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Please refer to the New York State Department of Health Clinical Laboratory Reference System Guide to Program Requirements and Services to obtain information regarding proficiency testing materials available in each category.

ANDROLOGY

This category is required for laboratories that perform tests of male fertility on patient or donor specimens. These tests include, but are not limited to, semen analysis (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 the categories of either Andrology or Hematology. Measurements of reproductive hormones, such as testosterone, FSH or LH activity, are included in the Endocrinology category. Testing to detect genetic markers of infertility and preimplantation genetic diagnosis of embryos is included in the Genetic Testing – Molecular category.

BACTERIOLOGY

COMPREHENSIVE: This category is for laboratories that examine any type of clinical specimen for aerobic and/or anaerobic bacteria. These laboratories identify organisms to the genus and species level and may also perform antimicrobial susceptibility testing, molecular assays and direct detection techniques. Laboratories holding this category may also perform testing as described under any of the categories listed below.

GRAM STAINS: This category is for laboratories that prepare and examine gram-stained smears for the presence of bacterial organisms.

RESTRICTED: This category is for laboratories that restrict their testing to one or more of the following :

Gonorrhea and Chlamydia: for laboratories testing specimens for *Neisseria gonorrhoeae* and/or *Chlamydia trachomatis*.

Throat culture: for laboratories that perform throat cultures for Group A *Streptococcus* only.

Urine culture: for laboratories that isolate and identify bacteria from urine by culture. Identification may range from gram stain reactions to full genus and species identification, as well as antimicrobial susceptibility testing.

Antigen detection: for laboratories that use antigen detection techniques to examine specimens for one or more bacterial organisms.

OTHER: This category is for laboratories that perform only specialized tests not covered in the categories above or when no New York State proficiency test is available.

BLOOD pH AND GASES

This category is for laboratories performing measurements of blood pH, pCO₂ and/or pO₂. Blood gas laboratories may also perform testing for carboxyhemoglobin, oxyhemoglobin, methemoglobin and carbon monoxide under this category or they may be performed by a laboratory holding the category of Clinical Chemistry.

BLOOD SERVICES

Blood Services categories are for blood banks that collect, process, and/or issue blood for transfusion. One or more categories may be appropriate based on the scope of services. Additional permit categories may be needed if testing of donor specimens is performed on-site:

Immunohematology (red blood cell, granulocyte, and/or platelet-related testing for blood collection, transfusion, or pregnancy-associated purposes), Diagnostic Immunology – Donor Services Serology (serologic tests for specific markers of infectious disease), Hematology (for donor and/or unit qualification), Virology – Comprehensive (nucleic acid testing for viruses other than HIV), and Bacteriology – Other (bacteria detection).

COLLECTION: This category is for blood banks that collect, process, store, and distribute allogeneic and/or autogeneic blood for transfusion or fractionation purposes.

COLLECTION - AUTOGENEIC ONLY: This category is for blood banks that collect only blood for autogeneic (autologous) transfusion and do not cross over these units or their components for allogeneic use.

TRANSFUSION: This category is for blood banks that perform pre-transfusion testing and issue blood for transfusion. Such sites must also hold Immunohematology. A hospital's permit in Blood Services-Transfusion covers transfusions performed at any site owned and operated by the hospital AND located on the hospital campus. In order to perform transfusions, remote satellite sites and non-hospital sites that do not meet these criteria and do not hold a permit in the Blood Services – Transfusion-Storage Only category must be approved as a **LIMITED TRANSFUSION SERVICE**. Inquiries regarding Limited Transfusion Services should be directed to the Blood and Tissue Resources Program at (518) 485-5341.

TRANSFUSION - STORAGE ONLY: This category is for permitted laboratories that issue blood for transfusion, but rely on a blood bank holding a permit in Blood Services – Transfusion and Immunohematology to perform pre-transfusion testing.

PLASMA PROCESSING: This category is for facilities that fractionate plasma into infusable derivatives and/or perform viral reduction/inactivation of pooled plasma.

CELLULAR IMMUNOLOGY

Laboratories analyzing the function and/or phenotype of cells in the immune system must hold any or all of the categories below that describe the scope of their services.

LEUKOCYTE FUNCTION: This category is for laboratories testing **lymphocyte function** by *in vitro* assays (e.g., antigen-induced proliferation, alloantigen-stimulated proliferation, mitogen-stimulated proliferation, cytolytic assays, and cytokine or immunoglobulin production). This category also includes testing monocytic and myeloid functions by *in vitro* assays (e.g., neutrophil generation of reactive oxygen species, monocyte phagocytosis, and production of cytokines).

NOTE: The determination of cytokines in serum, plasma or CSF is included in the Cytokine category.

CELLULAR IMMUNOLOGY – continued

NON-MALIGNANT LEUKOCYTE IMMUNOPHENOTYPING: This category is for laboratories performing Lymphoid and T-Lymphoid Immunophenotyping. This includes the identification and enumeration of non-malignant lymphocytes that bear different surface markers for the purpose of assessing the immunological status of an individual (e.g., quantifying CD4⁺ T-lymphocytes). This category also includes Non-Lymphoid Immunophenotyping. This includes methodologies to quantify the number of non-malignant leukocytes other than lymphocytes (e.g., viable Lin⁻/CD34⁺ stem cells; CD55 & CD59 for PNH; CD15s, CD11a, b, c & CD18 for LAD; and TLRs for innate immunity).

MALIGNANT LEUKOCYTE IMMUNOPHENOTYPING: This category is for laboratories performing identification and characterization of leukemias or lymphomas in blood and tissue specimens based on cell phenotype (including cell surface and cytoplasmic antigens) with or without ploidy analysis.

CLINICAL CHEMISTRY

This category is for laboratories performing one or more of the analytes available in the New York State proficiency testing program. A list of these analytes can be found in the Program Guide available on our website. All diagnostic clinical chemistry tests including substrates, enzymes, electrolytes, and metal analyses are included in this category. Laboratories issued a Clinical Chemistry permit may perform a full scope of clinical chemistry testing except in those areas defined by the Blood pH and Gases, Trace Elements, Therapeutic Substance Monitoring/Quantitative Toxicology, Endocrinology and/or the Genetic Testing - Biochemistry categories.

CLINICAL CHEMISTRY – RESTRICTED: This category is for laboratories that only perform tests for substrates, enzymes, and electrolytes that are not included in the New York State proficiency testing program for clinical chemistry, except for tests that are included in the Blood pH and Gases, Trace Elements, Therapeutic Substance Monitoring/Quantitative Toxicology, Endocrinology and/or the Genetic Testing - Biochemistry categories.

CYTOGENETICS

Cytogenetics is the analysis of the chromosome complement of human cells for changes in chromosome number or structure. Methods used include metaphase chromosome analysis by G-banding, fluorescence *in situ* hybridization (FISH), and array comparative genomic hybridization (aCGH). Molecular cytogenetic assays such as FISH and aCGH are adjunct methods to standard metaphase chromosome analysis under many circumstances and, unless approved or cleared by the FDA, must be validated and submitted to the department for approval.

Array-based copy number assays for constitutional disorders may be performed under a Cytogenetics – Prenatal, Cytogenetics - Restricted, or a Genetic Testing - Molecular permit. Confirmation of abnormal array results is required by all laboratories; confirmation by FISH requires a permit in the appropriate Cytogenetics category, while PCR-based confirmation methods require a Genetic Testing - Molecular permit. Array-based copy number assays for acquired aberrations are performed under the Oncology - Molecular and Cellular Tumor Markers category under most circumstances.

PRENATAL: This category is for laboratories performing prenatal and preimplantation cytogenetic diagnosis. Laboratories applying for this category must demonstrate accuracy and timeliness of diagnosis for amniotic fluid and must submit method validation documentation for approval to offer preimplantation testing.

CYTOGENETICS – continued

CANCER: This category is for laboratories performing diagnostic evaluations, including metaphase and interphase FISH, of blood dyscrasias and acquired cytogenetic changes of neoplasias.

Chromosome enumeration probe FISH testing (CEPX/CEPY) to monitor bone marrow transplant status is performed under this category.

In addition, interphase FISH to detect acquired changes in chromosome number or structure in non-dividing cells may be performed under an Oncology - Molecular and Cellular Tumor Markers permit; provided the Oncology laboratory has a documented arrangement with a permitted Cytogenetics laboratory and/or a qualified Cytogeneticist to assist in the required metaphase components of validation and to provide ongoing consultation. A limited number of FDA - cleared FISH tests may also be performed under Histopathology - General or Cytopathology - Non-gynecological Testing (refer to those category descriptions for details).

RESTRICTED: This category is for laboratories performing cytogenetic tests exclusive of prenatal diagnosis and cancer cytogenetics. While testing of material derived from an ongoing pregnancy falls under the category of Cytogenetics - Prenatal, testing of material derived from a failed pregnancy (e.g. products of conception) falls under Cytogenetics - Restricted.

CYTOKINES

This category is for laboratories performing the quantification of cytokines and chemokines in biological fluids, by methods such as ELISA, FIA, or RIA. Cytokines and chemokines include both immunoregulatory molecules as well as molecules that influence the activity of other organ systems. The measurement of cytokines and chemokines in leukocytes, or the measurement of cytokines in supernatant from *in vitro* leukocyte cultures would be included in the Cellular Immunology - Leukocyte Function category.

CYTOPATHOLOGY

This category is for laboratories preparing and examining cells and tissue fragments that have exfoliated freely from tissue surfaces or that have been collected by brushing, scraping, washing, lavage or needle aspiration. The laboratory must hold each appropriate subcategory for the testing being performed as described below:

GYNECOLOGICAL TESTING: This category is for laboratories that perform gynecological cytopathology testing on patient specimens for diagnostic or prognostic purposes. All laboratories offering gynecologic cytopathology services are required to enroll in a proficiency testing program approved by the Centers for Medicare and Medicaid Services (CMS). The New York State Department of Health does not currently offer proficiency testing in this category.

NON-GYNECOLOGICAL TESTING: This category is for laboratories that perform non-gynecological cytopathology testing on patient specimens for diagnostic or prognostic purposes. Approved laboratories may offer the FDA-cleared UroVysion™ assay under this category.

DIAGNOSTIC IMMUNOLOGY

The Diagnostic Immunology categories are for laboratories performing the following types of tests: serologic tests for autoantibodies (excluding tests for antibodies against blood cells performed under the categories of Hematology, Immunohematology, and Histocompatibility and excluding tests for antibodies against spermatozoa performed under the category of Andrology), serologic tests for specific markers of infectious diseases or exposure to such diseases (e.g., antibody/antigen), and tests for nonspecific indicators of infectious diseases or exposure to such diseases (e.g., immunoglobulin or complement levels). Serologic testing for human immunodeficiency virus may be performed under the category of Diagnostic Immunology – Diagnostic Services Serology or Diagnostic Immunology – Donor Services Serology depending on the nature of the laboratory's service.

DIAGNOSTIC SERVICES SEROLOGY: This category is for laboratories that perform any diagnostic immunologic test on patient specimens for diagnostic or prognostic purposes.

DONOR SERVICES SEROLOGY: This category is for donor banks, and laboratories under contract to donor banks, that perform tests on donors of human organs, tissues and/or blood for transfer, transfusion or transplantation. Mandated tests include syphilis-reagin or treponemal antibody, hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), hepatitis C antibody (anti-HCV), human T lymphotropic virus I/II antibody and human immunodeficiency virus (HIV). However, donor banks that perform any additional serologic tests, e.g., cytomegalovirus (CMV) antibody, must also hold this category. Donor Services laboratories must also hold the category Diagnostic Services Serology if they perform tests on patient specimens for diagnostic or prognostic purposes.

ENDOCRINOLOGY

This category is for laboratories evaluating endocrine function and vitamin status in the body by measuring hormones, vitamins and related analytes in body fluids.

FETAL DEFECT MARKERS

This category is for laboratories performing assays for prenatal screening for chromosomal abnormalities or other defects of the fetus (e.g., neural tube defects) in any trimester. These assays measure analytes in maternal serum, amniotic fluid, and other bodily fluids. Results from these tests are generally quantitative. Methodologies used include radioimmunoassay (RIA), enzyme immunoassay (EIA) or chemiluminoassay (CIA). Results must be compared to the individual laboratory normative data of weekly values. Laboratories that measure gestational age-dependent Alpha fetoprotein (AFP) in amniotic fluid for neural tube defects by quantitative methods and as a statistical comparison to an internal normative curve must also determine contamination with fetal blood. Methods used include counter immunoelectrophoresis, radioimmunodiffusion, isoelectric focusing (centrifuged fluids), and Kleinhauer-Betke elution technique (uncentrifuged fluids) for the determination of fetomaternal bleed occurring during amniocentesis. Amniotic fluid screening results for neural tube defects need to be confirmed by electrophoretic identification of acetylcholinesterase and fetal hemoglobin. **Please note** that prenatal screening for chromosomal abnormalities using plasma-derived DNA or RNA amplification and sequencing techniques (e.g., MaterniT21™) is performed under the category of Genetic Testing - Molecular.

FORENSIC IDENTITY

This category is for laboratories that perform DNA-based procedures for the determination of identity, or for the determination of parentage, for forensic purposes. Also included under this category are screening procedures to determine the presence of bodily fluids on evidentiary materials for forensic purposes. At this time, the standards for this category are those based on 1) the New York State DOH Forensic Identity Standards, effective March 2008; and 2) the recommendations of the federal DNA Advisory Board and subsequent standards as issued by the Director of the Federal Bureau of Investigation (FBI) as the "Quality Assurance Standards for Forensic DNA Testing Laboratories" and the "Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories", both effective July 1, 2009. The NYS Forensic Identity Standards can be accessed via the Program website at <http://www.wadsworth.org/labcert/lep>. The FBI standards can be accessed via the FBI's websites at <http://www.fbi.gov> in the October 2008 issue of Forensic Science Communications.

GENETIC TESTING

The Genetic Testing categories are for laboratories performing procedures for the purpose of providing information for the diagnosis of a genetic disease or its carrier state, risk assessment for drug metabolism, disease susceptibility, hemostasis, and disease risk and lifestyle assessments. Predisposition testing for inherited cancers, preimplantation diagnosis (including molecular analysis of cells from embryos to detect single gene disorders, haplotype analysis for complex mutations, or HLA haplotyping for a sibling match prior to implantation) and pharmacogenetics applications are all included in the Genetic Testing category. Also, 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 and tests using genetic markers to monitor disease progression.

Some applications of molecular methods are not included in the Genetic Testing categories. Laboratories may also need to hold the additional categories including Forensic Identity, Histocompatibility, Immunohematology, Parentage/Identity, and/or Oncology – Molecular and Cellular Tumor Markers (for somatic changes in tumor tissue), as appropriate.

GENETIC TESTING – MOLECULAR: This category is for laboratories performing diagnostic and predictive genetic testing utilizing DNA and/or RNA-based methodologies. Laboratories performing comparative genomic hybridization (CGH) and confirming results via molecular methods other than FISH may perform the entire test under the Genetic Testing – Molecular category.

GENETIC TESTING – BIOCHEMISTRY: This category is for laboratories performing genetic testing utilizing biochemical procedures in laboratories where a specific genetic diagnosis or carrier status is being determined.

HEMATOLOGY

CELLULAR HEMATOLOGY: This category is for laboratories performing one or more of the following cellular hematology tests: white cell count, red cell count, hemoglobin, hematocrit, automated differentials, and platelet count, with or without other tests such as red cell indices, reticulocyte count, and erythrocyte sedimentation rate. Laboratories performing manual differentials or manual confirmation of abnormal automated differentials must hold the Cytohematology Diagnostic category described below.

HEMATOLOGY - continued

COAGULATION: This category is for laboratories performing routine coagulation testing including prothrombin time, activated partial thromboplastin time and quantitative fibrinogen, with or without other tests such as thrombin time, factor assays and bleeding time.

CYTOHEMATOLOGY DIAGNOSTIC: This category is for laboratories performing manual differentials, smear examinations, or automated differentials with manual confirmation performed on-site. If blood-borne parasites are observed during the routine smear examination, they may be reported as presumptive; however the examination of blood smears specifically for parasites or the identification of parasites requires a permit in the Parasitology - Blood Smears Only category.

HISTOCOMPATIBILITY

GENERAL: This category is for laboratories performing all phases of histocompatibility testing for organ/tissue transplantation. Testing includes HLA antigen typing, antibody screening, and when necessary, crossmatching. Laboratories performing testing to monitor the status of a patient following an organ or tissue transplant must hold the category of Transplant Monitoring.

HLA TYPING ONLY: This category is for laboratories offering only HLA antigen typing. This category would apply to those laboratories performing histocompatibility testing for initial pre-transplant typing, bone marrow donor screenings, disease associations or pharmacogenetics.

HISTOPATHOLOGY

The Histopathology categories are for laboratories performing gross and microscopic examination of tissues, including special stains and immunohistochemistry. Certain *in situ* hybridization tests, such as FDA-cleared fluorescence *in situ* hybridization tests (FISH) for the detection of Her-2/neu and TOP2A gene amplifications can be performed under either the Histopathology – General or Oncology – Molecular and Cellular Tumor Markers categories.

GENERAL: Testing includes all tissue. Testing for HPV in tissue is performed under this category. All other HPV testing is performed under Oncology – Human Papillomavirus Testing.

ORAL PATHOLOGY: Testing is limited to the oral cavity.

DERMATOPATHOLOGY: Testing is limited to skin.

IMMUNOHEMATOLOGY

This category is for laboratories that perform red blood cell-, granulocyte- and/or platelet-related testing for blood collection, transfusion or pregnancy-associated purposes. Methodologies include serologic, molecular and flow cytometric techniques for tests such as: red blood cell antigen and antibody testing, direct antiglobulin testing, compatibility testing, granulocyte antigen and antibody testing, platelet antigen and antibody testing, and assessment of fetomaternal hemorrhage.

MYCOBACTERIOLOGY

COMPREHENSIVE: This category is for laboratories that process and examine smears for acid-fast bacilli, isolate and identify all mycobacteria to the extent of their abilities, and perform susceptibility testing on all Mycobacterium tuberculosis complex organisms. This category also includes testing using molecular methods.

MYCOBACTERIOLOGY - continued

RESTRICTED: This category is for laboratories that restrict their testing to processing and examining smears for acid-fast bacilli, and isolating and identifying all mycobacteria to the extent of their abilities. Susceptibility testing is not performed under this category.

SMEARS ONLY: This category is for laboratories that only process and examine smears for acid-fast bacilli. Laboratories holding this category must submit all specimens for growth detection and identification to a laboratory holding a New York State permit in the appropriate Mycobacteriology category.

MYCOLOGY

COMPREHENSIVE: This category is for laboratories that examine clinical specimens for pathogenic molds and yeasts routinely encountered in a clinical microbiology laboratory. These laboratories are expected to identify fungi to the genus and species level as appropriate. Laboratories holding this category may also perform antifungal susceptibility testing, antigen detection, molecular identification or other tests described under any of the categories listed below.

RESTRICTED: This category is for laboratories that restrict their testing to one or more of the following:

Identification Yeast only: This category is for laboratories that isolate and identify to genus and species, as appropriate, yeast-like fungi routinely encountered in a clinical microbiology laboratory. Laboratories holding this category may also perform susceptibility testing on yeast. These laboratories are expected to refer mold specimens to other laboratories holding a Mycology – Comprehensive permit.

Antigen detection: This category is for laboratories that perform direct antigen detection methods.

OTHER: This category is for laboratories that perform only specialized tests such as KOH mounts, wet mounts, PNA-FISH or any other mycology test not covered in the categories above or when no New York State proficiency test is available.

ONCOLOGY

The Oncology categories includes tests used in tumor screening, diagnosis, prognosis and management, including the standard serum-based tumor markers, as well as tests for tumor cell specific acquired genotypic and/or phenotypic alterations. Due to the different methodologies used, there are three categories:

SOLUBLE TUMOR MARKERS: This category is for laboratories performing tests for soluble tumor markers found in body fluids such as serum, urine, etc. Results from these tests are generally quantitative. Methodologies used include radioimmunoassay (RIA), enzyme immunoassay (EIA), or chemiluminoassay (CIA), as well as mass spectrometry (MS) and bead-based assays such as Luminex®.

MOLECULAR AND CELLULAR TUMOR MARKERS: This category is for laboratories performing tests on cellular or tumor tissue material to detect tumor-specific acquired genetic or phenotypic alterations. It includes, but is not limited to, tests that detect gene rearrangements, chromosomal aberrations such as gain/loss of chromosome regions, translocations, mutations, altered gene/protein expression, and *ex vivo* determination of chemotherapeutic drug sensitivity. Methodologies used are generally, though not exclusively, molecular biology-based, and results can be qualitative and/or quantitative. Array comparative genomic hybridization (aCGH) assays for acquired chromosomal aberrations (gain or loss) may be performed under this category. However, if the confirmatory test is by FISH, then the provisions below for FISH testing apply.

ONCOLOGY - continued

Laboratories that want to perform diagnostic evaluations of blood dyscrasias and acquired cytogenetic changes of neoplasias in non-dividing cells or tissue by interphase FISH may do so under the following provisions:

1. The Oncology laboratory has a documented collaborative arrangement with a permitted Cytogenetics laboratory and/or a qualified Cytogeneticist to assist in performing validations and to provide ongoing consultation. Alternatively, these tests may be offered under the Cytogenetics – Cancer permit.
2. Laboratories that offer interphase FISH testing for hematological neoplasias under the Oncology – Molecular and Cellular Tumor Markers permit category are expected to participate in that category's proficiency testing.
3. A limited number of interphase FISH tests may also be performed under the categories of Histopathology - General or Cytopathology – Non-gynecological (refer to those category descriptions for details)

HUMAN PAPILLOMAVIRUS (HPV) TESTING: This category is for laboratories that perform HPV testing on cells, such as cells collected in liquid media from cervical swabs, as well as various other body locations.

PARASITOLOGY

COMPREHENSIVE: This category is for laboratories that examine patient specimens for parasites. Specimen types include blood, stool, tissue biopsies and other materials submitted for gross or microscopic examination and identification. Laboratories holding this category may also perform antigen detection, molecular identification or other tests described under any of the categories listed below.

BLOOD SMEARS ONLY: This category is for laboratories that only examine blood smears for blood-borne parasites.

RESTRICTED: This category is for laboratories that restrict their testing to immunoassay detection.

OTHER: This category is for laboratories with a restricted test menu, for example, laboratories that perform only specialized tests where proficiency testing from New York State is not available.

PARENTAGE/IDENTITY TESTING

The Parentage/Identity testing category is for laboratories that perform procedures for the determination of parentage or relationship. Laboratories performing parentage and/or identity tests for forensic purposes must hold a permit in the Forensic Identity category.

THERAPEUTIC SUBSTANCE MONITORING/QUANTITATIVE TOXICOLOGY

This category is for laboratories providing quantitative analysis of drugs (therapeutic or abused) in serum and/or blood. Drugs represented include, but are not limited to, digoxin, procainamide, quinidine, phenobarbital, phenytoin, gentamicin, theophylline, acetaminophen, salicylate, lithium and ethanol, including breath alcohol for non-forensic purposes.

TOXICOLOGY

BLOOD LEAD – COMPREHENSIVE: This category is for laboratories that perform blood lead measurements using reference systems based on atomic absorption spectrometry (AAS) and/or induction coupled plasma mass spectrometry (ICP-MS); or bench-top anodic stripping voltammetry (ASV; i.e. Model 3010B by ESA Biosciences, Inc.). Laboratories holding this category may also perform testing using point-of-care lead analyzers provided they also perform reference methods. This category includes testing for erythrocyte protoporphyrin. Testing for electrolytes such as sodium, potassium, magnesium and calcium are included under the Clinical Chemistry category. Testing for trace elements such as arsenic, cadmium, mercury, copper, zinc, selenium and aluminum are included under the Trace Elements category.

BLOOD LEAD - SCREENING TESTS ONLY: This category is for laboratories using point-of-care lead analyzers such as the LeadCare® II (ESA Biosciences, Inc.) that are based on single-use, disposable sensors, i.e. screen printed electrode technology. Laboratories holding this category must either refer presumptive positive specimens (i.e., $\geq 8 \mu\text{g/dL}$) to a laboratory holding a Blood Lead - Comprehensive permit for confirmatory testing using a reference method or, when a confirmatory specimen is unavailable, identify on the report the method/manufacturer used and the need for confirmation by reference method.

FORENSIC TOXICOLOGY: The Forensic Toxicology categories are for laboratories that provide the analysis of urine and alternative specimens, including hair, oral fluid, sweat and breath, for abused substances where the legal defensibility of laboratory services must be established and maintained. Such services include pre-employment screening; for cause (i.e., incident/accident-related) and return to work testing, random employment testing; any testing situation where employment, benefits or services may be terminated or denied as the result of positive finding; and postmortem toxicology testing conducted by private sector laboratories. Laboratories qualifying for these categories must have protocols for specimen chain-of-custody and laboratory security.

INITIAL TESTING ONLY: This category is for laboratories performing forensic drug-testing limited to initial (screening) testing only. Laboratories holding this category must refer presumptive positive specimens to a laboratory holding a Forensic Toxicology-Comprehensive permit for confirmatory testing.

COMPREHENSIVE: This category is for laboratories performing on-site confirmation analysis of presumptive positive drug screens using confirmatory methods acceptable to the Department.

CLINICAL TOXICOLOGY: The Clinical Toxicology categories are for laboratories performing qualitative toxicology testing, including ethanol, the results of which are intended to assist medical professionals in patient management.

INITIAL TESTING ONLY: This category is for laboratories providing clinical toxicology services that are limited to initial (screening) tests. When requested by the health care provider, laboratories must refer presumptive positive specimens to a laboratory holding a Clinical Toxicology – Comprehensive permit for confirmatory testing.

COMPREHENSIVE: This category is for laboratories performing on-site confirmation analysis of presumptive positive drug screens using confirmatory methods acceptable to the Department.

TRACE ELEMENTS

This category is for laboratories performing testing for trace elements (e.g. arsenic, cadmium, mercury, copper, zinc, selenium, aluminum) in clinical specimens, including whole blood, serum or urine. Testing for blood lead is included under the Toxicology – Blood Lead categories. Testing for electrolytes such as sodium, potassium, calcium and magnesium is performed under the Clinical Chemistry category.

TRANSPLANT MONITORING

This category is for laboratories performing testing to monitor the status of a patient following an organ or tissue transplant. This includes engraftment monitoring, molecular assays that monitor for rejection, and the FDA-cleared Cylex™ ImmunKnow® assay for monitoring immune function following transplant.

URINALYSIS

This category is for laboratories performing a qualitative or semi-quantitative analysis of urinary glucose, protein, ketones, pH, hemoglobin, bilirubin, specific gravity, and a microscopic evaluation of urine for cellular and formed elements such as casts, crystals, white blood cells, and red blood cells. Laboratories holding this category may also report the presence of bacteria, yeast, and *Trichomonas vaginalis*. However, the culture or identification of these elements may only be performed under the appropriate microbiology category. Quantitative urine testing is performed under appropriate categories of Clinical Chemistry or Toxicology.

URINE PREGNANCY TESTING

This category is for laboratories performing urine pregnancy tests. Serum pregnancy tests (serum *beta*-hCG determinations) for the purpose of assessing pregnancy are performed under the category of Endocrinology.

VIROLOGY

COMPREHENSIVE: This category is for laboratories that perform virus culture and identification or molecular techniques for the detection and identification of any of the viral agents routinely encountered in a clinical virology laboratory. Laboratories holding this category may also perform various methods for virus antigen detection and testing for antiviral drug susceptibility. Human Immunodeficiency Virus identification test may be performed under the category of Virology – Comprehensive.

RESTRICTED: This category is for laboratories that restrict their testing to one or more of the following viruses: influenza virus, respiratory syncytial virus, and rotavirus; using FDA-approved kits such as enzyme immunoassay, immunochromatographic assay, or latex agglutination.

WET MOUNTS

This category is for laboratories performing a direct, unstained examination of urogenital specimens (vaginal and urethral secretions) for the presence or absence of *Trichomonas vaginalis*, yeast, or bacteria, or to identify clue cells. It also includes tests for vaginal pH. Laboratories performing Gram stains on urogenital specimens must also hold the category of Bacteriology-Gram Stains.