Focus on Compliance

Staying in Sync: CAP Accreditation Checklist Changes for 2024

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Disclosure

The following authors/planners/reviewers/speakers have no financial interests/relationships to disclose:

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Objectives

- List key changes in the 2024 version of the CAP Accreditation Program requirements.
- Explain the rationale for the 2024 requirement changes.
- Identify laboratory/practice improvement opportunities to align with 2024 requirements.
- Examine CAP resources to identify changes and compliance solutions.

Summary of Changes in 2024

Checklist	Requirements	New	Significant Changes	Deleted	Moved/Merged
ANP	192	6	10	0	0
BAP	177	1	5	0	0
CBG	73	0	0	0	0
CHM	155	3	4	0	10
COM	84	0	15	0	1
CYG	66	0	5	1	0
CYP	88	3	18	0	0
DRA	22	2	3	0	0
FDT	106	0	0	0	0
FLO	51	2	5	0	1
GEN	256	1	18	0	0
HEM	182	1	5	0	0
HSC	147	3	14	2	0
IMM	66	0	2	0	0
LSV	285	7	11	0	0
MIC	222	1	5	0	3
MOL	162	0	23	2	0
POC	69	5	4	0	0
RLM	118	0	3	0	0
TRM	259	1	12	0	0
URN	27	0	0	0	0
TOTAL	2,807	36	162	5	15

Annual Checklist Changes: Why…

- **Scientific updates**
  - Emerging technologies
  - Advancement in technology
  - CAP Scientific Resource Committees
- **Regulatory changes/updates**
  - Clinical Laboratory Improvement Amendments (CLIA)/Centers for Medicare & Medicaid Services (CMS)
  - Food and Drug Administration (FDA)
  - World Health Organization (WHO)
  - Other internationally recognized agencies
- **Improve clarity**

Laboratory General Checklist Changes

GEN.13806 Quality Management System (QMS)

The laboratory has a document that describes the overall QMS.

If the laboratory is part of a larger organization, the laboratory QMS describes its process for communicating quality monitors or concerns appropriate for the organization's overall QM program. This process may include participation in a medical executive committee, the organization's quality management reporting structure, or direct interaction with other departments in the organization. Evidence of participation may include submission of data, minutes from the organizational QM activity, or records of standing meetings. Laboratory quality initiatives that may be reported through this process include, but are not limited to, unexpected post-operative diagnoses, blood component usage, or test ordering practices.

- **Added content to ensure that laboratories that are part of a larger organization have a process to communicate quality data with the overall QM program.**

GEN.41096 Report Elements

The paper or electronic report includes the following elements…

The laboratory must report reference intervals or interpretations with patient/client results, where such exist, to allow for proper interpretation of patient/client data. Age- and/or sex-specific reference intervals or interpretive ranges must be reported with patient test results, as applicable. In addition, the use of high and low flags is recommended. It is not necessary to include reference intervals when test results are reported as part of a treatment protocol that includes clinical actions which are based on the test result (eg, activated clotting time in cardiac surgery).

Under some circumstances it may be appropriate to distribute lists or tables of reference intervals (printed copies or electronic data) to users and sites where reports are received. The laboratory must ensure that such data is up to date.

- **Merged content from COM.29950 into GEN.41096 for Report Elements to include Reference Intervals.**

GEN.41096 Report Elements – Remote Sites

- **Added new content for remote sites under the laboratory's CAP/CLIA certificate where digitized images or data and reviewed and interpreted by laboratory personnel on a recurrent or regular basis:**

All required report elements must be included on the patient report.

The remote site location (using the address or coding system) must be included on the report.

Remote sites with a separate CAP/CLIA certificate are considered under the purview of the separate laboratory.

Review of physical slides at a remote site is not allowed by the CMS unless it has its own CLIA certificate.

More stringent state, and local regulations relating to remote sites must be followed.

Remote staff must be included on Laboratory Personnel Evaluation Roster (GEN.54025).

Reference: QSO-23-15-CLIA

GEN.41316 Infectious Disease Reporting

The laboratory ensures communication of diagnoses of infectious diseases of particular significance to the physician or other clinical personnel responsible for patient care and records of those communications are retained.

Note: Certain infectious disease diagnoses may be considered significant and warrant special communication to the responsible physician or other clinical personnel responsible for patient care. The laboratory, ideally in consultation with medical staff and infection control, must determine which infectious diseases (eg, HIV, tuberculosis) are considered "particularly significant." Considerations include isolation procedures or contact precautions that may be initiated based on a specific diagnosis.

- **Clarified the intent of GEN.41316 to ensure particularly significant infectious diseases are communicated appropriately.**

GEN.41318 Reporting to Public Health Authorities

The laboratory ensures there is a mechanism in place to report test results and submit materials (specimens and/or culture isolates) to public health authorities, if required by national, federal, state (or provincial), and local laws and regulations.

- **Added new requirement for reporting results and submitting materials to public health authorities.**

GEN.77400 Emergency Eyewash

The laboratory has adequate plumbed or self-contained emergency eyewash facilities safely placed in every area where exposure to the eye from corrosive chemicals, as defined by the laboratory's chemical hygiene plan, may occur. Testing records are retained.

Evidence of Compliance:

- ✓ Records of weekly activation (for plumbed systems) or weekly visual examination
- ✓ (for self-contained units) **AND**
- ✓ Maintenance records

- **Risk-based approach for appropriate eyewash placement.**
- **Disposable eyewash bottles should be located away from bottles containing chemicals.**
- **Manufacturer's instructions must be followed for maintenance.**
- **Inspector responsibility to determine if the eyewash location is acceptable.**

Knowledge Check

Scenario

You are inspecting the microbiology section of a laboratory. You notice that there is a stain rack in the sink where the eyewash station is located, and the sink looks heavily stained. You then see another staff member discard urine supernatant into the same sink.

As an inspector, do you think the eyewash station is safely located?

Answer

No: With the waste from the stain and potential biologic hazard from the urine supernatant, there is an exposure risk for any staff member that may need to use the eyewash station through splashing of water with the waste and other hazards in the sink.

All Common Checklist Changes

COM.01200 Activity Menu

The laboratory's current CAP Activity Menu accurately reflects the testing performed.

*Note: The laboratory's CAP Activity Menu must include all patient/client testing performed by the laboratory**...***

- **Revised the note to address frequently asked questions and commonly cited deficiencies.**
- **Clarified the following:**
  - **Testing must be included on a laboratory's CAP activity menu regardless of PT provider.**
  - **Activity menu must include review/interpretation of digitized images and data at remote sites under the laboratory's CAP/CLIA certificate.**
  - **Not the same as an instrument list.**
  - **Includes analytes that are directly measured.**
  - **Testing performed under a separate CLIA certificate must not be listed.**
  - **Includes research testing that has patient-specific results.**

COM.01500 Alternative Performance Assessment

For tests for which the CAP does not require proficiency testing (PT), the laboratory at least semiannually exercises an alternative performance assessment system for determining the reliability of analytic testing.

Note 5: Calculated test results derived from directly measured test results (eg, O2 saturation) do not require PT or alternative assessment, with the exception of nonwaived calculated INR, calculated hematocrit, and estimated hemoglobin. PT or alternative performance assessment requirements apply to the measured analytes used to obtain the calculated result.

- **Added note 5 to clarify calculated results.**

COM.30750 Temperature Checks

The laboratory monitors and records temperatures using a calibrated thermometer as defined in written procedure for the following:

- **Temperature-dependent storage devices (eg, refrigerators, freezers, incubators)**
- **Temperature-dependent equipment (eg, water baths, heat blocks)**
- **Temperature-dependent environments (eg, ambient reagent or specimen storage, conditions for instrument operation and test performance)**

- **Revised the note to address frequently asked questions and commonly cited deficiencies.**
- **Clarified the following:**
  - **If minimum/maximum thermometer used during closures, must record both high and low.**
  - **Instruments/devices with built-in, fail-safe technology that will disable use if temperatures are out of range are exempted from the daily temperature check.**

Knowledge Check

Scenario

You are inspecting a remote laboratory that is closed on weeknights and weekends. The laboratory uses a min/max thermometer to monitor temperatures during closures. You are reviewing the temperature log and see a high and a low temperature documented following the weekends and holiday closures. You then see a single daily temperature documented on the workdays of the week.

QC CHART : REFRIGERATOR			RANGE : 2-8°C		
MONTH: SEPTEMBER			YEAR: 2024		
DATE	TEMPERATURE		DAILY TEMPERATURE	INITIALS	CORRECTIVE ACTIONS
	MIN	MAX			
1					
2					
3	3C	7C	5C	SLM	
4			6C	EJO	
5			4C	PWE	
6			7C	SME	
7					
8					
9	4C	8C	6C	EJO	
10			6C	SME	
11			4C	PWE	
12			5C	SME	
13			4C	EJO	

Is this laboratory in compliance with COM.30750?

Answer

Yes: For days where the laboratory is in operation and a temperature is recorded, it is not necessary to record a high/low temperature the following day, unless required by laboratory policy. For closures where the laboratory was not open the previous day, a high/low temperature must be measured during the period when the laboratory is closed and evaluated when the laboratory reopens.

Contract Research Organization Laboratories: COM.40300, 40325, 40350

Tests performed strictly for research purposes

- Laboratory may accept validation/verification studies performed by the sponsor or manufacturer
- Laboratory must retain records showing:
  - Attestation by the manufacturer/contractor of validation/verification AND
  - How the test is used AND
  - Attestation that it is used for research only

Tests performed to render decisions that may affect the study subject

- The laboratory is responsible for on-site test method validation/verification
- This includes tests used to determine:
  - Study enrollment
  - Continued participation in a study
  - Outcome measures in patients

CLIA Final Rule Changes

CAP Personnel Guidance Document

- **Illustrates the minimum qualifications for meeting the CLIA and CAP personnel qualifications**
- **Provides relevant CLIA definitions, such as laboratory and supervisory training and experience**
- **Organized by CLIA role**
- **Provided allowances for individuals qualified and serving in their current role in a CLIA-certified laboratory as of December 28, 2024, to continue to fill that role**

Personnel Guidance Document: Example

Director Qualifications for Laboratories Subject to US Regulations (DRA.10100)

Table LD1: High Complexity Laboratory Director Qualifications

Qualifying Degree	Board Certification Required	CE required	Training and experience
MD or DO licensed to practice in the jurisdiction in which the laboratory is located (if required)	Anatomic or clinical pathology, or both, by the American Board of Pathology or American Osteopathic Board of Pathology		
MD, DO, or DPM licensed to practice in the jurisdiction in which the laboratory is located (if required)		At least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities*	At least 2 years directing or supervising high complexity laboratory testing
Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution	Board approved by HHS	At least 20 CE credit hours in laboratory practice that cover the director responsibilities*	At least 2 years of: Laboratory training or experience, or both, **and** Laboratory experience directing or supervising high complexity testing

***This does not apply to existing laboratory directors that have remained continuously employed in their role since December 28, 2024.**

Director On-site Visits

Added two new requirements addressing laboratory director on-site visits:

- **Apply when the director is not routinely onsite**
- **If there are multiple locations under a single CLIA certificate, only one site needs to be visited**
- **More frequent visits may be defined based on input from medical staff and administration, and the complexity and volume of testing**

DRA.10432 - Laboratories Subject to US Regulations	**Visits to occur at least every six months, with at least four months between visits**
DRA.10433 - Laboratories not Subject to US Regulations	**Visits to occur at least once per year**

TRM.50050/GEN.53400 Technical Supervisors

The transfusion service medical director or physician designee…

- Retained qualifications for the section director/technical supervisor for the transfusion service laboratory to be a licensed physician (MD, DO, DPM)
- Responsibilities involve clinical areas where decisions require medical judgement, examples include:
  - Transfusion reaction interpretation, deviations from SOPs, and therapeutic phlebotomy medical oversight
- Added provisions to allow for specific technical supervisor functions to be delegated to an individual qualifying with a minimum of a bachelor's degree and four years of laboratory training/experience in immunohematology, examples include:
  - Signing the PT attestation statement – COM.01400
  - Oversight of quality control – TRM.31400, TRM.30000
- Department of Defense laboratories will continue as previously noted

TRM.50050/GEN.53400 Technical Supervisors

CLIA Regulation – 42CFR493.1449(d)	CAP Requirement – TRM.50050
Allows the technical supervisor to have a: • Master's or bachelor's degree in a biological, chemical, clinical or medical laboratory science, or medical technology AND • Two years of training/experience for master's degree OR • Four years of training/experience for bachelor's degree	Requires the transfusion service section director/technical supervisor to be a licensed physician (MD, DO, DPM) with: • Board certification in blood banking/transfusion medicine or clinical pathology OR • At least one year of training or experience in immunohematology

- CAP added provisions to allow for specific technical supervisor functions to be delegated to an individual qualifying under 42CFR493.1449(d), such as:
  - Signing the PT attestation statement – COM.01400
  - Oversight of quality control – TRM.31400, TRM.30000

GEN.55510/POC.06920 Competency Assessment Qualifications

For laboratories subject to US regulations, the following include the minimum qualifications for assessors:

- **High-complexity testing: Section director (technical supervisor) or individual meeting general supervisor qualifications (GEN.53400, GEN.53600)**
- **Moderate-complexity testing: Technical consultant or individual meeting those qualifications (GEN.53625)***
- **Waived testing: May be determined by the laboratory director**

If both moderate- and high-complexity testing is performed, a general supervisor or individual meeting those qualifications may assess the competency for both moderate- and high-complexity testing.

Competency of moderate-complexity point-of-care and blood gas supervisory personnel must be assessed by an individual meeting technical consultant qualifications in laboratories performing only moderate complexity testing.

Anatomic Pathology Changes

ANP.10290 Instructions for Body Handling

There are documented instructions covering such items as receipt, storage, and release of bodies.

Note: In some institutions, such policies and procedures may reside in the nursing or security manuals. In such cases, the laboratory must have copies of the manuals available at the time of inspection.

This requirement is not applicable if the laboratory is not responsible for handling bodies.

- **Requires laboratories that have responsibilities for handling bodies to ensure that proper body handling instructions are available.**
  - **Applies whether or not autopsy services are provided on-site.**
  - **Instructions may reside in nursing manuals or other areas outside of the laboratory.**

ANP.22550/CYP.04330/BAP.05380 IHC/ICC QC – Synthetic Materials/Cell Lines

- **Revised the notes for these requirements for IHC and immunocytochemistry (ICC) positive controls to include:**
  - **Synthetic materials (eg, microbeads) and cell lines containing IHC/ICC analytes of interest may be run as controls in addition to positive tissue controls.**
  - **Controls need to contain the target epitope of the assay and be sensitive to the antigen retrieval step.**
  - **Synthetic and cell line-based controls may be useful to assess assay performance at low expression levels.**
- **Synthetic materials and cell lines may be used in addition to tissue and cellular controls for IHC and ICC assays but do not replace them.**

ANP.22560/CYP.04335/ BAP.05348 NEW
IHC QC Control Range Establishment or Verification

If synthetic or commercial controls are used for quantitative testing, the laboratory establishes or verifies an acceptable control range for each lot of synthetic or commercial control material.

Note: The laboratory must verify control ranges supplied by the manufacturer if provided and establish an acceptable range by repetitive analysis if control ranges are not provided by the manufacturer.

Control values supplied by the manufacturer may be used without verification for qualitative (eg, positive or negative) testing.

- **Laboratories need to ensure that synthetic or commercial QC materials used for IHC or ICC assays work as expected and have defined acceptability criteria.**

IHC/ICC/ISH Validation Verification

- **Impacts the ANP, CYP, BAP, CYG, and MOL checklists**
- Updates requirements for predictive and non-predictive marker assay validation and verification based on the latest published CAP guidelines*
- Modifies the minimum numbers of samples required for validation/verification for newly introduced assays
- Brings consistency to the overall concordance criteria for validation/verification of IHC and ICC assays - at least 90% between the new test and comparator test or expected results

*Goldsmith JD, Troxell ML, Roy-Chowdhuri SR, et al. Principles of analytic validation of immunohistochemical assays: Guideline update. *Arch Pathol Lab Med*. 2024;148(6):e111-e153.

IHC/ICC/ISH Validation Verification

Non-predictive Marker IHC Assays

ANP.22750/BAP.05360/CYP.04370

- FDA-cleared/approved assays - follow instructions provided by the manufacturer. If instructions do not list a minimum number, test 10 positive and 10 negative tissues/cellular samples.
- LDTs and modified FDA-cleared/approved assays - test 10 positive and 10 negative tissues/cellular samples.

Predictive Marker IHC/ISH Assays

ANP.22978/CYP.04530/CYG.48399/MOL.39323

- FDA-cleared/approved assays - follow instructions provided by the manufacturer. If instructions do not list a minimum number, test 20 positive and 20 negative tissues/cellular samples.
- LDTs and modified FDA-cleared/approved assays - test 20 positive and 20 negative tissues/cellular samples.

- **If the laboratory director determines that a fewer number of cases are sufficient (eg, rare antigen, tissue, gene, or probe) the rationale needs to be recorded.**
- **Use tissues or cellular samples that have been processed using the same fixative and processing methods as cases that will be tested clinically.**
- **For IHC, positive cases should span the expected range of clinical results (expression levels).**

ANP.22970/CYP.04520 Annual Result Comparison

For HER2 and ER IHC tests performed on breast carcinoma that provide independent predictive information, the laboratory at least annually compares its patient results with published benchmarks.

- **Removed content on evaluation of interobserver variability for HER2 and ER predictive marker IHC and ISH assays; IHC moved to new requirements (ANP.22975/CYP.04525).**
- **Discontinued annual comparison of patient results with published benchmarks for HER2 ISH predictive marker assays.**
- **Will continue to require comparison of patient results with published benchmarks at least annually for predictive marker HER2 and ER IHC predictive marker assays performed on breast carcinoma.**

CYG.47885/MOL.39315 Annual Result Comparison

~~For in situ hybridization (ISH) tests performed on breast carcinoma that provide independent predictive information, the laboratory at least annually compares its patient results with published benchmarks and evaluates interobserver variability between individuals performing the technical component of ISH testing (ie, scoring of ISH slides).~~

- **Deleted CYG.47885 and MOL.39315**
- **Discontinued annual result comparison for predictive marker ISH tests performed on breast carcinoma due to:**
  - **Lack of available published benchmarks for HER2 FISH positivity in breast cancer**
  - **Lower variability for FISH based on automated methods in use**

ANP.22975/CYP.04525 Annual Assessment of *Each* Pathologist

NEW

Each pathologist interpreting IHC predictive markers participates in an annual analyte-specific quality assessment for each of the following predictive markers, as applicable:

- **Breast HER2**
- **Breast ER**
- **Gastric HER2**
- **Lung highly sensitive ALK**
- **Lung PD-L1 tumor proportion score (TPS)**

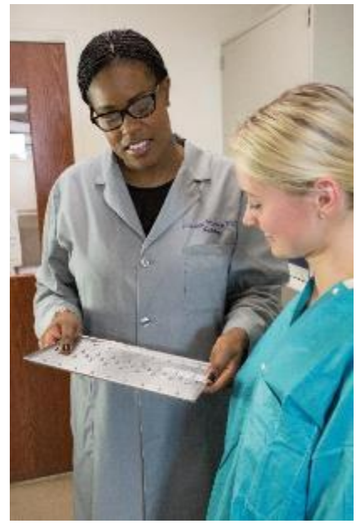
- **Applies to all pathologists that interpret one or more predictive marker**
- **Individual pathologists can participate at one location**
- **Assessment must include comparison of each pathologist's interpretation against intended results using laboratory defined criteria**
- **Examples for how this can be met include:**
  - **Use of IHC PT-stained slides or images after the deadline of submission**
  - **Educational, peer-based, interpretation-based programs that provide stained slides or images**
  - **Laboratory-developed programs for sharing stained slides or images**

HPV/Dual Stains

Cytopathology and Microbiology

Primary HPV Versus Co-testing

- **Introduction of primary HPV screening and p16/Ki-67 dual stain:**
  - **Recommendations from the 2020 ACS Cervical Cancer Guidelines and the 2019 American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines.**
- **Primary HPV screening is a stand-alone HPV test that is performed as an initial cervical cancer screen, with reflex to additional testing, as necessary. This is different than HPV/PAP co-testing where both tests are performed together.**



Primary HPV, Co-testing, Dual Stain

Requirements revised to include provisions for primary HPV screening, co-testing, or dual stain

CYP.05300	Report Elements
CYP.07452	Unsatisfactory Specimens – Gynecologic Cytopathology
CYP.07465	Pathologist Interpretation
CYP.07478	10% Rescreen
CYP.07582	False-Negative Notification
CYP.07600	Statistical Records – Gynecologic Cytopathology
CYP.08500	Workload Recording

CYP.07600 Statistical Records: Gynecologic Cytopathology

For gynecologic cytopathology cases (not including those reflexed from primary HPV screening), statistical records are maintained and evaluated at least annually, and include the following:

- **Total number of gynecologic cytology cases examined**
- **Number of cases reported by diagnosis for each specimen type (including the number reported as unsatisfactory for diagnostic interpretation)**
- **Number of cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison**
- **Number of cases where cytology and histology are discrepant**
- **Number of cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms**
- **Number of negative cases rescreened before sign-out**
- **Number of positive and negative p16/Ki-67 dual stains performed**

- **Content added to include statistical records for positive and negative dual stains**

CYP.07620 Reflexed Gynecological Statistical Records

For gynecologic cytopathology cases reflexed from primary HPV screening, statistical records are maintained and evaluated at least annually, and include the following:

- Number of primary HPV screening tests performed, if available
- Number of Paps reflexed from primary HPV screening
- Number of reflexed Paps reported by diagnosis for each specimen type (including the number reported as unsatisfactory for diagnostic interpretation)
- Number of cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison
- Number of cases where cytology and histology are discrepant
- Number of cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms
- Number of positive and negative p16/Ki-67 dual stains performed

- **Maintain statistics for GYN cases reflexed from primary HPV screening**
- **Evaluate statistics annually**

MIC.65610 Primary HPV Screening/Reflex

For laboratories performing primary HPV screening, the laboratory follows established professional recommendations or guidelines, and has a defined process for notifying providers when appropriate reflex testing or clinical follow-up is advised.

Note: Primary HPV screening is a stand-alone HPV test that is performed as an initial cervical cancer screen, with reflex to additional testing as necessary. This requirement does not apply to HPV/PAP co-testing where both tests are performed together.

If additional testing after a primary screening test is needed, the laboratory provides guidance to providers on submission of additional specimens.

- **Laboratory must have a defined process for reflex testing of positive primary HPV screening results**
- **Does not apply to HPV/PAP co-testing**

Discipline-Specific Checklist Changes

- Chemistry
- Hematology and Coagulation
- Point-of-Care
- Immunology
- Flow Cytometry
- Microbiology
- Transfusion Medicine
- Histocompatibility

CHM.12925/POC.03325/LSV.40010 Hemoglobin A1C Testing

For laboratories that use accuracy-based proficiency testing (PT) for hemoglobin A1C, the laboratory evaluates its results based on acceptable performance criteria of +/- 6% from the target value, with appropriate corrective action taken for each unacceptable result.

Note: The CAP recommends use of accuracy-based PT products, when possible, to evaluate the accuracy of hemoglobin A1C results. Due to limitations in product stability, this may not be available for laboratories outside of the US.

The Centers for Medicare and Medicaid Services (CMS) have established acceptable performance criteria for hemoglobin A1C as a regulated analyte at +/- 8% from the target value. The CAP and all CAP-accepted PT providers must use the +/- 8% criteria in the formal grading of the PT for reporting non-waived results to the CMS. For laboratories participating in the CAP's accuracy-based PT program for hemoglobin A1C, the CAP will also evaluate their results against the target value using +/- 6% performance criteria. This is provided in the participant evaluation and participant summary report. Laboratories must review their performance against the +/- 6% criteria and perform corrective action for each unacceptable result.

- **Added in response to CMS PT final rule changes**

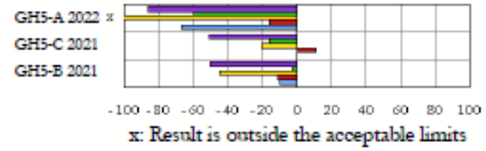
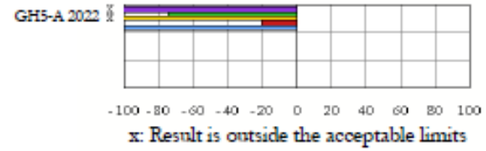
Hemoglobin A1C Testing: PT Evaluation Example

COLLEGE of AMERICAN PATHOLOGISTS
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • cap.org

CAP Number: Kit# 1 Kit ID:
Institution: EXAMPLE Kit Mailed:
Attention: Original Evaluation:
City / State:

EVALUATION
TEST

GH5-A Hemoglobin A1c, 5 Challenges

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade	Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation
HBA1c % / % / XYZ Instrument	GH-01	7.8	8.42				7.7	9.1	Acceptable	
	GH-02	6.0	6.31				5.8	6.9	Acceptable	
	GH-03	8.2	9.05				8.3	9.8	Unacceptable	
	GH-04	5.1	5.18				4.7	5.6	Acceptable	
	GH-05	6.3	6.72				6.1	7.3	Acceptable	
HBA1c % / % / CAP Accreditation 6%	GH-01	7.8	8.42				7.9	9.0	Unacceptable	
	GH-02	6.0	6.31				5.9	6.7	Acceptable	
	GH-03	8.2	9.05				8.5	9.6	Unacceptable	
	GH-04	5.1	5.18				4.8	5.5	Acceptable	
	GH-05	6.3	6.72				6.3	7.2	Acceptable	

- Starting in 2025, CAP accuracy-based PT laboratory evaluation will display two sets of grading:
  - 1st evaluation is based on the CLIA acceptance limit of 8% (grade reported to CMS)
  - 2nd evaluation uses the 6% grading to help laboratories meet CAP accreditation program requirements (not reported to CMS)
- Review both evaluations and document corrective action for unacceptable results for CAP checklist compliance

CHM.15225/POC.04425/LSV.41325 eGFR & LDL Calculations

Clinicians have access to information regarding the equation used to calculate results for estimated glomerular filtration rates (eGFR) and low-density lipoprotein (LDL) cholesterol.

Note: Calculated results may differ based on which equation is used. This may limit clinical assessment of results and/or comparability of calculated results across laboratories, particularly when the source equation is not readily available to providers.

The information can be made available to clinicians using different approaches, such as on the patient report, test reference guide, or inclusion of the equation name in the test name.

- **Ensures that information will be available to clinicians on the equations used for eGFR and LDL calculations**
- **Avoids confusion about potentially differing results and/or clinical interpretation based on where testing is performed**

CHM.31150 Prenatal Screen Risk Calculation

- **Combines 10 existing requirements* and simplifies the content**

The laboratory determines which information and adjustments to include in the prenatal screening risk calculation.

Note: Expected elements in the prenatal risk calculation include:

- *Gestational age*
- *In vitro fertilization method, if applicable*
- *Initial or repeat testing*
- *Maternal age*
- *Maternal race or subpopulation as defined by the laboratory*
- *Maternal weight*
- *Medications to control diabetes*
- *Multiple gestation, if applicable*
- *Smoking status*

The rationale for exclusion of any expected element must be documented. Additional elements may be included in calculating the risk categorization. The rationale for additional elements must be documented.

***Merges CHM.31100, CHM.31200, CHM.31300, CHM.31400, CHM.31500, CHM.31550, CHM.31600, CHM.31600, CHM.31700, CHM.32100**

HEM.35414 Background Checks

Note: For any external diluting fluid not part of the instrument's reagent system, the laboratory must check for interfering background particulates each day of use. Checking can be done by examining samples of these fluids under the microscope. If commercial microdilution systems are used, daily checks are not required but each lot must be examined visually for uniformity of filling and clarity. If diluting fluids are prepared by the laboratory, they must be prepared aseptically; refrigeration is recommended to prevent contamination with microorganisms.

Evidence of Compliance:

- ✓ Records of background checks **OR** records of interfering background particulate checks on external dilution fluids/reagents

- **Pertains to automated body fluid cell counts**
- **Note added to ensure diluents external to the instrument are checked for interfering background particulates each day of use**

HEM.36960/POC.09146/LSV.38698 Whole Blood-Based Coag

NEW

Specimens for whole blood-based coagulation testing are handled according to manufacturer's instructions or as validated by the laboratory.

Note: Specimens must not be:

- *Heated, refrigerated, or frozen.*
- *Centrifuged - Centrifuged specimens must be rejected. Reconstitution of a centrifuged specimen by mixing is not adequate.*

For additional specimen handling for platelet function studies, refer to HEM.38350.

POC.09146/09147/09148 Coagulation Section

POC.09146	Specimen Handling for Whole Blood-Based Testing – Coagulation
POC.09147	Specimen Handling – Platelets
POC.09148	Coagulation Testing and Therapeutic Anticoagulant Recommendations

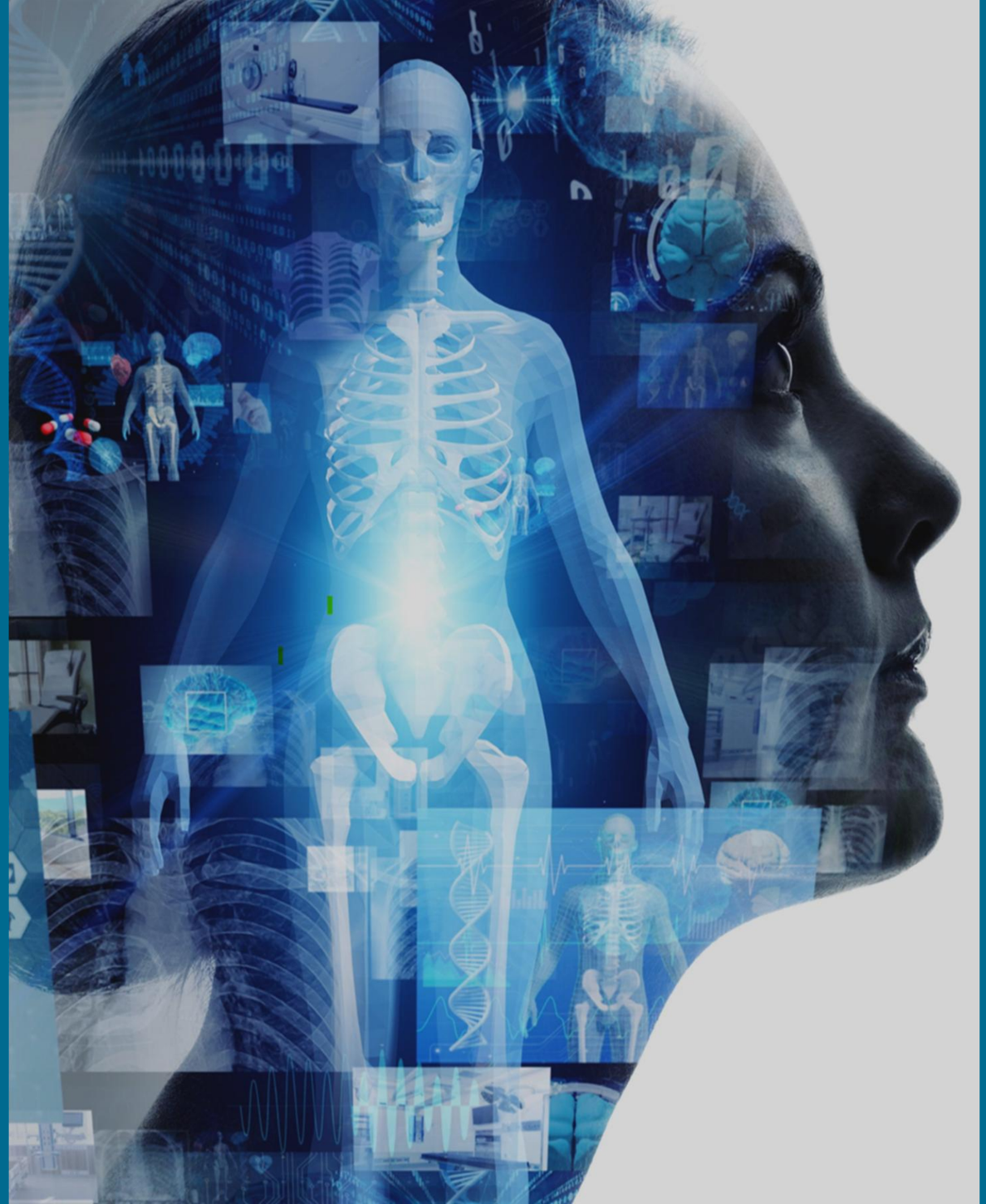
- Coagulation section added due to testing commonly performed at point-of-care
- Includes requirements for specimen handling and for providing recommendations to clinicians for monitoring anticoagulant therapy

IMM.41420 Syphilis Antibody Screening

If the laboratory offers screening for syphilis, a complete screening algorithm is followed including appropriate confirmatory/secondary tests.

- **Revised the note to require laboratories to perform a complete screening algorithm for syphilis screening tests that include both traditional and reverse sequence screening algorithms**
- **Does not apply to testing performed on CSF or testing not performed for screening (eg, patients with prior history of syphilis)**

Algorithm	Initial Test Performed	Secondary Method for Positive Results on Initial Test	Additional Testing
Traditional Screening	Nontreponemal (lipoidal antigen) antibody test (eg, VDRL, RPR)	Treponemal antibody test	
Reverse Sequence Screening	Treponemal antibody test (eg, EIA, TPPA)	Nontreponemal assay	Repeat treponemal antibody test for discordant results (positive treponemal/negative nontreponemal)



Knowledge Check

Scenario

My laboratory uses the reverse algorithm for syphilis screening. If a patient tests positive using an EIA anti-treponemal test and tests negative using a non-treponemal RPR test, am I required to perform a repeat treponemal antibody test if I find that the patient has documented past history of treated syphilis?

Answer

No

If the testing is performed on patients previously diagnosed with syphilis, it would not be considered screening. The complete screening algorithm would not need to be followed.

Guidance needs to be available to clinicians on test ordering.

Anti-treponemal antibodies persist after successful treatment.

Nontreponemal (lipoidal antigen) titers should be ordered directly for following serologic response to treatment.

FLO.23335 New Antibody Cocktail Confirmation of Acceptability

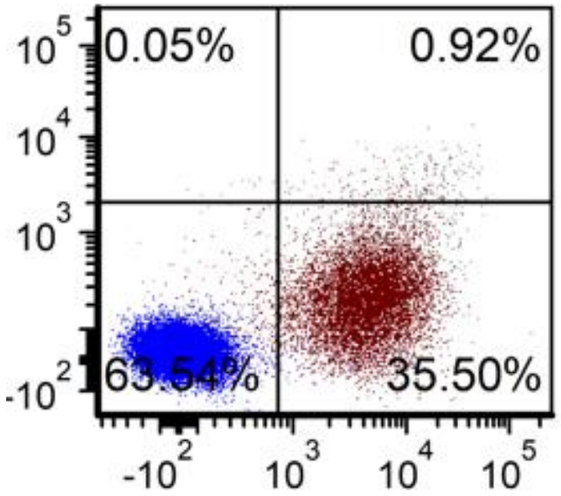
The laboratory evaluates performance of newly prepared antibody cocktails before or concurrently with being placed into service and assigns an expiration date for the cocktail.

- Cocktail stability is established during assay validation
- Newly prepared cocktails are evaluated, and expiration dates assigned
- Defined acceptability criteria must include positive and negative controls for each component of the cocktail (except rare flow antigens)
- Parallel testing of old and new cocktails is not required since individual antibody lots/shipments are already checked (FLO.23325)

FLO.23737 QC for Qualitative Assays

The laboratory evaluates negative and positive staining patterns of the residual normal cell population for qualitative assays (eg, leukemia/lymphoma analysis) each day of patient testing.

- Assay performance must be evaluated each day of patient testing
- Control materials include normal populations in patient samples, commercial controls, cryopreserved cells, and normal patient/volunteer samples
- Acceptability criteria must include a positive and negative control for each antibody/stain
- Rare flow antigens evaluation method must be defined, with positive staining evaluation performed at least every six months



Additional Flow Cytometry Checklist Changes

Flow Cytometry Checklist	
FLO.23325	FLO.23325 New Reagent Lot/Shipment Confirmation of Acceptability
FLO.30275	Carryover Mitigation (Renumbered from FLO.30825)
FLO.30595	CD34 Cell Count Sample Dilutions

Anatomic Pathology Checklist – Flow Cytometry Interpretation Only	
ANP.29680	Cellular Viability
ANP.29720	Rare Event Flow Cytometric Assays

MIC.11038/LSV.45390 Media QC: Purchased/Acquired

An appropriate sample from each lot and shipment of each purchased/acquired medium for bacterial, mycobacterial, or mycologic culture is checked before or concurrent with initial use…

An individualized quality control plan (IQCP), including all required elements of IQCP, may be implemented by the laboratory to allow for the acceptance of the quality control performed by the media supplier. The media supplier's records must be retained and show that the QC performed meets the checklist requirements. Please refer to the IQCP section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP.

- **Revised to allow an IQCP to be used for all purchased culture media**

Knowledge Check

Scenario

We have been performing QC per lot/shipment for our chocolate and Thayer-Martin agar and would like to implement an IQCP. What should we do?

A. **Simply add chocolate and TM agar to the list of media covered by the existing IQCP**

B. **Incorporate media-specific data and reassess the risks in the existing media IQCP**

C. **Do nothing**

Answer

A. Simply add chocolate and TM agar to the list of media covered by the existing IQCP
B. Incorporate media-specific data into the existing IQCP and reassess the risks
C. Do nothing

A laboratory may modify an existing IQCP; however, there may be new or different risks not previously addressed by the existing risk assessment and quality control plan. The laboratory can use historical QC records, media visual exam records, problem logs, and manufacturer certificates of quality to reassess the risks and review and update the quality control plan. The IQCP must also be reapproved by the laboratory director.

MIC.11375 Review of Nomenclature

The laboratory maintains consistent nomenclature across testing platforms and considers use of contemporary nomenclature.

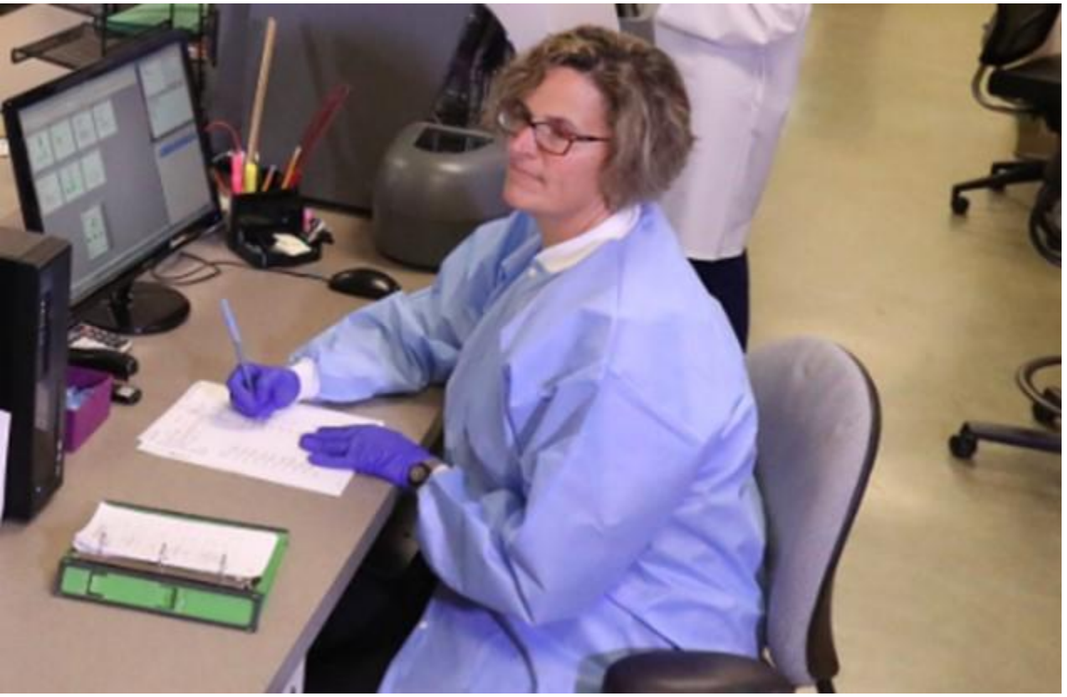
Note: The CAP does not require adoption of new or contemporary nomenclature for compliance with this requirement.

Nomenclature updates may impact the extent of workup in the laboratory, public health reporting, and/or interpretation of antimicrobial susceptibility testing results. The laboratory should take these factors into consideration when reviewing nomenclature updates to decide whether to adopt contemporary nomenclature.

The laboratory should be aware that multiple identification systems may generate conflicting names for the same organism and must mitigate or eliminate these inconsistencies.

- **Simplified to focus on awareness and consistent reporting**
  - **Nomenclature changes may impact organism workup or susceptibility**
  - **Labs must consider these factors, but are not required to adopt nomenclature changes**

TRM.40300, TRM.40670, TRM.40820, IMM.40755, LSV.65656 Historical Record Checks



- **Revised note added to clarify ABO and Rh historical records that may be used to compare with current results to detect discrepancies**

Acceptable ABO and Rh historical records for transfusion purposes are only those generated or entered by laboratory personnel into the health system's laboratory information system and performed by an accredited laboratory/certified by the relevant government agency in its jurisdiction.

TRM.40705 Low Titer Group O Whole Blood

If low titer group O whole blood is used, the laboratory follows written policies and procedures for its use.

Note: The following must be defined:

- *Indications for use*
- *Product specifications*
- *Administration instructions*
- *Indications to switch to component therapy and ABO type selection*

The limit on the number of units to be transfused for each patient during a bleeding event or within a time period.

- **Revised TRM.40700 for selection criteria or blood components to separately call out ABO group-specific whole blood and group O whole blood with low anti-A/B titers if given to non-O patients**

TRM.44850 Platelet Preparation and Storage

- **Revised requirement to differentiate preparation and storage requirements for cold-stored platelets versus conventional platelets**

Product Type	Requirements
Cold-stored platelets	• **Place units in storage at 1-6 °C no later than four hours from the end of collection if an FDA-approved pathogen reduction device is not used** • **Place units at 1-6 °C no later than four hours after completion of pathogen reduction if a pathogen reduction device is used**
Conventional (room-temperature) platelets	• **Separate platelets from whole blood that has not been cooled below 20 °C within 8 hours** • **Store platelets at 20-24 °C with agitation**

Histocompatibility Checklist Changes

New Requirements	
HSC.20985	Extracted Nucleic Acid Specimens
HSC.21340	Laboratory Records
HSC.38098	IPD-IMGT/HLA Database

Revised Requirements	
HSC.21800	Reagent and Specimen Storage
HSC.22775	Thermocycler Temperature Checks
HSC.34731	Specimen Preservation and Storage
HSC.34918	Nucleic Acid Quantity and Quality

Deleted Requirements	
HSC.35105	High-Molecular-Weight DNA/RNA Quality
HSC.38100	Probe Characteristics – HLA Typing

Using CAP Resources to Identify and Implement Changes

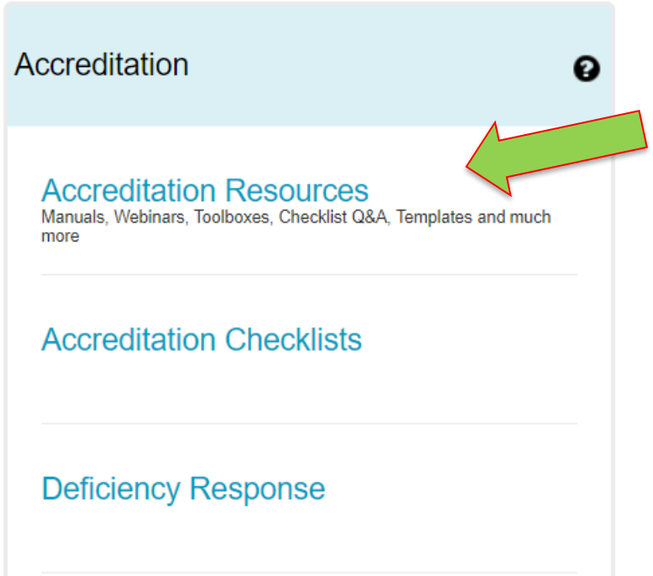
Educational Resources Provided by The CAP

- *Archives of Pathology & Laboratory Medicine* and *CAP TODAY*
- Educational Webinars
- CAP Annual Meeting
- Checklists
- Protocols and Guidelines https://www.cap.org/protocols-and-guidelines
- Cancer Protocols
- AP Monthly Case Study
- Education Offerings https://learn.cap.org/lms/home

Visit CAP Accreditation Resources on cap.org

Log into e-LAB Solutions Suite to find:

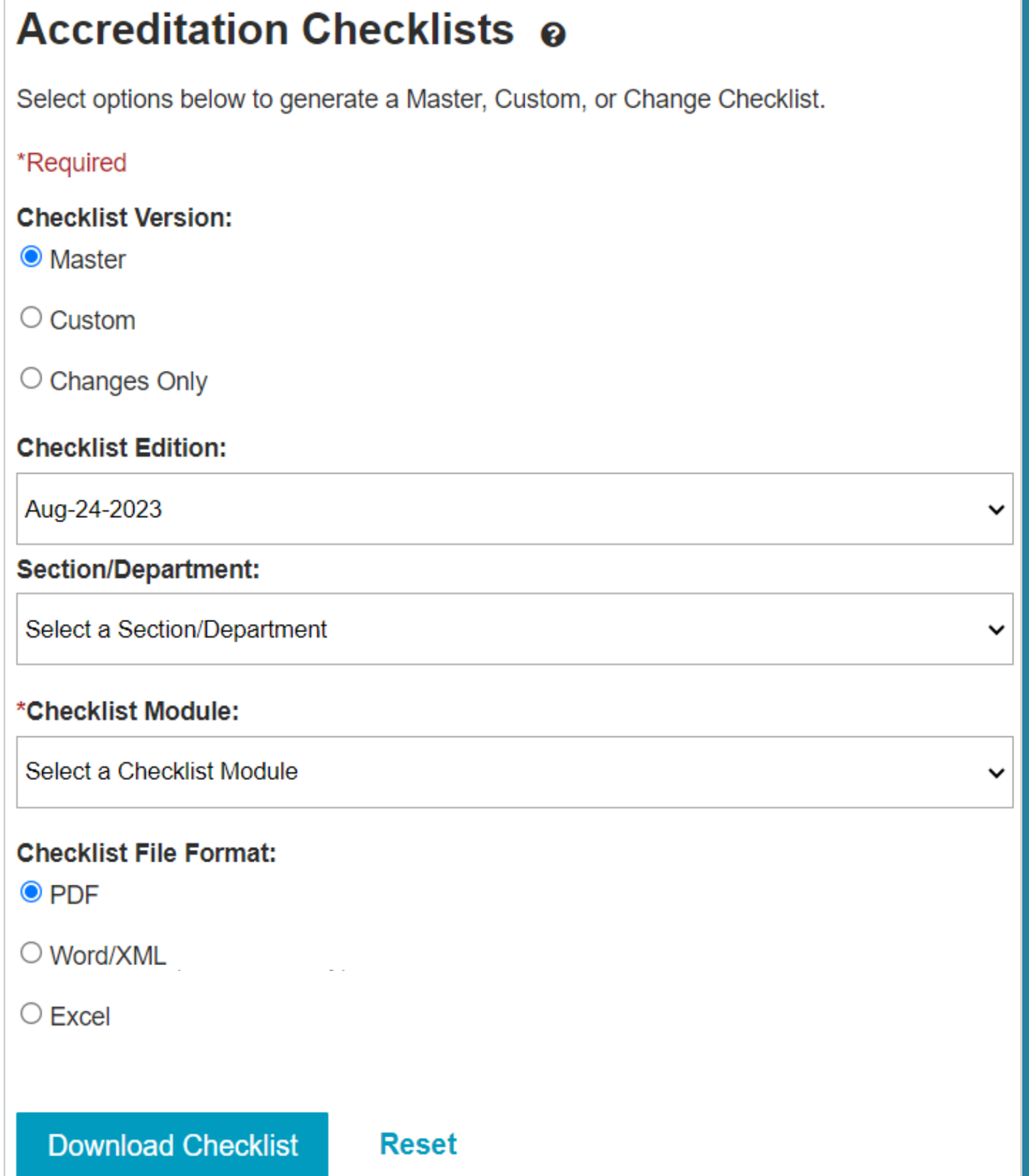
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification)
- Proficiency testing FAQs, forms, and troubleshooting guides
- Quality management resources
- IQCP resources
- Self- and post-inspection tools
- Inspection tip sheets
- Library of past webinars and laboratory inspection preparation videos



Download Checklists From cap.org

- **Select from master, custom, and changes-only versions**
  Tip: The changes only version makes it easy to see what changed since the last checklist edition.

- **Select the file type that works best for you.**
  Tip: Checklists can be saved locally and be annotated to efficiently identify compliance documents.



Comparison of Top 10 Deficiencies: 2024 vs 2023

Checklist Requirement		2024 Ranking	2023 Ranking
COM.10000	Policy and Procedure Manual	1	1
GEN.55500	Competency Assessment Elements – Non-waived Testing	2	4
COM.01200	Activity Menu	3	2
COM.04250	Comparability of Instruments/Methods – Non-waived Testing	4	3
COM.01700	PT and Alternative Performance Assessment Result Evaluation	5	5
COM.30600	Maintenance/Function Checks	6	6
COM.04200	Instrument/Equipment Record Review	7	7
COM.30300	Reagent Labeling – Nonwaived Tests	8	13
COM.01400	PT Attestation Statement	9	10
COM.01100	Ungraded PT Challenges	10	8

Summary

- **Key changes in 2024 checklists**
- **Rationale for the key changes in 2024**
- **Help in recognizing areas of change for each laboratory related to the changes**
- **Resources for managing key changes**

Questions?

- **Visit our accreditation resources page:**
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- **Send inquires to accred@cap.org**
- **Contact the accreditation technical specialists at:**
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