



## 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
<b>All Common</b>	N/A	<ul style="list-style-type: none"> <li>• Proficiency testing</li> <li>• Policy and procedure manuals</li> <li>• Specimen collection and handling</li> <li>• Quality management</li> <li>• Reporting of results</li> <li>• Reagents</li> <li>• Instruments and equipment maintenance/function checks</li> <li>• Thermometers and temperature-dependent equipment and environments</li> <li>• Pipettes and analytical balances</li> <li>• Waived test implementation</li> <li>• Test method validation/verification – nonwaived tests</li> <li>• Individualized quality control plans</li> </ul>
<b>Anatomic Pathology</b>	<ul style="list-style-type: none"> <li>• Anatomic Pathology Processing</li> <li>• Autopsy Pathology</li> <li>• Circulating Tumor Cell Analysis</li> <li>• Digital Image Analysis</li> <li>• Electron Microscopy</li> <li>• Flow Cytometry Data Interpretation</li> <li>• Intra-operative Consultation</li> <li>• In Vivo Microscopy</li> <li>• Molecular Anatomic Pathology</li> <li>• Surgical Pathology</li> </ul>	<ul style="list-style-type: none"> <li>• Surgical pathology</li> <li>• Intra-operative consultation</li> <li>• Fine-needle aspiration</li> <li>• Histology</li> <li>• Immunocytochemistry and immunofluorescence microscopy</li> <li>• In situ hybridization (ISH)</li> <li>• Predictive marker testing</li> <li>• Digital image analysis</li> <li>• Flow cytometry data interpretation</li> <li>• Circulating tumor cell analysis</li> <li>• Autopsy pathology</li> <li>• Forensic pathology</li> <li>• Electron microscopy</li> <li>• In vivo and ex vivo microscopy</li> </ul>
<b>Biorepository</b>	<ul style="list-style-type: none"> <li>• General Specimen Processing</li> <li>• Specimen Collection/Procurement</li> </ul>	<ul style="list-style-type: none"> <li>• Quality management</li> <li>• Biospecimen collection and handling</li> </ul>



	<ul style="list-style-type: none"><li>• Specimen Distribution and Agreements</li><li>• Specimen Informatics</li><li>• Specimen Storage</li></ul>	<ul style="list-style-type: none"><li>• Biospecimen processing and quality, including DNA/RNA extraction/amplification, cell fractionization, cell and tissue culture, and histology</li><li>• Specialized techniques, such as whole slide imaging, digital image analysis, tissue microarray, laser capture microdissection, and molecular methods</li><li>• Inventory management system</li><li>• Storage</li><li>• Source and sponsor facilities</li><li>• Informed consent and institutional review board</li><li>• Distribution policies and agreements</li></ul>
<b>Chemistry and Toxicology</b>	<ul style="list-style-type: none"><li>• Blood Gases</li><li>• Chemistry</li><li>• Special Chemistry</li><li>• Toxicology</li></ul>	<ul style="list-style-type: none"><li>• Automated chemistry procedures</li><li>• Blood gas analysis</li><li>• Therapeutic drug monitoring</li><li>• Toxicology screening and confirmatory testing</li><li>• Prenatal screening</li><li>• Cystic fibrosis sweat testing</li><li>• Tumor marker, immune system, and infectious disease immunoassays</li><li>• Hemoglobin separation</li><li>• 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</li></ul>
<b>Clinical Biochemical Genetics</b>	<ul style="list-style-type: none"><li>• Clinical Biochemical Genetics</li><li>• Newborn Screening</li></ul>	<ul style="list-style-type: none"><li>• Diagnostic testing for inborn errors of metabolism</li><li>• Methods, such as enzyme assays, TLC, GC, HPLC, MS, electrophoresis, and RIA</li><li>• Newborn screening</li></ul>



<b>Cytogenetics</b>	<ul style="list-style-type: none"> <li>• Conventional Cytogenetics</li> <li>• Genomic Copy Number Microarray</li> <li>• In Situ Hybridization</li> <li>• Remote Data Assessment</li> </ul>	<ul style="list-style-type: none"> <li>• Cytogenetic studies for constitutional and neoplastic disorders</li> <li>• ISH for constitutional and neoplastic disorders, including predictive marker testing</li> <li>• Digital image analysis</li> <li>• Genomic copy number analysis using arrays</li> </ul>
<b>Cytopathology</b>	<ul style="list-style-type: none"> <li>• Cytology Processing</li> <li>• Cytology Screening</li> <li>• Gynecologic Cytopathology</li> <li>• Non-gynecologic Cytopathology</li> </ul>	<ul style="list-style-type: none"> <li>• Cytology processing and staining</li> <li>• Cytology screening, manual and automated</li> <li>• Immunocytochemistry, including predictive marker testing</li> <li>• Gynecologic cytopathology</li> <li>• Non-gynecologic cytology (including fine-needle aspiration)</li> </ul>
<b>Director Assessment</b>	N/A	<ul style="list-style-type: none"> <li>• Laboratory director qualifications</li> <li>• Laboratory director responsibilities</li> </ul>
<b>Flow Cytometry</b>	<ul style="list-style-type: none"> <li>• Flow Cytometry</li> </ul>	<ul style="list-style-type: none"> <li>• Blood lymphocyte subset enumeration</li> <li>• CD34 stem cell enumeration</li> <li>• Leukemia and lymphoma immunophenotyping</li> <li>• DNA content and cell cycle analysis</li> <li>• Rare event flow cytometric assays</li> </ul>
<b>Forensic Drug Testing</b>	<ul style="list-style-type: none"> <li>• Drug Testing – Hair</li> <li>• Drug Testing – Meconium</li> <li>• Drug Testing – Nails</li> <li>• Drug Testing – Oral fluid</li> <li>• Drug Testing – Umbilical Cord</li> <li>• Drug Testing – Urine</li> <li>• Drug Testing – Urine Screen Only</li> <li>• Drug Testing – Whole Blood</li> </ul>	<ul style="list-style-type: none"> <li>• Non-medical drug testing</li> <li>• Screening and confirmatory testing for different specimen types (urine, blood, oral fluid, hair, meconium, umbilical cord, and nails)</li> <li>• Specimen handling and chain-of-custody</li> <li>• Certification/inspection of results</li> <li>• Methods, such as immunoassays, LC, GC, and MS</li> </ul>
<b>Hematology and Coagulation</b>	<ul style="list-style-type: none"> <li>• Body Fluid Analysis</li> <li>• Coagulation</li> </ul>	<ul style="list-style-type: none"> <li>• CBC and differentials, automated and manual</li> </ul>



	<ul style="list-style-type: none"> <li>Hematology</li> </ul>	<ul style="list-style-type: none"> <li>Reticulocytes, automated and manual</li> <li>Bone marrow preparations</li> <li>Abnormal hemoglobin detection</li> <li>Blood film examination for microorganisms</li> <li>Semen analysis, automated and manual</li> <li>Routine coagulation assays</li> <li>Specialized coagulation assays, including factor assays, mixing studies, D-dimer, electrophoresis studies, and platelet function assays</li> </ul>
<b>Histocompatibility</b>	<ul style="list-style-type: none"> <li>Clinical Transplantation Support</li> <li>HLA Cellular Functional Tests</li> <li>HLA Flow Cytometry</li> <li>HLA Molecular</li> <li>HLA Serology</li> <li>HLA Solid Phase Assays</li> </ul>	<ul style="list-style-type: none"> <li>HLA testing by serologic, molecular, flowcytometry, immunoassay, and solid phase methods</li> <li>Class I and II antigen typing</li> <li>HLA antibody screening, identification, and crossmatching</li> <li>DNA typing, including low and high resolution typing, and DNA sequence-based typing</li> <li>Donor-recipient histocompatibility, including renal, hematopoietic progenitor cell, and non-renal organ transplants</li> <li>Hematopoietic progenitor cell engraftment and monitoring</li> </ul>
<b>Immunology</b>	<ul style="list-style-type: none"> <li>Immunology</li> </ul>	<ul style="list-style-type: none"> <li>General immunology assays, manual and automated</li> <li>Immune system profiles</li> <li>Tumor marker and infectious disease immunoassays</li> <li>Microbial antigen testing</li> <li>Waived molecular-based microbiology tests</li> <li>ABO/Rh and antibody screening (non-transfusion related)</li> <li>Syphilis serology</li> <li>HIV Primary diagnostic testing</li> <li>Western blot</li> </ul>
<b>Laboratory General</b>	N/A	<ul style="list-style-type: none"> <li>Quality management system</li> </ul>



		<ul style="list-style-type: none"> <li>• Specimen collection</li> <li>• Chain-of-custody specimen collection and handling</li> <li>• Direct-to-consumer testing</li> <li>• Specimen transport and tracking</li> <li>• Result reporting</li> <li>• Quality of water</li> <li>• Laboratory computer services</li> <li>• Telepathology and remote data assessment</li> <li>• Whole slide imaging</li> <li>• Personnel</li> <li>• Physical facilities</li> <li>• Laboratory Safety</li> <li>• California laboratory licensure requirements</li> </ul>
<p><b>Limited Service</b></p>	<ul style="list-style-type: none"> <li>• Body Fluid Analysis</li> <li>• Coagulation</li> <li>• Hematology</li> <li>• Blood Gas Analysis</li> <li>• Chemistry</li> <li>• Special Chemistry</li> <li>• Toxicology</li> <li>• Bacteriology</li> <li>• Parasitology</li> <li>• Mycology</li> <li>• Virology</li> <li>• Urinalysis</li> <li>• Immunology</li> <li>• Immunohematology</li> </ul>	<p>Contains a limited subset of requirements from the checklists, including:</p> <ul style="list-style-type: none"> <li>• Automated and manual hematology testing, including CBC, reticulocytes, and differentials</li> <li>• Routine coagulation assays</li> <li>• Body fluid analysis, including semen analysis</li> <li>• Automated general chemistry</li> <li>• Blood gas analysis</li> <li>• Therapeutic drug monitoring</li> <li>• Screening for drugs of abuse</li> <li>• Tumor marker and infectious disease immunoassays</li> <li>• Urinalysis dipstick and microscopy, manual and automated methods</li> <li>• Microbiology specimen set up, direct specimen examination, stains, and antigen typing for various subdisciplines</li> <li>• General immunology assays, including anti-nuclear antibody testing, HIV primary diagnostic testing, and immune system profiles</li> <li>• Microbial antigen/antibody testing</li> <li>• Non-transfusion-related immunohematology testing</li> <li>• Syphilis serology</li> </ul>



		<ul style="list-style-type: none"> <li>• Waived molecular based microbiology tests</li> </ul>
<b>Microbiology</b>	<ul style="list-style-type: none"> <li>• Bacteriology</li> <li>• Molecular Microbiology</li> <li>• Mycobacteriology</li> <li>• Mycology</li> <li>• Parasitology</li> <li>• Virology</li> </ul>	<ul style="list-style-type: none"> <li>• Culture setup, staining, antigen typing, screening, identification, and susceptibility testing for bacteriology, mycology, mycobacteriology, and virology</li> <li>• Parasitology, including stool for ova and parasites and blood films for microorganisms</li> <li>• Molecular microbiology, including waived and non-waived FDA-cleared/approved methods, modified methods, and laboratory-developed methods</li> <li>• Microbial identification, using methods such as MALDI-TOF MS, GC, HPLC, ISH, target and signal amplification, and sequencing</li> </ul>
<b>Molecular Pathology</b>	<ul style="list-style-type: none"> <li>• Inherited Genetics</li> <li>• Molecular Oncology – Hematologic Diseases</li> <li>• Molecular Oncology – Solid Tumor</li> <li>• Molecular Pathology</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical molecular genetics testing, including oncology, inherited disease, pharmacogenomics, HLA, forensic identity, and relationship testing applications</li> <li>• Molecular assay validation</li> <li>• ISH for constitutional and neoplastic disorders, including predictive marker testing</li> <li>• Methods, such as electrophoresis, PCR, arrays, digital image analysis, and sequencing</li> <li>• Next-generation sequencing, including non-invasive screening of maternal plasma to detect fetal trisomy</li> <li>• Hematopoietic progenitor cell engraftment monitoring</li> </ul>
<b>Point-of-Care Testing (POC)</b>	<ul style="list-style-type: none"> <li>• POCT – Nonwaived</li> <li>• POCT – Provider-Performed Microscopy and Limited Waived Testing</li> <li>• POCT - Waived</li> </ul>	<ul style="list-style-type: none"> <li>• Tests performed at or near the patient bedside (non-dedicated space)</li> <li>• Waived and moderate-complexity testing</li> </ul>



		<ul style="list-style-type: none"> <li>• Kit tests or hand-carried instruments) or otherwise transported to the patient location)</li> <li>• Blood gas analysis</li> <li>• D-dimer studies</li> <li>• HIV primary diagnostic testing</li> <li>• Waived molecular-based microbiology testing</li> <li>• Provider-performed microscopy</li> </ul>
<b>Reproductive Laboratory Medicine</b>	<ul style="list-style-type: none"> <li>• Andrology</li> <li>• Embryology</li> </ul>	<ul style="list-style-type: none"> <li>• Complete semen analysis, automated and manual methods</li> <li>• Biochemical testing</li> <li>• Anti-sperm antibody testing</li> <li>• Sperm processing for therapeutic insemination</li> <li>• Embryology procedures</li> <li>• Embryo and gamete cryopreservation</li> <li>• Donor reproductive cell/tissue programs</li> </ul>
<b>Transfusion Medicine</b>	<ul style="list-style-type: none"> <li>• Cellular Therapy Services</li> <li>• Donor Services</li> <li>• Immunohematology</li> <li>• Tissue Storage and Issue</li> <li>• Transfusion Services</li> </ul>	<ul style="list-style-type: none"> <li>• Immunohematology testing, manual and automated</li> <li>• Compatibility testing, including computer crossmatches</li> <li>• Perinatal testing</li> <li>• Transfusion procedures and adverse reactions</li> <li>• Therapeutic phlebotomy</li> <li>• Donor and therapeutic apheresis</li> <li>• Component preparation, storage, and modification</li> <li>• Cellular therapy</li> <li>• Tissue storage and issue</li> <li>• Donor section, collection, and testing</li> </ul>
<b>Urinalysis</b>	<ul style="list-style-type: none"> <li>• Urinalysis</li> </ul>	<ul style="list-style-type: none"> <li>• Urinalysis dipstick, automated and manual methods</li> <li>• Manual urine microscopy</li> <li>• Automated microscopy systems</li> </ul>