCATION: List all medical and graduate schools attended in chronological order whether or not a degree was received. Applicants with a doctoral degree in a chemical, physical, or biological science must provide an official transcript of their doctoral studies. Doctoral degrees earned at foreign colleges or universities must be evaluated for equivalency to the requirements of schools in the United States. Equivalency evaluations must be performed by the International Education Research Foundation, Inc., Credentials Evaluation Service, Post Office Box 3665, Culver City, California 90231-3655, Telephone: (310) 258-9451; Fax: (310) 342-7086. Evaluations are valid only if received in a sealed envelope or directly from the International Education Research Foundation.

3. BOARD CERTIFICATION: Enter abbreviation of board and specialty (see below) and date certified. Applicants must provide a copy of their board certificate(s) and any recertifications. If you have completed all requirements for certification but a certificate has not yet been issued to you, a letter from the board to the Clinical Laboratory Evaluation Program, stating that you have successfully completed all requirements including all appropriate examination(s), is acceptable.

ABBREVIATIONS FOR BOARD CERTIFICATION:

ABCC(CC)	American Board of Clinical Chemistry in Clinical Chemistry
ABCC(TC)	American Board of Clinical Chemistry in Toxicological Chemistry
ABD	American Board of Dermatology
ABFT	American Board of Forensic Toxicology
ABIM(Hem)	American Board of Internal Medicine in Hematology
ABMLI	American Board of Medical Laboratory Immunology
ABMM	American Board of Medical Microbiology
ABOMP	American Board of Oral and Maxillofacial Pathology (formerly ABOP)
ABP(AP)	American Board of Pathology in Anatomic Pathology
ABP(BB/TM)	American Board of Pathology in Blood Banking/Transfusion Medicine
ABP(CP)	American Board of Pathology in Clinical Pathology
ABP(DP)	American Board of Pathology in Dermatopathology
ABP(MMB)	American Board of Pathology in Medical Microbiology

4. **LICENSURE:** Physicians and dentists who are licensed and registered with the New York State Education Department must provide a copy of their current registration. Applicants not licensed in New York State but in another state must provide a copy of their current registration in their state of practice. Unlicensed applicants must provide an **official** transcript of their medical studies.

5. **POSTDOCTORAL TRAINING AND EXPERIENCE:** List all positions held in reverse chronological order. List any additional information in the same format on an attached continuation sheet.

6. **CURRENT EMPLOYMENT/EXPERIENCE:** List all sites of current employment, along with job titles at each site, whether or not you serve as laboratory director/assistant director, the name(s) of your supervisor(s), if any, and provide a description of your laboratory duties and areas of responsibility. If you are currently unemployed, retired, or otherwise inactive, indicate under Description of Duties.

7. **CATEGORIES REQUESTED:** **Be sure to check off each category you seek to hold on your certificate.** See **DEFINITION AND SCOPE OF NEW YORK STATE CATEGORIES** included with these instructions. To direct clinical testing in any category in a facility under New York State laboratory permit, you must hold the appropriate category on your certificate of qualification. See attached **CERTIFICATE OF QUALIFICATION CATEGORIES REQUIRED TO DIRECT CURRENT PERMIT CATEGORIES** included with these instructions.

When applying for CQ categories, please note the following definitions:

Experience means four years of postdoctoral training and/or experience in an acceptable laboratory, including two years in current methods and techniques in each category sought and in general laboratory management, or an equivalent combination of training and/or experience. Training and/or experience must be documented in the form of letters from laboratory directors or other individuals with whom the training or experience was acquired. These letters should state specific details about the dates and type of training and experience, including laboratory name, address, facility type (hospital, medical research, etc.), and types and numbers of laboratory tests performed, supervised and/or directed. Letters from administrators or other responsible third parties are acceptable only if the applicant documents that primary supervisors are not available. **Letters documenting your experience and a current curriculum vitae with a bibliography, must be attached to this application when a candidate is applying for a certificate of qualification by means of training or experience.**

Recency means acceptable training or experience in laboratory medicine, or board certification or recertification, within the six years prior to this application. If you are applying for a category that has a qualifying board listed on page 1, and you have been certified or recertified by that board within six years of your application, specific letters of documentation attesting to your training/experience gained within the previous six years are not required unless experience is indicated as an additional requirement for the category. If you were certified/recertified more than six years prior to your application, one or more letters of documentation attesting to your recent training/experience gained within the previous six years are required. Individuals who are not board certified, or who are certified by a board that is not indicated on page 1, must provide letters of documentation attesting to their training/experience (as explained under Experience above), a portion of which must have been obtained within the previous six years.

Abbreviations for board certification. See instructions to Item 3, **BOARD CERTIFICATION**.

8. **CERTIFICATION:** Check off the appropriate boxes in part a. The application must be signed and dated in part b.

You must enclose a \$40.00 application fee payment. Your check or money order should be made payable to the New York State Department of Health. Submit forms and the \$ 40.00 application fee to:

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DEFINITION AND SCOPE OF NEW YORK STATE CERTIFICATE OF QUALIFICATION CATEGORIES

ANDROLOGY. All aspects of andrology testing performed on patients and donors for the assessment of fertility or for the assessment of semen intended for use in artificial insemination or assisted reproductive procedures. The category includes tests such as sperm concentration/count, sperm motility, sperm morphology, semen biochemical tests, cervical mucus penetration tests, anti-sperm antibody tests, and sperm-egg interaction tests. The category does not include endocrinology tests, such as measurement of FSH or LH activity.

BACTERIOLOGY. All aspects of bacteriology testing from Gram stains only to full workup of anaerobes and aerobes. Holder is also qualified to direct restricted virology testing in VIROLOGY-DIRECT DETECTION and WET MOUNTS.

BLOOD BANKING: COLLECTION-COMPREHENSIVE. The selection of donors, collection of blood or blood components, and preparation of blood components for allogeneic or autogeneic transfusion, or for fractionation into infusible plasma derivatives. Donor screening for hemoglobin/hematocrit, plus total serum protein of plasmapheresis donors, mandated immunohematologic donor testing including blood grouping and alloantibody screening, and mandated serologic and enzymologic donor testing for infectious blood-borne agents in the blood collection facility are included in this category.

BLOOD BANKING: COLLECTION-LIMITED. The collection of blood or blood components for autogeneic transfusion. Mandated transfusion-related immunohematologic testing of donor blood. This category excludes testing for transmissible disease markers. Testing for transmissible disease markers may be directed under a Certificate of Qualification in any of the applicable categories described for Blood Banking: Collection-Comprehensive.

BLOOD LEAD. The quantitative determination of lead in blood for screening and/or diagnosis of lead poisoning. Holder is also qualified to direct TRACE ELEMENTS.

BLOOD pH AND GASES. Measurement of blood pH, pO₂, and pCO₂. Holder is also qualified to direct hemoglobin/hematocrit testing and/or blood electrolytes testing when performed on blood gas instruments for analysis of blood pH and gases and related metabolic parameters.

CELLULAR IMMUNOLOGY. Covers the analysis of function and phenotype in the immune system, including:

Lymphoid Function (formerly Limited I) - *in vitro* testing of lymphocyte function;

Lymphoid Immunophenotyping (formerly Limited II) - enumeration of non-malignant lymphocyte subsets by flow cytometry, which may be **restricted to T-Lymphoid Immunophenotyping (formerly Limited IIB)** as required, for individuals who only have experience with CD4+ and CD8+ T-lymphocyte enumeration by flow cytometry or non-flow cytometric methods;

Non-Lymphoid Analysis (formerly Limited III) - which may be **restricted to Non-Lymphoid Function**, for individuals who only have experience with *in vitro* testing of non-lymphoid function, e.g., functional analysis of monocytes and granulocytes; or **restricted to Non-Lymphoid Immunophenotyping**, for individuals who only have experience with the enumeration of non-malignant, non-lymphoid subsets by flow cytometry, e.g., analysis of monocytes, granulocytes, and hematopoietic stem cells; and

Malignant Leukocyte Immunophenotyping (formerly Limited IV) - immunophenotyping of leukemias and lymphomas by flow cytometry.

Lymphoid Function or Non-Lymphoid Function also covers the quantification of cytokines in serum, plasma, or CSF.

Note: For renewal applicants who currently hold the Cellular Immunology III category, the appropriate limitation will be assigned as part of a review of your renewal application and experience documentation currently on file; please provide a summary of your current experience in this area as part of your renewal application to assist our reviewer in assigning the correct category.

CLINICAL CHEMISTRY. General chemistry testing including electrolytes, metals and metal ions, substrates, metabolites, lipids, and proteins in blood or other patient materials. Also includes clinical enzymology. Holder also qualified to direct ONCOLOGY - SERA AND SOLUBLE TUMOR MARKERS, TRACE ELEMENTS, URINALYSIS and URINE PREGNANCY TESTING. Biochemistry testing for inherited metabolic disease is covered under Genetic Testing.

CLINICAL TOXICOLOGY. The screening for or qualitative determination of drugs, therapeutic or abused, in urine, blood, or other body fluids, for patient management, emergency toxicology screening, or drug rehabilitation monitoring.

CYTOGENETICS. The special culture and microscopic examination of metaphase chromosomes from cells from blood, body fluids, or other tissues to detect changes diagnostic of or associated with hereditary disorders, neoplastic diseases, or possible mutagenesis.

CYTOPATHOLOGY. The microscopic examination of cells exfoliated from epithelial surfaces or removed from tissues and cavities.

DIAGNOSTIC IMMUNOLOGY. Serologic tests for autoantibodies (exclusive of those against blood cells as performed in HEMATOLOGY, IMMUNOHEMATOLOGY, and HISTOCOMPATIBILITY TESTING), for antibody or antigen markers of infectious diseases, and tests for nonspecific reactive indicators of infectious diseases. The category also includes HIV serology. Covers both diagnostic serologic testing on patient specimens and mandated serologic testing of donors of blood, organs, or other tissues for infectious blood-borne agents. Holder is also qualified to direct URINE PREGNANCY TESTING, CYTOKINES, and MYCOLOGY - DIRECT DETECTION.

ENDOCRINOLOGY. The measurement of hormones, hormone-like molecules, and their metabolites in blood or other patient materials, and analysis of their effects on metabolism. The category also includes vitamin assays (B6, B12, folate). Holder is also qualified to direct URINE PREGNANCY TESTING.

ERYTHROCYTE PROTOPORPHYRIN. The quantitative determination of erythrocyte protoporphyrin, as free protoporphyrin IX or as zinc protoporphyrin, for lead toxicity or monitoring the trends in disruption of heme biosynthesis.

FETAL DEFECT MARKERS. The quantitative measurement of biomarkers in bodily fluids (e.g. maternal serum, amniotic fluid) during pregnancy (any trimester), with the purpose of assessing the risk for fetal defects, such as neural tube defects and chromosomal abnormalities (e.g. Down's syndrome by multiple marker assay). Markers measured include, but are not limited to, alpha-fetoprotein (AFP), beta-human chorionic gonadotropin (beta-hCG), unconjugated estriol (uE3), inhibin A, and PAPP-A.

FORENSIC IDENTITY. The resolution of forensic identity issues in accordance with mandated legal protocols; testing of subject materials for histocompatibility markers, red cell and serum markers, and/or DNA markers.

FORENSIC TOXICOLOGY. The qualitative detection and semiquantitative or quantitative confirmation of drugs or other toxic substances in blood, body fluids, tissues, or other subject materials under protocols for sample custody, laboratory security, and subject confidentiality, with interpretation of findings in certain legal contexts (e.g. workplace drug abuse screening, issues of driving while intoxicated). Holder is also qualified to direct CLINICAL TOXICOLOGY.

GENETIC TESTING. The performance of procedures for the purpose of providing information for the diagnosis of a genetic disease or its carrier state or risk assessment for drug metabolism and/or hemostasis. Predisposition testing for inherited cancers; tests using genetic markers to monitor disease progression, therapeutic response, preimplantation diagnosis; and pharmacogenetics applications are all included in the Genetic Testing category. In addition, this category includes the use of genetic markers to test for zygosity for pregnancy management and maternal cell contamination in the context of genetic diagnosis. Some applications of these methodologies are excluded from approval in the Genetic Testing category, such as paternity testing, forensic testing, somatic changes in tumor tissue (molecular oncology) and tissue typing services. The category may be limited to molecular or biochemical assays, depending on experience documented.

HEMATOLOGY. Covers cellular hematology (blood cell counts and differentials), hemostasis and coagulation, and specialized screening and quantitative hematology tests. Semen analysis and other non-endocrinologic andrology tests are now included under ANDROLOGY. Holder is also qualified to direct URINALYSIS and CELLULAR IMMUNOLOGY-T-LYMPHOID IMMUNOPHENOTYPING (dependent on instrumentation).

HISTOCOMPATIBILITY. The determination of phenotypic or genotypic polymorphisms of the human leukocyte antigen system by typing of lymphocytes or other cell materials for blood component transfusion, tissue or organ transplantation or analysis of HLA linkage with specific diseases. Typing methods may be based on cell-mediated immunity, serology, or DNA markers.

HISTOPATHOLOGY. Gross and microscopic examination of organ systems, organs, and tissues. The subcategory of ORAL PATHOLOGY is limited to examination of the oral cavity; DERMATOPATHOLOGY to the examination of the skin. Individuals certified by the American Board of Dermatology rather than the American Board of Pathology in Dermatopathology may qualify for Dermatopathology-Mohs testing.

IMMUNOHEMATOLOGY. Covers the testing of red blood cells, serum, or plasma for purposes not directly related to blood transfusion including: blood grouping, antibody identification, red cell phenotyping, and direct antiglobulin testing.

MYCOBACTERIOLOGY. All aspects of mycobacteriology testing from smear examination only for acid-fast bacteria to full workup of all mycobacteria encountered in the clinical mycobacteriology laboratory.

MYCOLOGY. All aspects of mycology from workup of yeasts only to all fungi and actinomycetes encountered in the clinical mycology laboratory. Holder is also qualified to direct WET MOUNTS.

ONCOLOGY - SERA AND SOLUBLE TUMOR MARKERS. The performance of tests for sera and other soluble tumor markers found in body fluids (serum, urine, etc.) including, but not limited to, tests for alphafetoprotein (AFP), prostate specific antigen (PSA), carcinoembryonic antigen (CEA), CA125, CA27-29, NMP22. Results from these tests are generally quantitative. Methodologies used include radioimmunoassay (RIA), enzymeimmunoassay (EIA) or chemiluminoassay. Holders of a certificate of qualification in Clinical Chemistry (unrestricted) are also qualified to perform this testing.

ONCOLOGY-CELLULAR TUMOR MARKERS (formerly Oncology-Molecular Detection). This category is for laboratories performing tests on cellular material to detect tumor-specific acquired genetic or phenotypic alterations. It includes, but is not limited to, tests that detect chromosomal rearrangements by Southern blot or (RT)-PCR, detection of mutations in oncogenes or tumor suppressor genes (e.g., p53) by any technique (e.g., sequencing, SSCP, and chip analysis) and detection of altered gene/protein expression by DNA chip analysis, Western blot or any other appropriate semi-quantitative technique. Also included in this category is *ex vivo* determination of chemotherapeutic drug sensitivity.

PARASITOLOGY. Examination of feces, blood, urine, or other patient-derived materials for helminth and protozoan parasites. Holder is also qualified to direct WET MOUNTS.

PARENTAGE/IDENTITY TESTING. The resolution of paternity issues in accordance with mandated legal protocols; testing of subject specimens for histocompatibility markers and/or DNA markers.

THERAPEUTIC SUBSTANCE MONITORING/ QUANTITATIVE TOXICOLOGY. Quantitative determination of therapeutic or abused drugs in blood or body fluids to monitor dosage or check for toxicity.

TRANSFUSION SERVICES. The selection and storage of donor blood, blood components, or derivatives for transfusion. Mandated transfusion-related immunohematologic testing including blood grouping of each recipient and unit to be transfused, screening recipients for unexpected alloantibodies and compatibility testing. Directors of transfusion services serving New York State recipients must be licensed and currently registered as physicians in New York State.

TRANSPLANT MONITORING. The performance of molecular tests to monitor the status of a transplanted organ or tissue. This includes the monitoring of engraftment following the transplantation of hematopoietic progenitor cells (e.g., bone marrow) by short tandem repeat (STR) analysis and monitoring for rejection using gene expression analysis. This does not include cellular based assays for monitoring rejection or chemistry assays for determining immunosuppressive drug levels. The performance of fluorescence in situ hybridization (FISH) methodologies to monitoring engraftment requires a certificate in the Cytogenetics category.

VIROLOGY. All aspects of virology testing including molecular tests, direct antigen detection of selected viruses, and isolation and identification of all viruses encountered in a clinical virology laboratory.

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**CERTIFICATE OF QUALIFICATION CATEGORIES
REQUIRED TO DIRECT CURRENT PERMIT CATEGORIES**

Director Certificate of Qualification Category*	Laboratory Permit Category*
Andrology	Andrology
Bacteriology	Bacteriology - all subcategories Virology - Direct Detection Wet Mounts
Blood Banking Collection - Comprehensive	Bacteriology- Other (for bacterial screening) Blood Services - Collection - all subcategories Blood Services - Plasma Processing Immunohematology Diagnostic Immunology - Donor Services Serology Human Immunodeficiency Virus - all subcategories, donor testing only Clinical Chemistry - limited to ALT and total serum protein Cellular Hematology
Blood Banking Collection - Limited	Blood Services - Collection - Autogeneic Only Immunohematology
Blood Lead	Toxicology - Blood Lead Trace Elements
Blood pH and Gases	Blood pH and Gases Hematology - Cellular Hematology - limited to hemoglobin and hematocrit tests only Clinical Chemistry - limited to blood electrolytes
Cellular Immunology – Lymphoid Function (formerly Limited I)	Cellular Immunology – Lymphoid Function; Cytokines
Cellular Immunology - Lymphoid Immunophenotyping (formerly Limited II/IIB)	Cellular Immunology – Lymphoid Immunophenotyping; T-Lymphoid Immunophenotyping
Cellular Immunology – Non-Lymphoid Analysis (formerly Limited III)	Cellular Immunology – Non-Lymphoid Function; Non-Lymphoid Immunophenotyping; Cytokines
Cellular Immunology – Malignant Leukocyte Immunophenotyping (formerly Limited IV)	Cellular Immunology – Malignant Leukocyte Immunophenotyping
Clinical Chemistry	Clinical Chemistry - all subcategories Oncology - Sera and Soluble Tumor Markers Trace Elements Urinalysis Urine Pregnancy Testing
Clinical Toxicology (formerly Drug Analysis/Qualitative)	Toxicology - Clinical Toxicology-Comprehensive Toxicology - Clinical Toxicology-Initial Testing Only Forensic Toxicology-Initial Testing Only
Cytogenetics	Cytogenetics - all subcategories
Cytopathology	Cytopathology
Diagnostic Immunology	Diagnostic Immunology - all subcategories Human Immunodeficiency Virus - Limited & General Urine Pregnancy Testing Cytokines Mycology-Direct Detection
Endocrinology	Endocrinology (including andrologic endocrinology) Urine Pregnancy Testing
Erythrocyte Protoporphyrin	Toxicology - Erythrocyte Protoporphyrin
Fetal Defect Markers	Fetal Defect Markers

Director Certificate of Qualification Category*	Laboratory Permit Category
Forensic Identity	Forensic Identity
Forensic Toxicology	Toxicology - Forensic Toxicology - Initial & Comprehensive Toxicology - Clinical Toxicology - Comprehensive Toxicology - Clinical Toxicology - Initial Testing Only
Genetic Testing	Genetic Testing - all subcategories
Genetic Testing- limited to Molecular (formerly Genetic Testing limited to DNA)	Genetic Testing – Molecular
Genetic Testing-limited to Biochemistry	Genetic Testing - Biochemistry
Hematology	Hematology - all subcategories Cellular Immunology – T-Lymphoid Immunophenotyping (dependent on instrumentation) Urinalysis
Histocompatibility	Histocompatibility - all subcategories
Histopathology	Histopathology - all subcategories
Oral Pathology	Histopathology - Oral Pathology
Dermatopathology	Histopathology - Dermatopathology
Immunochemistry (<i>Immunochemistry testing for Transfusion Services or Blood Banking Collection requires a certificate in these categories</i>)	Immunochemistry
Mycobacteriology	Mycobacteriology - all subcategories
Mycology	Mycology - all subcategories Wet Mounts
Oncology - Sera & Soluble Tumor Markers	Oncology - Sera & Soluble Tumor Markers
Oncology – Cellular Tumor Markers (formerly Oncology – Molecular Detection)	Oncology – Cellular Tumor Markers (formerly Oncology-Molecular Detection)
Parasitology	Parasitology-all subcategories Wet Mounts
Parentage/Identity Testing - HLA Testing	Parentage/Identity Testing - HLA Testing Only
Parentage/Identity Testing - DNA Testing	Parentage/Identity Testing - DNA Testing Only
Therapeutic Substance Monitoring/Quantitative Toxicology	Therapeutic Substance Monitoring/Quantitative Toxicology
Transfusion Services	Blood Services - Transfusion Blood Services - Transfusion - Storage Only Immunochemistry
Transplant Monitoring	Transplant Monitoring
Virology	Virology - all subcategories Human Immunodeficiency Virus - Viral Identification

* Certificate and permit categories may be limited to specific subcategories, tests, and analytes as appropriate to training and experience of applicant and/or the test(s) capabilities of the clinical laboratory.