COLLEGE of AMERICAN PATHOLOGISTS

CAP Accreditation Checklists – 2023 Edition

The College of American Pathologists (CAP) accreditation checklists contain the CAP accreditation program requirements, developed on more than 50 years of insight and pathology expertise. The following is a complete list of the CAP accreditation checklists:

CHECKLISTS	SUBDISCIPLINES	DESCRIPTION OF CONTENTS
All Common	N/A	• Proficiency testing • Policy and procedure manuals • Specimen collection and handling • Quality management • Reporting of results • Reagents • Instruments and equipment maintenance/function checks • Thermometers and temperature-dependent equipment and environments • Pipettes and analytical balances • Waived test implementation • Test method validation/verification – nonwaived tests • Individualized quality control plans
Anatomic Pathology	• Anatomic Pathology Processing • Autopsy Pathology • Circulating Tumor Cell Analysis • Digital Image Analysis • Electron Microscopy • Flow Cytometry Data Interpretation • Intra-operative Consultation • In Vivo Microscopy • Molecular Anatomic Pathology • Surgical Pathology	• Surgical pathology • Intra-operative consultation • Fine-needle aspiration • Histology • Immunochemistry and immunofluorescence microscopy • In situ hybridization (ISH) • Predictive marker testing • Digital image analysis • Flow cytometry data interpretation • Circulating tumor cell analysis • Autopsy pathology • Forensic pathology • Electron microscopy • In vivo and ex vivo microscopy
Biorepository	• General Specimen Processing • Specimen Collection/Procurement	• Quality management • Biospecimen collection and handling • Biospecimen processing and quality, including DNA/RNA

	• Specimen Distribution and Agreements • Specimen Informatics • Specimen Storage	extraction/amplification, cell fractionization, cell and tissue culture, and histology • Specialized techniques, such as whole slide imaging, digital image analysis, tissue microarray, laser capture microdissection, and molecular methods • Inventory management system • Storage • Source and sponsor facilities • Informed consent and institutional review board • Distribution policies and agreements
Chemistry and Toxicology	• Blood Gases • Chemistry • Special Chemistry • Toxicology	• Automated chemistry procedures • Blood gas analysis • Therapeutic drug monitoring • Toxicology screening and confirmatory testing • Prenatal screening • Cystic fibrosis sweat testing • Tumor marker, immune system, and infectious disease immunoassays • Hemoglobin separation • Methods, such as thin layer chromatography (TLC), gas chromatography (GC), high performance liquid chromatograph (HPLC), mass spectrometry (MS), Imaging MS, atomic absorption, radioimmunoassay (RIA), and electrophoresis
Clinical Biochemical Genetics	• Clinical Biochemical Genetics • Newborn Screening	• Diagnostic testing for inborn errors of metabolism • Methods, such as enzyme assays, TLC, GC, HPLC, MS, electrophoresis, and RIA • Newborn screening

Cytogenetics	• Conventional Cytogenetics • Genomic Copy Number Microarray • In Situ Hybridization • Remote Data Assessment	• Cytogenetic studies for constitutional and neoplastic disorders • ISH for constitutional and neoplastic disorders, including predictive marker testing • Digital image analysis • Genomic copy number analysis using arrays
Cytopathology	• Cytology Processing • Cytology Screening • Gynecologic Cytopathology • Non-gynecologic Cytopathology	• Cytology processing and staining • Cytology screening, manual and automated • Immunocytochemistry, including predictive marker testing • Gynecologic cytopathology • Non-gynecologic cytology (including fine-needle aspiration)
Director Assessment	N/A	• Laboratory director qualifications • Laboratory director responsibilities
Flow Cytometry	• Flow Cytometry	• Blood lymphocyte subset enumeration • CD34 stem cell enumeration • Leukemia and lymphoma immunophenotyping • DNA content and cell cycle analysis • Rare event flow cytometric assays
Forensic Drug Testing	• Drug Testing – Hair • Drug Testing – Meconium • Drug Testing – Nails • Drug Testing – Oral fluid • Drug Testing – Umbilical Cord • Drug Testing – Urine • Drug Testing – Urine Screen Only • Drug Testing – Whole Blood	• Non-medical drug testing • Screening and confirmatory testing for different specimen types (urine, blood, oral fluid, hair, meconium, umbilical cord, and nails) • Specimen handling and chain-of-custody • Certification/inspection of results • Methods, such as immunoassays, LC, GC, and MS
Hematology and Coagulation	• Body Fluid Analysis • Coagulation • Hematology	• CBC and differentials, automated and manual

		• Reticulocytes, automated and manual • Bone marrow preparations • Abnormal hemoglobin detection • Blood film examination for microorganisms • Semen analysis, automated and manual • Routine coagulation assays • Specialized coagulation assays, including factor assays, mixing studies, D-dimer, electrophoresis studies, platelet function assays, and viscoelastic testing.
Histocompatibility	• Clinical Transplantation Support • HLA Cellular Functional Tests • HLA Flow Cytometry • HLA Serology • HLA Solid Phase Assays • HLA Molecular Non-NGS	• HLA testing by serologic, molecular, flowcytometry, immunoassay, and solid phase methods • Class I and II antigen typing • HLA antibody screening, identification, and crossmatching • DNA typing, including low and high resolution typing, and DNA sequence-based typing • Donor-recipient histocompatibility, including renal, hematopoietic progenitor cell, and non-renal organ transplants • Hematopoietic progenitor cell engraftment and monitoring
Immunology	• Immunology	• General immunology assays, manual and automated • Immune system profiles • Tumor marker and infectious disease immunoassays • Microbial antigen testing • Waived molecular-based microbiology tests • ABO/Rh and antibody screening (non-transfusion related) • Syphilis serology • HIV Primary diagnostic testing • Western blot
Laboratory General	N/A	• Quality management system

		• Specimen collection • Chain-of-custody specimen collection and handling • Direct-to-consumer testing • Specimen transport and tracking • Result reporting • Quality of water • Laboratory computer services • Telepathology and remote data assessment • Whole slide imaging • Personnel • Physical facilities • Laboratory Safety • California laboratory licensure requirements
Limited Service	• Body Fluid Analysis • Coagulation • Hematology • Blood Gas Analysis • Chemistry • Special Chemistry • Toxicology • Bacteriology • Parasitology • Mycology • Virology • Urinalysis • Immunology • Immunohematology	Contains a limited subset of requirements from the checklists, including: • Automated and manual hematology testing, including CBC, reticulocytes, and differentials • Routine coagulation assays • Body fluid analysis, including semen analysis • Automated general chemistry • Blood gas analysis • Therapeutic drug monitoring • Screening for drugs of abuse • Tumor marker and infectious disease immunoassays • Urinalysis dipstick and microscopy, manual and automated methods • Microbiology specimen set up, direct specimen examination, stains, and antigen typing for various subdisciplines • General immunology assays, including anti-nuclear antibody testing, HIV primary diagnostic testing, and immune system profiles • Microbial antigen/antibody testing • Non-transfusion-related immunohematology testing • Syphilis serology

		• Waived molecular based microbiology tests
Microbiology	• Bacteriology • Molecular Microbiology • Mycobacteriology • Mycology • Parasitology • Virology	• Culture setup, staining, antigen typing, screening, identification, and susceptibility testing for bacteriology, mycology, mycobacteriology, and virology • Parasitology, including stool for ova and parasites and blood films for microorganisms • Molecular microbiology, including waived and non-waived FDA-cleared/approved methods, modified methods, and laboratory-developed methods • Microbial identification, using methods such as MALDI-TOF MS, GC, HPLC, ISH, target and signal amplification, and sequencing
Molecular Pathology	• Inherited Genetics • Molecular Oncology – Hematologic Diseases • Molecular Oncology – Solid Tumor • Infectious Disease NGS • HLA NGS	• Clinical molecular genetics testing, including oncology, inherited disease, pharmacogenomics, HLA, forensic identity, and relationship testing applications • Molecular assay validation • ISH for constitutional and neoplastic disorders, including predictive marker testing • Methods, such as electrophoresis, PCR, arrays, digital image analysis, and sequencing • Next-generation sequencing for inherited diseases, including non-invasive screening of maternal plasma to detect fetal trisomy, inherited diseases, oncology, infectious disease, and HLA. • Hematopoietic progenitor cell engraftment monitoring
Point-of-Care Testing (POC)	• POCT – Nonwaived • POCT – Provider-Performed Microscopy and Limited Waived Testing	• Tests performed at or near the patient bedside (non-dedicated space)

	• POCT - Waived	• Waived and moderate-complexity testing • Kit tests or hand-carried instruments transported to the patient location • Blood gas analysis • D-dimer studies • HIV primary diagnostic testing • Waived molecular-based microbiology testing • Provider-performed microscopy
Reproductive Laboratory Medicine	• Andrology • Embryology	• Complete semen analysis, automated and manual methods • Biochemical testing • Anti-sperm antibody testing • Sperm processing for therapeutic insemination • Embryology procedures • Embryo and gamete cryopreservation • Donor reproductive cell/tissue programs
Transfusion Medicine	• Cellular Therapy Services • Donor Services • Immunohematology • Tissue Storage and Issue • Transfusion Services	• Immunohematology testing, manual and automated • Compatibility testing, including computer crossmatches • Perinatal testing • Transfusion procedures and adverse reactions • Therapeutic phlebotomy • Donor and therapeutic apheresis • Component preparation, storage, and modification • Cellular therapy • Tissue storage and issue • Donor section, collection, and testing
Urinalysis	• Urinalysis	• Urinalysis dipstick, automated and manual methods • Manual urine microscopy • Automated microscopy systems