COLLEGE of AMERICAN PATHOLOGISTS

2020 Checklist Edition

Revised requirements	Subject Header	Type of Change	Key Changes
ANATOMIC PATHOLOGY CHECKLIST (ANP)			
ANP.10010	Professional Competency	Revision	Added the phrase "at defined intervals" to clarify that the frequency of assessment of professional competency must be defined in policy.
ANP.11600	Gross Examination - Qualifications	Revision	Added the word "qualified" in front of the term pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
ANP.12075	Residual Frozen Tissue After Frozen Section Examination	Revision	Added new exceptions and clarified existing content for retention of residual frozen section tissue for the following: - Frozen tissue to be submitted at the time of initial diagnosis for specialized studies; or frozen tissue from lesions that have the potential for additional studies using archived frozen tissue at a later time - Other frozen sections where the margin or lesion has been exhausted during the frozen section evaluation and no pertinent residual tissue remains - Mohs frozen sections, unless warranted (see checklist for more detail).
ANP.12175	Significant and Unexpected Findings	Revision	Streamlined content and clarified the pathology department's role in defining surgical pathology diagnoses warranting special communication to the clinician.
ANP.12185	Amended Reports	Revision	Added new content that the amended report must state the reason for the amendment.
ANP.12350	Cancer Protocols	Revision	Added instructions for when to issue an amended or addendum report when errors are found during the self-audit of cancer reports. - Laboratories must issue an amended or addendum report for reports missing required data elements or have omissions/errors that may adversely affect patient care. - Laboratories are not required to issue an amended or addendum report for errors that have no measurable effect on patient care.
ANP.21832	Reagent Expiration Date	Moved/Merged	Merged with COM.30400 to standardize content.

ANP.22966	ISH Interpretation	Revision	Added the word "qualified" in front of the term pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
ANP.22970	Annual Result Comparison - Breast Carcinoma	Revision	Clarified applicability of the requirement to HER2 and ER immunohistochemistry tests on breast carcinoma that provide independent predictive information.
ANP.22978	Predictive Marker Testing - Validation/Verification	Revision	Removed PgR as a predictive marker. The CAP has determined that PgR is a prognostic marker rather than a predictive marker.
ANP.22979	Estrogen Receptor and HER2 Testing in Breast Cancer Samples	Revision	Removed PgR as a predictive marker. The CAP has determined that PgR is a prognostic marker rather than a predictive marker. Removed the NOTE because it was redundant with the stem of the requirement.
ANP.22983	Fixation - HER2 and ER Breast Cancer Predictive Marker Testing	Revision	Removed PgR as a predictive marker. The CAP has determined that PgR is a prognostic marker rather than a predictive marker.
ANP.23027	Area of Analysis	Revision	Deleted content explaining what is considered a qualified pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
ANP.23350	Paraffin Baths, Flotation Baths, and Embedding Stations	Revision	Added detail for proper monitoring of paraffin baths and dispensers.
ANP.30160	Significant and Unexpected Findings	Revision	Streamlined content to clarify laboratory responsibility in communicating significant and unexpected autopsy findings and how they may be communicated.
ANP.34000	Safety	Revision	Updated terminology from universal precautions to standard precautions.
ANP.34150	Special Handling of Transmissible Spongiform Encephalopathies (TSE)	Revision	Updated terminology from universal precautions to standard precautions.
BIOREPOSITORY CHECKLIST (BAP)			
BAP.02300	Procedure for Handling Specimens for Infectious Diseases	Revision	Updated terminology from universal precautions to standard precautions.
BAP.03825	Reagent Expiration Date	Moved/Merged	Merged with COM.30400 to standardize content.
BAP.05100	Neoplastic Cell Content	Revision	Added the word "qualified" in front of the term pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.

BAP.05440	Area of Analysis	Revision	Deleted content explaining what is considered a qualified pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
BAP.06790	ISH Interpretation	Revision	Added the word "qualified" in front of the term pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
BAP.07400	Paraffin, Flotation Baths, and Embedding Stations	Revision	Added detail for proper monitoring of paraffin baths and dispensers.
CHEMISTRY & TOXICOLOGY CHECKLIST (CHM)			
CHM.14200	Alternative Control Procedures	Revision	Modified the requirement for consistency with other checklists to clarify the need for "written" procedures and for a mechanism to detect "immediate" errors.
CHM.21440	Area of Analysis	Revision	Deleted content explaining what is considered a qualified pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
CHM.33790	HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing	New	Added new requirement for laboratories to follow public health recommendations or guidelines for HIV primary diagnostic testing to include screening and additional testing (confirmatory and/or supplemental testing).
CLINICAL AND BIOCHEMICAL GENETICS CHECKLIST (CBG)			
CBG.14900	Calibration and Calibration Verification	Revision	Clarified frequency for calibration and calibration verification for gas chromatography for each day of patient testing
CBG.15000	Quality Control - GC	Revision	Clarified frequency for gas chromatography
CBG.17800	Spectrophotometer Checks	Revision	Modified spectrophotometer check to include wavelength calibration, absorbance, and linearity.
CYTOGENETICS CHECKLIST (CYG)			
CYG.32700	Material Retention	Revision	Clarified retention of non-ISH images (eg, g-banded studies).
CYG.47866	ISH Interpretation	Revision	Added the word "qualified" in front of the term pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.

CYG.49485	Area of Analysis	Revision	Deleted content explaining what is considered a qualified pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
CYTOPATHOLOGY CHECKLIST (CYP)			
CYP.03925	Stain Assessment	Moved/Merged	Merged with COM.30400.
CYP.06450	Significant and Unexpected Findings	Revision	Streamlined content and clarified the cytopathology department's role in defining cytopathology diagnoses warranting special communication to the clinician.
CYP.06475	Amended Reports	Revision	Clarified requirement for issuing amended reports and notification to the responsible clinician for consistency with the Anatomic Pathology Checklist requirement.
FORENSIC DRUG TESTING CHECKLIST (FDT)			
FDT.05809	Specimen Validity	Moved/Merged	Merged with FDT.05811.
FDT.05811	Specimen Validity	Revision	Added new content for measures that can be taken to test for validity of the specimen.
FDT.05843	External Contamination	Moved/Merged	Merged with FDT.05841.
FLOW CYTOMETRY CHECKLIST (FLO)			
FLO.23325	New Reagent Lot/Shipment Confirmation of Acceptability	Revision	Broadened the scope of reagents for applicability of this requirement.
HEMATOLOGY & COAGULATION CHECKLIST (HEM)			
HEM.20050	Numeric QC Data	Revision	Modified for consistency with like requirements in other checklists.
HEM.30100	Detection/Correction Procedure - WBC	Revision	Clarified requirement for detection and correction of WBC counts in the presence of megakaryocytes and nucleated RBCs.
HEM.30150	Spurious CBC Results	Revision	Deleted redundant educational examples of causes of spurious CBC instrument results.
HEM.30200	Red Cell Indices	Revision	Deleted redundant educational examples of causes of random errors for RBC indices and content on semi-automated instruments.
HEM.34660	Ocular Micrometer	Moved/Merged	Merged with COM.30690
HEM.34665	Calibration/Recalibration - Ocular Micrometer	Moved/Merged	Merged with COM.30690
HEM.34687	Parasite Load Reporting	Revision	Added new content on the reporting of parasite load for malarial parasites and educational content on Babesia.
HEM.35905	Calibration/Recalibration - Ocular Micrometer	Moved/Merged	Merged with COM.30690
HEM.36325	Correlation of Results	Revision	Added molecular pathology to the listing of ancillary studies for correlation to bone marrow morphology findings.

HEM.36920	Specimen Quality Assessment - Coagulation	Revision	Clarified information on techniques to be used for checking coagulation specimens for clots prior to testing.
HEM.37960	Standard Curve Verification	Revision	Added content for methods that store two standard curves for factor assays.
HEM.37980	Factor Assay Criteria	Revision	Added content to clarify that the requirement does not apply to chromogenic factor assays or fibrinogen assays.
HEM.37982	Inhibitor Effect	Revision	Added content to explain how this requirement applies to non-immunologic fibrinogen methods.
HISTOCOMPATIBILITY CHECKLIST (HSC)			
HSC.29917	Reagent Expiration Date - Red Cell Typing	Moved/Merged	Merged with COM.30400.
HSC.30013	Cellular Viability	Revision	Clarified when cellular viability testing of specimens is required.
IMMUNOLOGY CHECKLIST (IMM)			
IMM.41450	HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing	New	Added new requirement for laboratories to follow public health recommendations or guidelines for HIV primary diagnostic testing to include screening and additional testing (confirmatory and/or supplemental testing).
LIMITED SERVICES CHECKLIST (LSV)			
LSV.37660	Detection/Correction Procedure - WBC	Revision	Clarified requirement for detection and correction of WBC counts in the presence of megakaryocytes and nucleated RBCs.
LSV.37680	Spurious CBC Results	Revision	Deleted redundant educational examples of causes of spurious CBC instrument results.
LSV.37700	Red Cell Indices	Revision	Deleted redundant educational examples of causes of random errors for RBC indices and content on semi-automated instruments.
LSV.38690	Specimen Quality Assessment - Coagulation	Revision	Clarified information on techniques to be used for checking coagulation specimens for clots prior to testing.
LSV.39510	Standard Curve	New	Added a new requirement for fibrinogen end point-based assays for three or more points to be plotted for the standard curve.
LSV.39520	Standard Curve Verification	New	Added a new requirement for non-immunologic fibrinogen assays to verify standard curves with at least two reference points each eight hours of testing or when an assay is performed.
LSV.39530	Inhibitor Effect	New	Added content to explain how this requirement applies to non-immunologic fibrinogen methods.
LSV.41346	HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing	New	Added new requirement for laboratories to follow public health recommendations or guidelines for HIV primary diagnostic testing to include screening and additional testing (confirmatory and/or supplemental testing).

LSV.41815	Hb S Primary Screen	New	Added a new requirement for laboratories that perform Hb solubility testing as a screening test for sickling hemoglobins to either: - have a second procedure performed to confirm the presence of Hb S OR - include a comment in the patient report recommending that confirmatory testing be performed.
LSV.42050	Urine Specimen Collection	Revision	Modified the NOTE to include a recommendation to have urinalysis specimen collection instructions in foreign languages common to the population served by the laboratory.
LSV.42290	Urine Specimen Examination	Revision	Clarified applicability of the requirement to specimens to be tested that have not been preserved or refrigerated and removed content relating to specimen preservation techniques.
LSV.42370	Urine Preservation	Revision	Added new content on specimen preservation techniques (refrigeration and preservatives) to be used to maintain the integrity of specimens if testing is delayed.
LSV.43864	Calibration/Recalibration - Ocular Micrometer	Moved/Merged	Merged with COM.30690
LSV.44610	Blood Culture Collection	Revision	Moved content from the checklist NOTE to MIC.22635.
LSV.44620	Blood Culture Contamination	New	Added a new requirement to focus on monitoring for blood culture contamination against defined thresholds and actions to reduce contamination.
LSV.45315	Ocular Micrometer	Moved/Merged	Merged with COM.30690
LSV.45320	Calibration/Recalibration - Ocular Micrometer	Moved/Merged	Merged with COM.30690
LSV.45560	Smear Preparation and Stain Quality	New	Added a new requirement to ensure that the quality of smear preparation and staining is satisfactory for all microbiology stains (ie, proper smear thickness, free of precipitate, proper cell distribution, appropriate staining reactions, etc.).
LSV.47050	HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing	New	Added new requirement for laboratories to follow public health recommendations or guidelines for HIV primary diagnostic testing to include screening and additional testing (confirmatory and/or supplemental testing).
MICROBIOLOGY CHECKLIST (MIC)			
MIC.21815	Campylobacter Incubation Conditions QC	Revision	Expanded requirement to address commonly isolated Campylobacter species.

MIC.21835	Direct Identification and Susceptibility from Blood Culture Broth	Revision	Modified to limit applicability of this requirement to direct organism identification and/or susceptibility testing from positive blood culture broths.
MIC.21855	Resistance Determinants and Phenotypic AST	Deletion	Removed this requirement due to problems interpreting this requirement for different types of specimens. This item will be further evaluated and may be brought back in a future edition with clarified wording.
MIC.22630	Blood Culture Collection	Revision	Moved content from the checklist NOTE to MIC.22635.
MIC.22635	Blood Culture Contamination	New	Added a new requirement to focus on monitoring for blood culture contamination against defined thresholds and actions to reduce contamination.
MIC.22870	GC Reagent Grade	Revision	Modified to address reagents, solvents, and gases.
MIC.32140	Rapid Method	Revision	Added MALDI-tof as a rapid method for identification of mycobacterial isolates.
MIC.32150	Rapid Detection of Mycobacterium tuberculosis Complex - Laboratories Subject to US Regulations	New	Added a new requirement for availability of a nucleic acid amplification test to detect *M. tuberculosis*, which may be performed in the laboratory or be referred to another laboratory. This requirement only applies to testing performed on patients suspected of having pulmonary tuberculosis.
MIC.32170	Rapid Detection of Mycobacterium Tuberculosis Complex - Laboratories Not Subject to US Regulations	New	Added a new requirement for availability of a nucleic acid amplification test to detect *M. tuberculosis*, which may be performed in the laboratory or be referred to another laboratory, OR for the laboratory to follow an established testing algorithm for the region/country. This requirement only applies to testing performed on patients suspected of having pulmonary tuberculosis.
MIC.42350	Differential Tests	Revision	Modified to include "where appropriate" to clarify that biochemical tests (eg, urease, carbohydrate assimilation and/or fermentation) on mycology isolates may not always be needed.
MIC.51210	Ocular Micrometer	Moved/Merged	Merged with COM.30690
MIC.51220	Calibration/Recalibration - Ocular Micrometer	Moved/Merged	Merged with COM.30690
MIC.52195	Parasite Load Reporting	Revision	Added new content on the reporting of parasite load for malaria parasites and educational content on Babesia.
MIC.64960	Validation or Verification Studies - Specimen Selection	Revision	Added guidance on the number of specimens and specimen types to be included in a validation or verification study for a molecular infectious disease test.

MIC.65620	HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing	new	Added new requirement for laboratories to follow public health recommendations or guidelines for HIV primary diagnostic testing to include screening and additional testing (confirmatory and/or supplemental testing).
MOLECULAR PATHOLOGY CHECKLIST (MOL)			
MOL.30785	Validation Study Approval	Revision	Added new content to clarify applicability to laboratories not subject to US regulations using instruments/methods approved by a internationally recognized regulatory authority that have been modified by the laboratory.
MOL.31130	Validation of Test Performance Specifications	Revision	Added new content to clarify applicability to laboratories not subject to US regulations using instruments/methods approved by a internationally recognized regulatory authority that have been modified by the laboratory.
MOL.32395	Neoplastic Cell Content	Revision	Added the word "qualified" in front of the term pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
MOL.35865	NGS Data Transfer Confidentiality	Revision	Added new content to the NOTE for methods to check data integrity, such as a hash/checksum (eg, MD5) pre and post-transfer of files during NGS workflow, to prevent modification/deletion of data and to ensure that complete and intact unmodified data have been transferred.
MOL.36015	NGS Analytical Wet Bench Process Validation	Revision	Added new content to the NOTE for validation of the detection of hotspot mutations.
MOL.36115	NGS Analytical Bioinformatics Process Validation	Revision	Modified the checklist NOTE to include additional aspects that need to be addressed during validation of the NGS analytical bioinformatics process.
MOL.36118	NGS Lower Limit of Detection	Revision	Added additional detail for the validation of the lower limit of detection for variants.
MOL.39155	ISH Interpretation	Revision	Added the word "qualified" in front of the term pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
MOL.39470	Area of Analysis	Revision	Deleted content explaining what is considered a qualified pathologist. A definition of the terms pathologist and qualified pathologist have been added to the Definition of Terms in the All Common and Laboratory General Checklists.
MOL.49575	Variant Database	Revision	Added a NOTE to provide guidance on variant databases.

POINT-OF-CARE TESTING CHECKLIST (POC)			
POC.08640	HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing	New	Added new requirement for laboratories to follow public health recommendations or guidelines for HIV primary diagnostic testing to include screening and additional testing (confirmatory and/or supplemental testing).
REPRODUCTIVE LABORATORY MEDICINE CHECKLIST (RLM)			
RLM.00950	Misidentification Risk	New	Added a new requirement for laboratories to implement a system to reduce the risk of misidentification of gametes and embryos during all critical procedural steps and monitor the effectiveness of the system implemented.
RLM.03915	Incubator Gas Concentrations	Revision	Added more detailed content to the NOTE for methods of monitoring gas concentrations in incubators, including the use of digital readouts and automated monitoring systems.
RLM.06450	Ocular Micrometer Calibration/Recalibration	Moved/Merged	Merged with COM.30690.
RLM.08700	Disposition of Oocytes	Revision	Modified to allow laboratories more flexibility in defining policies for the disposition or use of embryos with abnormal numbers of pronuclei.
TRANSFUSION MEDICINE CHECKLIST (TRM)			
TRM.30575	Misidentification Risk	Revision	Added a NOTE that states that laboratories are expected to monitor systems used to reduce the risk of mistransfusion.
TRM.30700	QC Records	Revision	Modified the requirement to clarify that records are needed for investigation, corrective taken, and final disposition of components prepared that do not meet the quality control requirements.
TRM.30800	Disposition Records	Revision	Added clarification that the method of destruction for unused products must be defined in laboratory policy/procedure.
TRM.31250	Reagent Expiration Date	Moved/Merged	Merged with COM.30400 to standardize content.
TRM.31400	Antisera/Reagent Red Cell QC	Revision	Added a new section in the NOTE to address antibody panel QC.
TRM.31900	Serologic Centrifuge Checks	Revision	Clarified the frequency of serologic centrifuge checks.
TRM.32250	Record Retention	Revision	Added retention information for policies, procedures, and other controlled documents for tissue records.
TRM.32350	Records QC	Moved/Merged	Moved this requirement for verifying copies of records to the Laboratory General Checklist, GEN.20430, and added specific detail for a process to ensure that all laboratory records being converted onto another medium for storage and retention be verified for accuracy, legibility, and completeness before the original record is destroyed.
TRM.40215	ABO Typing on Solid Organ Donors	Revision	Modified to require A subgroup typing for donors being evaluated for solid organ transplantation typing as type A or AB.

TRM.40700	Selection of Blood Components	Revision	Added provisions for the use of low-titer group 0 whole blood.
TRM.40720	Provisions for Special Components	Revision	Added provisions for the use of low-titer group 0 whole blood.
TRM.42500	Blood/Component Storage Monitoring	Revision	Clarified the need for room temperature monitoring for platelets stored outside of a platelet incubator.
TRM.42600	Consistent Temperature	Revision	Added educational content to the NOTE to explain how to determine the appropriate number and placement of probes and thermometers.
TRM.42750	Storage Unit Alarms	Revision	Added examples to the NOTE of recording systems that can be used to capture temperature alarm check data.
TRM.43605	Component Labeling - Final Inspection	New	Added a new requirement for final inspection of the component labeling process, which includes verifying that all the information is correct on the label by: - One appropriately trained member of the transfusion service using a validated process (eg, electronic system) OR - Two appropriately trained staff.
TRM.45254	Training and Competency for Donor Collection Personnel	Revision	Modified to require training and assessment of competency at least annually of personnel responsible for the donor selection process, pre-donation examination, and phlebotomy. - Competency is to be assessed as defined by the laboratory director and does not require all elements as stated in GEN.55500.
TRM.45270	Directed Donation Requirements	Revision	Modified to include a new option for handling directed donations between blood relatives that allows for irradiation of the component OR treatment by a method approved by the FDA to prevent transfusion associated graft-versus-host disease (TA-GVHD).
TRM.47100	Infectious Disease Testing	Revision	Modified the NOTE to include information on pathogen reduction methods as an alternative to testing in some circumstances and NAT testing for Babesia in some states.
TRM.48060	Pre-Collection Testing	New	Added a new requirement for cellular therapy collections to perform a complete blood count, including platelet count, within 24 hours prior to each collection.
TRM.48070	Assessment of Cellular Product	New	Added a new requirement for cellular therapy collection to have a process for assessing the quality of each product collected to confirm product safety, viability, and integrity.
TRM.48090	Donor Eligibility Status - Allogeneic Donors	New	Added a new requirement for cellular therapy collection facilities to provide records for each allogeneic cellular donor's eligibility to the processing facility.

TRM.50150	Training and Competency for Critical Tasks	New	Added a new requirement for training and assessment (at least annually) of transfusion service personnel responsible for performing critical tasks. - Defines critical tasks as any non-testing function performed in the transfusion service that can affect patient safety or the quality of the service performed (eg, issuing blood components, modification/manufacturing of blood products). - Allows competency is to be assessed as defined by the laboratory director and does not require all elements as stated in GEN.55500.
TRM.60710	Adequate Space - Cellular Therapy Products	New	Added a new requirement for adequate space in the cellular therapy area for: - Collection of cellular therapy products - Storage of equipment supplies, and reagents - Access of additional or emergency personnel in the event of an untoward event - Minimization of the risk of airborne microbial contamination, mix-ups and cross-contamination of products.
URINALYSIS CHECKLIST (URN)			
URN.22000	Urine Specimen Collection	Revision	Modified the NOTE to include a recommendation to have urinalysis specimen collection instructions in foreign languages common to the population served by the laboratory.
URN.22300	Urine Specimen Examination	Revision	Clarified applicability of the requirement to specimens that have not been preserved or refrigerated and removed content relating to specimen preservation techniques.
URN.22400	Urine Preservation	Revision	Added new content on specimen preservation techniques (refrigeration and preservatives) to maintain the integrity of specimen if testing is to be delayed.

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Instructions for Downloading the CAP Checklists

1. Go to cap.org and log in (you must be from a CAP-accredited laboratory and have user permission from your laboratory's site administrator to download checklists)
2. Click on the **Checklists** option in e-Lab Solutions Suite
3. Use the dropdown option for **Section/Dept** and **Checklist Module** to identify and select from checklists used in your laboratory's specific sections/departments
4. Click on the **Checklist Edition** that you want to download
5. Select the desired **Checklist Type** from the dropdown box. Options are:
    - **Master** – contain all requirements in the specified checklist and references
    - **Custom** – contain applicable requirements based upon each section/department's activity menu
    - **Changes Only** – Include only those requirements that have been changed, added, or deleted since the previous edition in a track changes format
6. Select the desired **Checklist Format** from the dropdown box. Options include:
    - **PDF**
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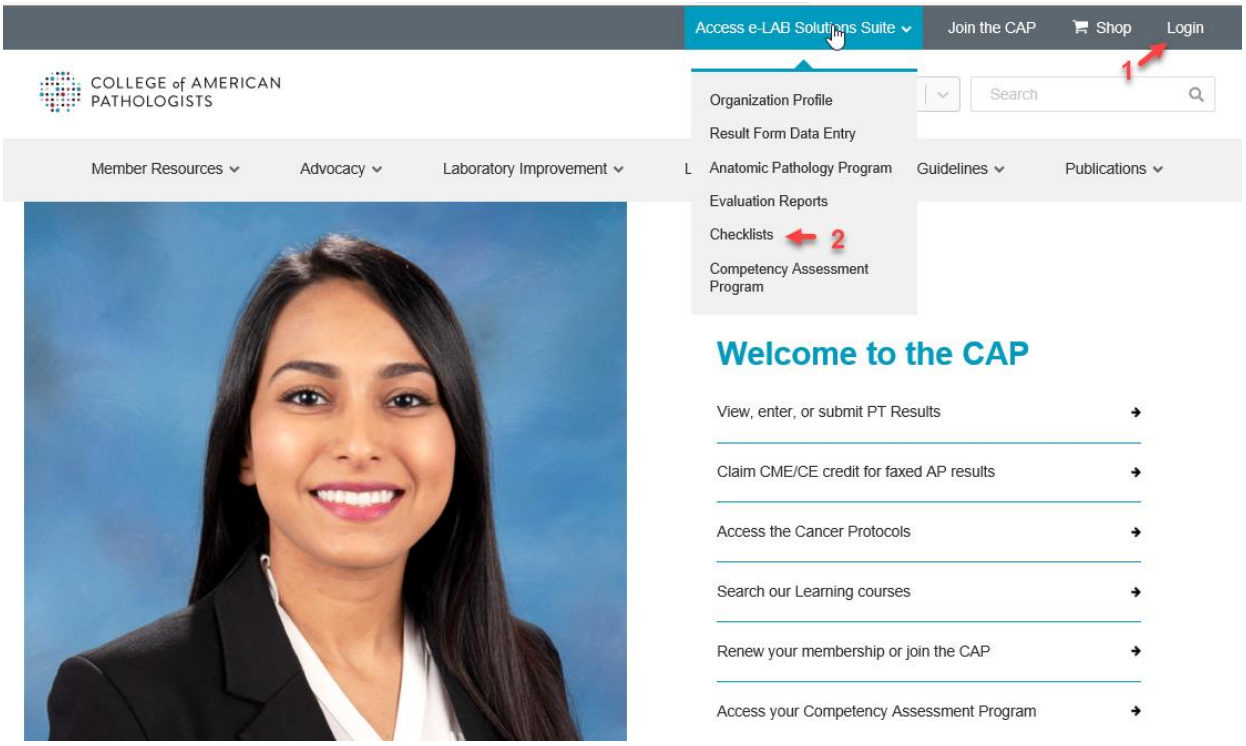
7. Click on **Download Checklist** to start the download process. The document will open in the format selected and can be saved locally.



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