

**New York State Department of Health
Clinical Laboratory Evaluation Program**

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CQ Categories:

Definitions, Scope, and Eligibility Requirements

General Requirement

Applicants must show relevant experience gained within the past 10 years for each requested category. Board recertification alone does not prove recent experience.

Andrology

Description: Tests on patients and donors to assess male fertility.

Examples: Sperm count/concentration, motility, morphology, semen biochemical tests, sperm DNA fragmentation, sperm DNA decondensation, sperm fructose tests, cervical mucus penetration, anti-sperm/anti-ovary antibodies sperm-egg interactions, and qualitative post-vasectomy testing for viable sperm.

Excluded: Endocrinology tests (such as FSH or LH) and genetic testing for infertility or preimplantation embryo diagnosis.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP) or ABB(ALD); OR
 - AOPath(LM) or ABB(BCLD) — each with 6 months of training or experience; OR
 - ABB(HCLD) with ABB exam in Andrology or 6 months of training or experience; OR
 - ABCC(CC) or NRCC(CC) — each with 1 year of training or experience.
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Bacteriology

Description: The detection, isolation, identification, and antimicrobial susceptibility testing of bacterial pathogens in clinical specimens using cultural, microscopic, and molecular methods.

Examples: Gram stains, full work-ups of anaerobes and aerobes, antigen identification of pathogens (including gastrointestinal, genital, Group A Streptococcus, meningitis, and urinary pathogens), bacterial toxin tests, culture identification of bacteria, molecular identification of pathogens (including blood, gastrointestinal, genital, meningitis, respiratory, and urinary pathogens), and bacterial susceptibility testing (AST).

Additional Requirements: Must also hold Mycology and Parasitology CQs to direct Wet Mounts.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), AOPath(LM), ABPath(MMB), ABMM, ABB(PHLD), ABB(BCLD), or ASCP(DMLI); OR
 - ABB(HCLD) with ABB exam in Microbiology, Public Health Microbiology, or Molecular Diagnostics.
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Blood Banking Collection – Comprehensive

Description: Donor selection, blood/component collection, and preparation of blood components for transfusion or plasma fractionation.

Examples: Whole blood collection, component preparation, leukapheresis, plasmapheresis, plateletpheresis, plasma fractionation, donor screening (hemoglobin, hematocrit, and total protein for plasmapheresis),

mandated immunohematologic testing (blood grouping and antibody screening), and mandated infectious disease testing at the collection facility.

Eligibility:

- Physician with 2 years of training or experience including 1 year in collection and testing for allogeneic transfusion.

Blood Banking Collection – Limited

Description: The collection of blood or blood components for autologous transfusion.

Examples: Autologous blood collection, and donor unit testing including ABO grouping, Rh typing, and antibody screening.

Excluded: Testing for transmissible disease markers.

Eligibility:

- Physician with ABPath(BB/TM), ABPath(CP), AOBPath(LM), ABIM(Hem), or AOBIM(Hem).

Blood Lead

Description: Screening, diagnosis, and monitoring of lead poisoning.

Examples: Blood lead determination (including LeadCare) and erythrocyte protoporphyrin.

Holder can also direct: Trace Elements.

Eligibility:

- 2 years of training or experience; OR
- ABCC(CC) or ABCC(TC).

Blood pH and Gases

Description: The measurement of blood pH, blood gases, and related metabolic parameters, including co-oximetry and electrolyte testing when performed on blood gas instruments.

Examples: pH, pO₂, pCO₂, tCO₂, carboxyhemoglobin, methemoglobin, oxyhemoglobin, hemoglobin, hematocrit, and electrolytes.

Eligibility:

- 2 years of training or experience; OR
- ABPath(CP), AOBPath(LM), or ABCC(CC).

Cellular Immunology – Leukocyte Function

Description: In vitro evaluation of lymphoid and non-lymphoid leukocyte functions, and the quantification of cytokines in clinical specimens.

Examples: Alloantigen- or antigen-induced leukocyte proliferation, B-cell function, chemotaxis, in vitro cytokine production, cytolytic tests, degranulation, GranToxiLux cytotoxicity NK cell tests, immunoglobulin production, mitogen-induced leukocyte proliferation, natural killer (NK) cell function, neutrophil reactive oxygen species, oxidative burst, phagocytosis, and T-cell function.

Eligibility:

- 2 years of training or experience; OR
- ABMLI or ASCP(DMLI); OR
- ABCC(CC) with 1 year of training or experience in flow cytometry; OR
- ABB(BCLD) with 1 year of training or experience in flow cytometry or ABB exam in Diagnostic Immunology and Hematology with 6 months of training or experience in flow cytometry; OR
- ABB(HCLD) with 1 year of training or experience in flow cytometry or ABB exam in Hematology with 6 months of training or experience in flow cytometry.

Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping

Description: The identification, characterization, and enumeration of non-malignant leukocyte populations using flow cytometry and related immunophenotyping methodologies.

Examples: Lymphocyte immunophenotyping, B-cell subsets, CD34+ stem cells, CD4+ T-lymphocyte quantification, interferon-gamma (IFN- γ) expressing lymphocytes, leukocyte adhesion deficiency (LAD) analysis, paroxysmal nocturnal hemoglobinuria (PNH) analysis, plasma cell assessment, regulatory T-cells (Tregs), T-lymphoid immunophenotyping, and toll-like receptor (TLR) expression.

Eligibility:

- 2 years of training or experience; OR
- ABMLI or ASCP(DMLI); OR
- ABCC(CC) with 1 year of training or experience in flow cytometry; OR
- ABB(BCLD) with 1 year of training or experience in flow cytometry or ABB exam in Diagnostic Immunology and Hematology with 6 months of training or experience in flow cytometry; OR
- ABB(HCLD) with 1 year of training or experience in flow cytometry or ABB exam in Hematology with 6 months of training or experience in flow cytometry.

Cellular Immunology – Malignant Leukocyte Immunophenotyping

Description: The identification, characterization, and immunophenotyping of leukemias, lymphomas, and other hematologic malignancies using flow cytometry.

Examples: Leukemia/lymphoma immunophenotyping, DNA ploidy by flow cytometry, intracytoplasmic kappa/lambda light chain, minimal residual disease (MRD), intracytoplasmic myeloperoxidase (cMPO), T-cell receptor (TCR) V β repertoire, and terminal deoxynucleotidyl transferase (TdT) by flow cytometry.

Eligibility:

- 2 years of training or experience; OR
- ABMLI or ASCP(DMLI); OR
- ABCC(CC) with 1 year of training or experience in flow cytometry; OR
- ABB(BCLD) with 1 year of training or experience in flow cytometry or ABB exam in Diagnostic Immunology and Hematology with 6 months of training or experience in flow cytometry; OR
- ABB(HCLD) with 1 year of training or experience in flow cytometry or ABB exam in Hematology with 6 months of training or experience in flow cytometry.

Clinical Chemistry

Description: General biochemical measurement of blood, urine, and other patient specimens.

Examples: Enzymes (ALT, AST, amylase, alkaline phosphatase, LDH, CK), electrolytes (sodium, potassium, chloride, carbon dioxide), lipids (cholesterol, triglycerides, HDL, LDL), proteins (albumin, total protein, haptoglobin, transferrin), metabolites (creatinine, urea nitrogen/BUN, uric acid, bilirubin), tumor markers (AFP, CEA, CA 125, CA 15-3, CA 27.29, PSA), cardiac markers (troponin I, troponin T, BNP, proBNP), and other tests (fecal occult blood, osmolality, specific gravity, urine protein screen).

Excluded: Testing covered under Blood pH and Gases, Trace Elements, and Therapeutic Substance Monitoring/Quantitative Toxicology. Inherited metabolic disease testing is covered under Genetic Testing.

Holder can also direct: Cytokines, Toxicology – Blood Lead – ASV Using Screen-Printed Sensors, and Urinalysis.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), AOBPath(LM), or ABCC(CC).
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Clinical Toxicology

Description: Screening, qualitative, or quantitative analysis of drugs and their metabolites in clinical specimens for patient management, emergency assessment, or rehabilitation monitoring.

Examples: Acetaminophen, amphetamines, barbiturates, benzodiazepines, cannabinoids (THC), cocaine metabolites (benzoylecgonine), ethanol, fentanyl, methadone, opiates, oxycodone, phencyclidine (PCP), propoxyphene, synthetic cannabinoids, and tricyclic antidepressants.

Holder can also direct: Forensic Toxicology – Initial Testing Only.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), AOBPath(LM), or ABCC(TC); OR
 - ABCC(CC) with 6 months of confirmatory testing. Applicants with less than 6 months of confirmatory testing experience may be limited to qualitative testing.
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Cytogenetics

Description: The culture and examination of chromosomes from blood, body fluids, or other tissues to detect structural or numerical genomic abnormalities associated with hereditary disorders, neoplastic diseases, or mutagenesis. This category also covers array-based copy number analysis tests for constitutional disorders.

Examples: Metaphase chromosome analysis (karyotyping, G-banding), chromosomal microarray analysis (CMA), fluorescence in situ hybridization (FISH) using CEP/CEN/subtelomere probes, preimplantation genetic diagnosis (PGD), products of conception (POC) chromosome studies, chorionic villus sampling, and specific gene/rearrangement panels (such as BCR/ABL, PML/RARA, HER2/neu, trisomy 21/18, and microdeletion syndromes like DiGeorge or Prader-Willi).

Additional Requirements: Directing FISH testing to confirm abnormal array results requires this CQ.

Eligibility:

- 4 years of training or experience in human genetics including 2 years in clinical cytogenetics.
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Cytopathology

Description: The microscopic examination of cells exfoliated from epithelial surfaces or obtained from tissues and cavities to detect inflammatory, infectious, or neoplastic changes.

Examples: Gynecological and non-gynecological specimen processing and slide reading (brushing, scraping, washing, lavage, or needle aspiration), including cytochemical stains, immunohistochemical stains, cell markers, and UroVysion.

Eligibility:

- Physician with ABPath(AP) or AOPath(AP).
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Diagnostic Immunology

Description: Serologic and immunologic testing for autoantibodies, antigen or antibody markers of infectious diseases, and nonspecific reactive indicators of infection. This covers diagnostic testing on patient specimens and mandated donor screening for blood, organs, and tissues.

Examples: Antinuclear antibody (ANA), extractable nuclear antigens, anti-double stranded DNA (dsDNA), rheumatoid factor, anti-cyclic citrullinated peptide (CCP), thyroid autoantibodies (TPO, Tg, TRAb), complement components (C3, C4), C-reactive protein (CRP), immunoglobulins (IgA, IgE, IgG, IgM), serologic markers for infectious diseases (such as HIV, hepatitis B/C, rubella, rubeola, syphilis, CMV, and Epstein-Barr/infectious mononucleosis), and interferon-gamma release tests (Quantiferon TB Gold, T-SPOT.TB).

Excluded: Serologic tests for autoantibodies against blood cells (covered in Hematology, Immunohematology, and Histocompatibility).

Holder can also direct: Cytokines.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), AOPath(LM), ABPath(MMB), ABCC(CC), ABMLI, ABMM, or ASCP(DMLI).
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Endocrinology

Description: Measuring hormones, vitamins, and their metabolites in blood or other samples, and analyzing their metabolic effects.

Examples: Thyroid-stimulating hormone (TSH), thyroxine (T4), triiodothyronine (T3), follicle-stimulating hormone (FSH), luteinizing hormone (LH), estradiol, progesterone, testosterone, cortisol, aldosterone, insulin, C-peptide, parathyroid hormone (PTH), human chorionic gonadotropin (hCG), vitamin B12, and folate.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), AOPath(LM), or ABCC(CC).
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Fetal Defect Markers

Description: Gestational biomarker analysis to assess risk for fetal defects, neural tube defects, and chromosomal abnormalities.

Examples: Alpha-fetoprotein (AFP), maternal serum AFP (MSAFP), total and free beta-hCG, unconjugated estriol (uE3), dimeric inhibin A, pregnancy-associated plasma protein A (PAPP-A), acetylcholinesterase (AChE), fetal hemoglobin (HbF) for neural tube defects, and risk assessments for Down syndrome (trisomy 21) and Edwards syndrome (trisomy 18).

Eligibility:

- 2 years of training or experience; OR
- ABPath(CP), AOPath(LM), or ABCC(CC).

Forensic Identity

Description: DNA-based human identity testing or bodily fluid screening for civil (non-criminal) court cases, provided the testing is requested by an authorized source.

Examples: Autosomal, mitochondrial, and Y-chromosome short tandem repeat (STR) analysis, quantitation of human and male DNA, and body fluid identification (blood, saliva, semen).

Eligibility:

- 2 years of training or experience.
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Forensic Toxicology

Description: The qualitative detection and quantitative confirmation of drugs, alcohol, or other toxic substances in blood, body fluids, tissues, or other subject materials under strict protocols for chain of custody, laboratory security, and confidentiality, including the interpretation of findings for legal or forensic purposes.

Examples: Post-mortem, workplace, or legal testing for drugs of abuse, therapeutic agents, and their metabolites (including 6-acetylmorphine, amphetamines, benzodiazepines, cannabinoids/THC, cocaine metabolites, ethanol, fentanyl, lysergic acid diethylamide/LSD, methadone, opiates, phencyclidine/PCP, propoxyphene, synthetic cannabinoids, synthetic cathinones, and tricyclic antidepressants).

Holder can also direct: Clinical Toxicology – Comprehensive and Clinical Toxicology – Initial Testing Only.

Eligibility:

- 2 years of training or experience; OR
 - ABFT.
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Genetic Testing

Description: Procedures to diagnose genetic diseases, identify carrier states, or assess risk for drug metabolism and hemostasis.

Examples:

- **Biochemical:** Newborn screening panels (amino acids, acylcarnitines), lysosomal storage disease enzymes (glucocerebrosidase, hexosaminidase, acid alpha-glucosidase), organic acid analysis, mucopolysaccharidosis screening (urinary glycosaminoglycans), and specific metabolic tests (such as galactosemia, homocystinuria, and porphyria testing).
- **Molecular:** Inherited cancer predisposition (BRCA1/BRCA2, Lynch syndrome/HNPCC), developmental and neurological disorders (fragile X, Huntington's, spinal muscular atrophy, muscular dystrophies), cardiovascular genetics (Factor V Leiden, prothrombin genotyping, long QT syndrome), pharmacogenetics (cytochrome P450 gene family, TPMT, MTHFR), and prenatal/preimplantation genetic diagnosis (PGD).

Excluded: Paternity testing, forensic testing, somatic tumor changes (covered under Oncology - Molecular and Cellular Tumor Markers), and tissue typing.

Additional Notes: May be limited to molecular or biochemical tests based on documented experience.

Eligibility:

- 2 years of training or experience; OR
 - ABCC(MD), AMBGG(CBG), or ABMGG(LGG).
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Hematology

Description: Quantitative and qualitative analysis of cellular blood elements, hemostasis, and coagulation.

Examples: Complete blood count (CBC) with white blood cell differential, erythrocyte and leukocyte counts, hematocrit, hemoglobin, red cell indices, reticulocyte count, hemoglobin electrophoresis (including A2 and fetal HbF), coagulation and hemostasis tests (PT/INR, APTT, activated clotting time, bleeding time, fibrinogen, D-dimer, factor tests, factor VIII/vWF, anti-thrombin III, protein S/Z), platelet function tests (aggregation, activation, P2Y12, heparin-induced thrombocytopenia serotonin release test), and qualitative semen analysis for viable sperm.

Excluded: Semen analysis and other non-endocrinologic andrology tests (covered under Andrology).

Holder can also direct: Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping (non-flow cytometry methods only), Genetic Testing – Biochemistry (limited to hemoglobinopathies), Toxicology – Blood Lead – ASV Using Screen-Printed Sensors, and Urinalysis.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP) or AOBPath(LM); OR
 - ABIM(Hem) or AOBIM(Hem) — each with 1 year of training or experience.
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Histocompatibility

Description: Determination of phenotypic or genotypic polymorphisms of the human leukocyte antigen (HLA) system to support blood component transfusion, tissue or organ transplantation, or the analysis of HLA linkage with specific diseases.

Examples: B-cell crossmatch, T-cell crossmatch, HLA antibody testing, and HLA Class I and Class II typing by DNA polymorphism analysis (SSP or SSO), DNA sequencing, or serology.

Eligibility:

- 4 years of training or experience in histocompatibility; OR
 - 2 years of training or experience in immunology and 2 years of training or experience in histocompatibility.
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Histopathology – General

Description: Gross and microscopic evaluation of tissue specimens and autopsies to diagnose disease.

Examples: Routine hematoxylin and eosin (H&E) staining, special histochemical stains, immunohistochemistry (IHC), human papillomavirus (HPV) by IHC, Mohs micrographic surgery tissue evaluation, Tzanck smears, and fluorescence in situ hybridization (FISH) on tissue sections (HER2/neu, TOP2A).

Eligibility:

- Physician with ABPath(AP) or AOBPath(AP).
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Histopathology – Dermatopathology

Description: Gross and microscopic evaluation of skin, hair, nail, and adjacent mucous membrane specimens to diagnose cutaneous diseases.

Examples: Skin biopsy and excision slide evaluation, histochemical stains, and Mohs micrographic surgery tissue evaluation.

Eligibility:

- Physician with ABPath(AP), ABPath(DP), AOBPath(AP), AOBPath(DP), ABD, or ABD(DP).
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Histopathology – Oral Pathology

Description: Gross and microscopic evaluation of specimens from the oral cavity, maxillofacial region, and adjacent structures to diagnose oral diseases.

Examples: Oral mucosal, gingival, and jaw biopsy slide evaluation, and histochemical stains.

Eligibility:

- Physician with ABPath(AP) or AOBPath(AP); OR
 - Dentist with ABOMP.
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Immunohematology

Description: Testing red blood cells, serum, or plasma for both transfusion and non-transfusion purposes.

Examples: ABO grouping, D (Rho) typing, weak D testing, Rh phenotyping, red blood cell (RBC) antibody detection and titration, unexpected antibody detection, compatibility testing, direct and indirect antiglobulin (Coombs) testing, platelet and granulocyte antigen/antibody testing, RBC/platelet antigen genotyping, and RhD genotyping (including fetal DNA in maternal blood).

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), ABPath(BB/TM), or AOBPath(LM).
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Mycobacteriology

Description: The detection, isolation, identification, and drug susceptibility testing of mycobacteria in clinical specimens.

Examples: Acid-fast smears, culture identification of mycobacteria, molecular identification of mycobacteria, and full work-ups of clinical mycobacteria.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), AOBPath(LM), ABPath(MMB), ABMM, ABB(PHLD), ABB(BCLD), or ASCP(DMLI); OR
 - ABB(HCLD) with ABB exam in Microbiology, Public Health Microbiology, or Molecular Diagnostics.
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Mycology

Description: The detection, isolation, identification, and drug susceptibility testing of yeasts, filamentous fungi, and actinomycetes in clinical specimens.

Examples: Potassium hydroxide preparation (KOH prep), germ tube formation, fungal antigen tests, yeast and filamentous fungi culture, molecular tests, and yeast or mold drug susceptibility testing.

Additional Requirements: Must also hold Bacteriology and Parasitology CQs to direct Wet Mounts.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), AOPath(LM), ABPath(MMB), ABMM, ABB(PHLD), ABB(BCLD), or ASCP(DMLI); OR
 - ABB(HCLD) with ABB exam in Microbiology, Public Health Microbiology, or Molecular Diagnostics.
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Oncology – Molecular and Cellular Tumor Markers

Description: Testing cellular material to detect tumor-specific acquired genetic or phenotypic changes.

Examples: Chromosomal rearrangements (Southern blot, RT-PCR), oncogene/tumor suppressor mutations (sequencing, SSCP, chip analysis), gene/protein expression (DNA chips, Western blot), and ex vivo chemotherapeutic drug sensitivity.

Eligibility:

- 2 years of training or experience; OR
 - ABCC(MD) or ABMGG(LGG); OR
 - ABPath(AP) or ABPath(CP) with ABPath(MGP).
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Parasitology

Description: The detection, identification, and characterization of parasites in clinical specimens.

Examples: Microscopic identification of parasites, antigen identification of parasites, molecular identification of gastrointestinal and genital parasites, helminth and protozoan parasite examinations, and anti-parasite drug susceptibility testing.

Additional Requirements: Must also hold Bacteriology and Mycology CQs to direct Wet Mounts.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), AOPath(LM), ABPath(MMB), ABMM, ABB(PHLD), ABB(BCLD), or ASCP(DMLI); OR
 - ABB(HCLD) with ABB exam in Microbiology, Public Health Microbiology, or Molecular Diagnostics.
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Parentage/Identity Testing

Description: Determination of paternity and familial relationships using genetic markers.

Examples: Short tandem repeat (STR) analysis, restriction fragment length polymorphism (RFLP) analysis, and HLA marker testing.

Eligibility:

- 2 years of training or experience.
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Therapeutic Substance Monitoring / Quantitative Toxicology

Description: Quantitative measurement of therapeutic drugs or toxic substances to monitor dosage, compliance, or toxicity.

Examples: Digoxin, lithium, theophylline, valproic acid, carbamazepine, phenytoin, phenobarbital, vancomycin, gentamicin, tobramycin, acetaminophen, salicylate, and ethanol in serum, plasma, and whole blood; and breath alcohol.

Eligibility:

- 2 years of training or experience; OR
 - ABPath(CP), AOBPath(LM), ABCC(CC), or ABCC(TC).
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Trace Elements

Description: Testing for trace elements in clinical specimens (blood, serum, urine).

Examples: Tests for arsenic, cadmium, mercury, copper, zinc, selenium, and aluminum.

Holder can also direct: Toxicology – Blood Lead - Comprehensive and Toxicology – Blood Lead – ASV Using Screen-Printed Sensors.

Eligibility:

- 2 years of training or experience in analytical atomic spectrometry.
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Transfusion Services

Description: Selecting and storing donor blood/components for transfusion.

Examples: Recipient and donor unit blood grouping, unexpected antibody screening, compatibility testing (crossmatching), and transfusion or storage of blood and blood components.

Holder can also direct: Immunohematology.

Eligibility:

- Physician with ABPath(BB/TM); OR
 - Physician with ABPath(CP), ABIM(Hem), or AOBIM(Hem) — each with 6 months of training or experience in transfusion medicine at a blood bank.
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Transplant Monitoring

Description: Molecular tests to monitor the status of transplanted organs or tissues.

Examples: Engraftment monitoring after hematopoietic progenitor cell transplants (using STR analysis) and rejection monitoring (using gene expression).

Excluded: Cellular-based tests for rejection or chemistry tests for drug levels.

Additional Requirements: Performing FISH for engraftment monitoring requires a Cytogenetics CQ.

Eligibility:

- 2 years of training or experience; OR
 - ABCC(MD).
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Virology

Description: The detection, isolation, identification, and drug susceptibility testing of viral pathogens in clinical specimens.

Examples: Direct antigen detection of viruses, viral culture, molecular identification of viral pathogens (including gastrointestinal, genital, respiratory, meningitis, and herpesvirus-related viruses), HIV detection, HIV viral load testing, HIV genotyping, and antiviral drug susceptibility testing.

Eligibility:

- 2 years of training or experience; OR
- ABPath(CP), AOPath(LM), ABPath(MMB), ABMM, ABB(PHLD), ABB(BCLD), or ASCP(DMLI); OR
- ABB(HCLD) with ABB exam in Microbiology, Public Health Microbiology, or Molecular Diagnostics.