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:

<table>
<thead>
<tr>
<th>CHECKLISTS</th>
<th>SUBDISCIPLINES</th>
<th>DESCRIPTION OF CONTENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Common</td>
<td>N/A</td>
<td>• Proficiency testing</td>
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<tr>
<td></td>
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<td>• Policy and procedure manuals</td>
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<tr>
<td></td>
<td></td>
<td>• Specimen collection and handling</td>
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<tr>
<td></td>
<td></td>
<td>• Quality management</td>
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<tr>
<td></td>
<td></td>
<td>• Reporting of results</td>
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<td></td>
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<td>• Reagents</td>
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<td></td>
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<td>• Instruments and equipment maintenance/function checks</td>
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<td></td>
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<td>• Thermometers and temperature-dependent equipment and environments</td>
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<tr>
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<td>• Pipettes and analytical balances</td>
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<td></td>
<td></td>
<td>• Waived test implementation</td>
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<td></td>
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<td>• Test method validation/verification – nonwaived tests</td>
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<td></td>
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<td>• Individualized quality control plans</td>
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| 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            |
|                    | • 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 |

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<table>
<thead>
<tr>
<th>Specimen Distribution and Agreements</th>
<th>Specimen Informatics</th>
<th>Specimen Storage</th>
<th>Biospecimen processing and quality, including DNA/RNA extraction/amplification, cell fractionization, cell and tissue culture, and histology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialized techniques, such as whole slide imaging, digital image analysis, tissue microarray, laser capture microdissection, and molecular methods</td>
<td>Inventory management system</td>
<td>Storage</td>
<td>Source and sponsor facilities</td>
</tr>
<tr>
<td>Informed consent and institutional review board</td>
<td>Distribution policies and agreements</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Chemistry and Toxicology</th>
<th>Blood Gases</th>
<th>Chemistry</th>
<th>Special Chemistry</th>
<th>Toxicology</th>
<th>Automated chemistry procedures</th>
<th>Blood gas analysis</th>
<th>Therapeutic drug monitoring</th>
<th>Toxicology screening and confirmatory testing</th>
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<td></td>
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<td></td>
<td>Prenatal screening</td>
<td>Cystic fibrosis sweat testing</td>
<td>Tumor marker, immune system, and infectious disease immunoassays</td>
<td>Hemoglobin separation</td>
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<td>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</td>
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<thead>
<tr>
<th>Clinical Biochemical Genetics</th>
<th>Clinical Biochemical Genetics</th>
<th>Newborn Screening</th>
<th>Diagnostic testing for inborn errors of metabolism</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td>Methods, such as enzyme assays, TLC, GC, HPLC, MS, electrophoresis, and RIA</td>
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<tr>
<td></td>
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<td>Newborn screening</td>
</tr>
</tbody>
</table>
| 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 |
|----------------|---------------------------------|---------------------------------------------------|
| Cytology Processing | • 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 cytopathology (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 | • CBC and differentials, automated and manual |
<table>
<thead>
<tr>
<th>Laboratory General</th>
<th>N/A</th>
<th>Quality management system</th>
</tr>
</thead>
</table>
| Hematology        | • 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 | • Clinical Transplantation Support  
                    |     | • 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  
<p>| Quality management system | | |</p>
<table>
<thead>
<tr>
<th>Limited Service</th>
<th>Contains a limited subset of requirements from the checklists, including:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Fluid Analysis</td>
<td>Automated and manual hematology testing, including CBC, reticulocytes, and differentials</td>
</tr>
<tr>
<td>Coagulation</td>
<td>Routine coagulation assays</td>
</tr>
<tr>
<td>Hematology</td>
<td>Body fluid analysis, including semen analysis</td>
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<tr>
<td>Blood Gas Analysis</td>
<td>Automated general chemistry</td>
</tr>
<tr>
<td>Chemistry</td>
<td>Blood gas analysis</td>
</tr>
<tr>
<td>Special Chemistry</td>
<td>Therapeutic drug monitoring</td>
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<tr>
<td>Toxicology</td>
<td>Screening for drugs of abuse</td>
</tr>
<tr>
<td>Bacteriology</td>
<td>Tumor marker and infectious disease immunoassays</td>
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<tr>
<td>Parasitology</td>
<td>Urinalysis dipstick and microscopy, manual and automated methods</td>
</tr>
<tr>
<td>Mycology</td>
<td>Microbiology specimen set up, direct specimen examination, stains, and antigen typing for various subdisciplines</td>
</tr>
<tr>
<td>Virology</td>
<td>General immunology assays, including anti-nuclear antibody testing, HIV primary diagnostic testing, and immune system profiles</td>
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<tr>
<td>Urinalysis</td>
<td>Microbial antigen/antibody testing</td>
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<tr>
<td>Immunology</td>
<td>Non-transfusion-related immunohematology testing</td>
</tr>
<tr>
<td>Immunohematology</td>
<td>Syphilis serology</td>
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<tr>
<td>Microbiology</td>
<td>• Waived molecular based microbiology tests</td>
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<td>----------------------------------------------</td>
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<tr>
<td>• Bacteriology</td>
<td>• Culture setup, staining, antigen typing,</td>
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<tr>
<td>• Molecular Microbiology</td>
<td>screening, identification, and</td>
</tr>
<tr>
<td>• Mycobacteriology</td>
<td>susceptibility testing for</td>
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<tr>
<td>• Mycology</td>
<td>bacteriology, mycology,</td>
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<tr>
<td>• Parasitology</td>
<td>mycobacteriology, and virology</td>
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<tr>
<td>• Virology</td>
<td>• Parasitology, including stool for ova</td>
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<td>and parasites and blood films for</td>
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<td></td>
<td>microorganisms</td>
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<td></td>
<td>• Molecular microbiology, including</td>
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<td></td>
<td>waived and non-waived FDA-cleared/approved</td>
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<td></td>
<td>methods, modified methods, and</td>
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<td></td>
<td>laboratory-developed methods</td>
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<td>• Microbial identification, using methods</td>
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<td>such as MALDI-TOF MS, GC, HPLC, ISH,</td>
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<td></td>
<td>target and signal amplification, and</td>
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<tr>
<td></td>
<td>sequencing</td>
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<tr>
<td>Molecular Pathology</td>
<td>• Inherited Genetics</td>
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<tr>
<td>• Inherited Genetics</td>
<td>• Clinical molecular genetics testing,</td>
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<tr>
<td>• Molecular Oncology – Hematologic Diseases</td>
<td>including oncology, inherited</td>
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<tr>
<td>• Molecular Oncology – Solid Tumor</td>
<td>disease, pharmacogenomics, HLA,</td>
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<tr>
<td>• Molecular Pathology</td>
<td>forensic identity, and relationship</td>
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<td></td>
<td>testing applications</td>
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<td></td>
<td>• Molecular assay validation</td>
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<td>• ISH for constitutional and neoplastic</td>
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<td>disorders, including predictive marker</td>
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<td></td>
<td>testing</td>
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<td>• Methods, such as electrophoresis,</td>
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<td>PCR, arrays, digital image analysis,</td>
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<td>and sequencing</td>
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<td>• Next-generation sequencing, including</td>
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<td>non-invasive screening of maternal</td>
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<td>plasma to detect fetal trisomy</td>
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<td></td>
<td>• Hematopoietic progenitor cell</td>
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<td>engraftment monitoring</td>
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<tr>
<td>Point-of-Care Testing (POC)</td>
<td>• POCT – Nonwaived</td>
</tr>
<tr>
<td>• POCT – Nonwaived</td>
<td>• Tests performed at or near the patient</td>
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<tr>
<td>• POCT – Provider-Performed Microscopy and</td>
<td>bedside (non-dedicated space)</td>
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<tr>
<td>Limited Waived Testing</td>
<td>• Waived and moderate-complexity testing</td>
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<tr>
<td>• POCT - Waived</td>
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<tr>
<td>Reproductive Laboratory Medicine</td>
<td>Andrology</td>
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<td>Transfusion Medicine</td>
<td>Cellular Therapy Services</td>
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