



CAP Accreditation Checklists – 2021 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Surgical pathology • Intra-operative consultation • Fine-needle aspiration • Histology • Immunocytochemistry 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	<ul style="list-style-type: none"> • General Specimen Processing • Specimen Collection/Procurement 	<ul style="list-style-type: none"> • Quality management • Biospecimen collection and handling



	<ul style="list-style-type: none">• Specimen Distribution and Agreements• Specimen Informatics• Specimen Storage	<ul style="list-style-type: none">• Biospecimen processing and quality, including DNA/RNA 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	<ul style="list-style-type: none">• Blood Gases• Chemistry• Special Chemistry• Toxicology	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Clinical Biochemical Genetics• Newborn Screening	<ul style="list-style-type: none">• Diagnostic testing for inborn errors of metabolism• Methods, such as enzyme assays, TLC, GC, HPLC, MS, electrophoresis, and RIA• Newborn screening



Cytogenetics	<ul style="list-style-type: none"> • Conventional Cytogenetics • Genomic Copy Number Microarray • In Situ Hybridization • Remote Data Assessment 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Cytology Processing • Cytology Screening • Gynecologic Cytopathology • Non-gynecologic Cytopathology 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Laboratory director qualifications • Laboratory director responsibilities
Flow Cytometry	<ul style="list-style-type: none"> • Flow Cytometry 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Body Fluid Analysis • Coagulation 	<ul style="list-style-type: none"> • CBC and differentials, automated and manual



	<ul style="list-style-type: none"> Hematology 	<ul style="list-style-type: none"> 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, and platelet function assays
Histocompatibility	<ul style="list-style-type: none"> Clinical Transplantation Support HLA Cellular Functional Tests HLA Flow Cytometry HLA Molecular HLA Serology HLA Solid Phase Assays 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Immunology 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Quality management system



		<ul style="list-style-type: none"> • 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
<p>Limited Service</p>	<ul style="list-style-type: none"> • Body Fluid Analysis • Coagulation • Hematology • Blood Gas Analysis • Chemistry • Special Chemistry • Toxicology • Bacteriology • Parasitology • Mycology • Virology • Urinalysis • Immunology • Immunochemistry 	<p>Contains a limited subset of requirements from the checklists, including:</p> <ul style="list-style-type: none"> • 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 immunochemistry testing • Syphilis serology



		<ul style="list-style-type: none"> • Waived molecular based microbiology tests
Microbiology	<ul style="list-style-type: none"> • Bacteriology • Molecular Microbiology • Mycobacteriology • Mycology • Parasitology • Virology 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Inherited Genetics • Molecular Oncology – Hematologic Diseases • Molecular Oncology – Solid Tumor • Molecular Pathology 	<ul style="list-style-type: none"> • 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, including non-invasive screening of maternal plasma to detect fetal trisomy • Hematopoietic progenitor cell engraftment monitoring
Point-of-Care Testing (POC)	<ul style="list-style-type: none"> • POCT – Nonwaived • POCT – Provider-Performed Microscopy and Limited Waived Testing • POCT - Waived 	<ul style="list-style-type: none"> • Tests performed at or near the patient bedside (non-dedicated space) • Waived and moderate-complexity testing



		<ul style="list-style-type: none"> • Kit tests or hand-carried instruments) or otherwise 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	<ul style="list-style-type: none"> • Andrology • Embryology 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Cellular Therapy Services • Donor Services • Immunohematology • Tissue Storage and Issue • Transfusion Services 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Urinalysis 	<ul style="list-style-type: none"> • Urinalysis dipstick, automated and manual methods • Manual urine microscopy • Automated microscopy systems