



## CAP Accreditation Checklists—2020 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>• 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</li> <li>• Pipettes and analytical balances</li> <li>• Waived test implementation</li> <li>• Test method validation/verification–nonwaived tests</li> <li>• Individualized quality control plan</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>• Intraoperative 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>• Intraoperative consultation</li> <li>• Fine-needle aspiration</li> <li>• Histology</li> <li>• Immunocytochemistry, immunofluorescence microscopy, and predictive markers</li> <li>• In situ hybridization (ISH)</li> <li>• Digital image analysis</li> <li>• Flow Cytometry Data Interpretation</li> <li>• Circulating tumor cell analysis</li> <li>• Autopsy pathology</li> <li>• Forensic Autopsy</li> <li>• Electronic microscopy</li> <li>• In vivo and ex vivo microscopy</li> </ul>
<b>Biorepository</b>	<ul style="list-style-type: none"> <li>• Specimen Collection/Procurement</li> <li>• Specimen Distribution and Agreements</li> <li>• Specimen Informatics</li> <li>• Nucleic Acid Extraction</li> <li>• General Specimen Processing</li> <li>• Specimen Storage</li> </ul>	<ul style="list-style-type: none"> <li>• Quality management</li> <li>• Biospecimen collection and handling</li> <li>• Biospecimen processing and quality, including DNA/ RNA extraction/amplification, cell fractionization, cell and tissue culture, and histology</li> <li>• Specialized techniques, such as digital image, tissue microarray, and laser capture microdissection</li> <li>• Inventory management system</li> </ul>

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CHECKLISTS	SUBDISCIPLINES	DESCRIPTION OF CONTENTS
<b>Biorepository</b>		<i>Continued</i> <ul style="list-style-type: none"> <li>• Storage</li> <li>• Source and sponsor facility</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>• Anti-nuclear antibody testing</li> <li>• HIV primary diagnostic testing</li> <li>• Hemoglobin separation</li> <li>• Methods, such as TLC, GC, HPLC, MS, Imaging MS, 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, and MS</li> <li>• Newborn screening</li> </ul>
<b>Cytogenetics</b>	<ul style="list-style-type: none"> <li>• Conventional Cytogenetics</li> <li>• In Situ Hybridization</li> <li>• Genomic Copy Number Microarray</li> <li>• Remote Data Assessment</li> </ul>	<ul style="list-style-type: none"> <li>• Cytogenetic studies for constitutional and neoplastic disorders</li> <li>• In situ hybridization ISH</li> <li>• Digital Image analysis</li> <li>• Genomic copy number analysis using array</li> </ul>
<b>Cytopathology</b>	<ul style="list-style-type: none"> <li>• Cytology Processing</li> <li>• Cytology Screening</li> <li>• Gynecologic Cytopathology</li> <li>• Nongynecologic Cytopathology</li> </ul>	<ul style="list-style-type: none"> <li>• Cytology processing and staining</li> <li>• Cytology screening, manual and automated</li> <li>• Gynecologic and nongynecologic cytology (includes FNA)</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 – Oral Fluid</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>• Nonmedical testing drug testing</li> <li>• Screening and confirmatory testing for different specimen types</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>

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<b>Hematology and Coagulation</b>	<ul style="list-style-type: none"> <li>• Body Fluid Analysis</li> <li>• Coagulation</li> <li>• Hematology</li> </ul>	<ul style="list-style-type: none"> <li>• CBC and differentials, automated and manual</li> <li>• Reticulocytes, automated and manual</li> <li>• Bone marrow preparations</li> <li>• Abnormal hemoglobin detection</li> <li>• Blood film examination for malaria and other parasites</li> <li>• Body fluid cell counts ( automated and manual) and differentials</li> <li>• Semen analysis</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, flow cytometry, 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 generic, high resolution, and DNA sequence based typing</li> <li>• Donor-recipient histocompatibility, including renal, hematopoietic progenitor cell, and nonrenal transplants</li> <li>• Hematopoietic progenitor cell engraftment 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>• Anti-nuclear antibody testing</li> <li>• Immune system profiles</li> <li>• Microbial antigen/antibody testing</li> <li>• Waived molecular-based microbiology tests</li> <li>• ABO/Rh and antibody screening (nontransfusion 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</li> <li>• Specimen collection</li> <li>• Chain-of-custody specimen collection and handling</li> <li>• Direct-to-consumer testing</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>

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<b>Limited Service</b>	<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>• Urinalysis dipstick and microscopy, manual and automated methods</li> <li>• Microbiology specimen setup, 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>• Nontransfusion-related immunohematology testing</li> <li>• Syphilis serology</li> <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 film examination for malaria and other parasites</li> <li>• Molecular microbiology, including waived and nonwaived FDA-cleared/-approved method, modified methods, and laboratory-developed methods</li> <li>• Microbial identification, using methods such as MALDI-TOF MS, GC, HPLC, target and signal amplification, and sequencing</li> </ul>
<b>Molecular Pathology</b>	<ul style="list-style-type: none"> <li>• Molecular Pathology</li> <li>• Inherited Genetics</li> <li>• Molecular Oncology – Hematologic Diseases</li> <li>• Molecular Oncology – Solid Tumor</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical molecular genetics testing, including oncology, inherited disease, pharmacogenomics, HLA typing, forensic identity, and relationship testing applications</li> <li>• Molecular assay validation</li> <li>• Methods, such as electrophoresis, PCR, arrays, FISH, and ISH, digital image analysis, and sequencing</li> <li>• Next-generation sequencing, including noninvasive screening of maternal plasma to detect fetal trisomy</li> <li>• Hematopoietic progenitor cell engraftment monitoring</li> </ul>

CHECKLISTS	SUBDISCIPLINES	DESCRIPTION OF CONTENTS
<b>Point-of-Care Testing (POCT)</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 (nondedicated space)</li> <li>• Kit tests or hand-carried instruments (or otherwise transported to the patient location)</li> <li>• Waived and moderate-complexity testing</li> <li>• POCT 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</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>• Antisperm 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>• Donor Services</li> <li>• Hematopoietic Progenitor Cell 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>• Hematopoietic progenitor cells</li> <li>• Tissue storage and issue</li> <li>• Donor selection, 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>