

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: CLEPCQ@health.state.ny.us  
Web: www.wadsworth.org/clep

DEFINITION AND SCOPE  
OF  
CERTIFICATE OF QUALIFICATION  
CATEGORIES

**ANDROLOGY.** All aspects of andrology testing performed on patients and donors for the assessment of male fertility. The category includes tests such as sperm concentration/count, sperm motility, sperm morphology, semen biochemical tests, sperm DNA fragmentation assays, cervical mucus penetration tests, anti-sperm and anti-ovary antibody tests, sperm-egg interaction tests and other sperm function tests. Qualitative post-vasectomy testing for the presence or absence of viable sperm may be performed under this category or Hematology. This category does not include endocrinology tests, such as measurement of FSH or LH activity. This category does not include genetic testing for markers of infertility and preimplantation diagnosis of embryos.

**BACTERIOLOGY.** All aspects of bacteriology testing from gram stains to full work-up of anaerobes and aerobes. CQ holder also qualified to direct the permit category of Virology-Restricted (for antigen detection). CQ holder must also hold Mycology and Parasitology to direct the permit category of 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 does not include testing for transmissible disease markers.

**BLOOD LEAD.** The quantitative determination of lead in blood for screening and/or diagnosis of lead poisoning. CQ holder is also qualified to direct the permit category of Trace Elements.

**BLOOD pH AND GASES.** Measurement of blood pH, pO<sub>2</sub>, and pCO<sub>2</sub>. CQ holder 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.**

**Leukocyte Function** - covers *in vitro* testing of lymphoid function (e.g. analysis of lymphocytes including proliferation, cytokine production, and cytolytic activity) and non-lymphoid function (e.g. analysis of granulocytes or monocytes including chemotaxis, adherence, phagocytosis, oxidative burst, and degranulation). This category also covers the quantification of cytokines in serum, plasma, or CSF.

**Non-malignant Leukocyte Immunophenotyping** - covers identification and enumeration of non-malignant leukocyte populations by flow cytometry. This immunophenotyping may include lymphoid and T-lymphoid subsets or non-lymphoid subsets (e.g. stem cell analysis, PNH analysis, LAD analysis, Toll-like Receptor analysis and evaluation of intracellular signaling molecules).

**Malignant Leukocyte Immunophenotyping** - covers identification and characterization of leukemias and lymphomas by flow cytometry.

**CLINICAL CHEMISTRY.** General chemistry testing including enzymes, electrolytes, metal analysis, substrates, metabolites, lipids, and proteins in blood or other patient materials. This category does not include testing in areas defined by Blood pH and Gases, Trace Elements, and Therapeutic Substance Monitoring/Quantitative Toxicology. Biochemistry testing for inherited metabolic disease is covered under Genetic Testing. CQ holder also qualified to direct the permit categories of Cytokines, Oncology - Soluble Tumor Markers, Toxicology – Blood Lead-Screening, Toxicology – Erythrocyte Protoporphyrin, Urinalysis and Urine Pregnancy 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. CQ holder also qualified to direct the permit category of Forensic Toxicology – Initial Testing Only.

**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. Array-based copy number analysis assays for constitutional disorders may be performed under this category or Genetic Testing – Molecular. Oversight of FISH testing to confirm abnormal array results requires a Cytogenetics CQ.

**CYTOPATHOLOGY.** The microscopic examination of cells exfoliated from epithelial surfaces or removed from tissues and cavities by brushing, scraping, washing, lavage or needle aspiration. CQ holder also qualified to direct the permit category of Oncology – HPV Testing.

**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. This category 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. CQ holder also qualified to direct the permit categories of Cytokines, HIV – Screening Tests Only, and Mycology – Restricted, Urine Pregnancy Testing and Virology – Restricted.

**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 (e.g. B6, B12, folate). CQ holder also qualified to direct the permit category of Urine Pregnancy.

**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 serological and 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). CQ holder also qualified to direct the permit categories of Clinical Toxicology – Comprehensive and Clinical Toxicology – Initial Testing Only.

**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 included under Andrology. CQ holder also qualified to direct the permit categories of Hematology, Cellular Immunology- Non-malignant Leukocyte Immunophenotyping (dependent on instrumentation), Toxicology – Blood Lead Screening Tests Only, Toxicology – Erythrocyte Protoporphyrin, and Urinalysis.

**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. CQ holder must also hold Bacteriology and Parasitology to direct the permit category of Wet Mounts.

**ONCOLOGY-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. A CQ holder in Clinical Chemistry (unrestricted) is also qualified to perform this testing.

**ONCOLOGY- MOLECULAR AND CELLULAR TUMOR MARKERS.** 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. CQ holder must also hold Bacteriology and Mycology to direct the permit category of 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.

**TRACE ELEMENTS.** Testing for trace elements (e.g. arsenic, cadmium, mercury, copper, zinc, selenium, aluminum) in clinical specimens, including whole blood, serum or urine. CQ holder also qualified to direct the permit categories of Toxicology – Blood Lead Comprehensive and Toxicology – Blood Lead Screening Tests Only.

**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. CQ holder also qualified to direct the permit category of Immunohematology.

**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 CQ 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. CQ holder also qualified to direct the permit categories of HIV – Viral Identification and Oncology – HPV Testing.