Changes that Matter: 2023 CAP Accreditation Checklist Updates

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Opinions expressed in this presentation are those of the speaker and do not express the views or opinions of Cardinal Health

Disclosure

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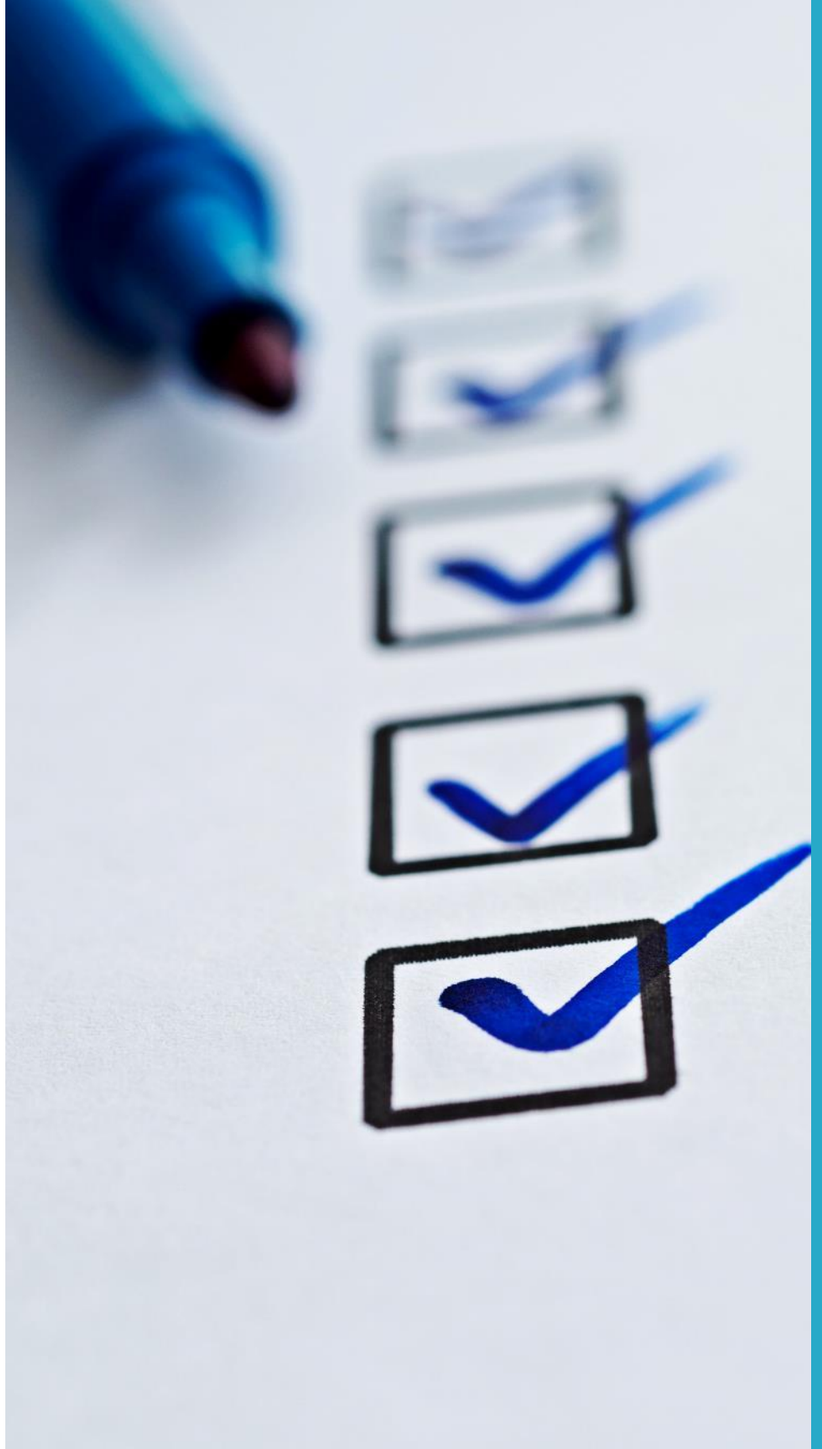
Objectives

- Describe key changes and the rationale for the changes in the 2023 edition of the CAP Accreditation Program requirements.
- Use the CAP resources to identify changes.
- Implement any necessary changes to ensure compliance with new accreditation requirements.

Summary of Changes in 2023

Fewer changes:

- Laboratory general
- All common
- Analytic measurement ranges
- Mass spectrometry
- Anatomic pathology and cytopathology
- Coagulation
- Point-of-care – provider-performed microscopy
- Transfusion medicine
- Microbiology
- Histocompatibility
- Resources to help comply changes



Summary of Changes in 2023

Checklist	Requirements	New	Significant Changes	Deleted	Moved / Merged
ANP	186	0	5	0	0
BAP	176	0	2	0	2
CBG	73	1	5	0	1
CHM	162	3	10	0	1
COM	85	1	10	0	0
CYG	67	0	2	0	1
CYP	85	0	4	0	0
DRA	20	0	0	0	0
FDT	106	2	4	1	3
FLO	48	0	0	0	1
GEN	255	1	18	0	2
HEM	181	1	7	0	0
HSC	146	0	2	0	2
IMM	66	0	3	0	0
LSV	278	1	19	1	2
MIC	222	1	20	2	10
MOL	164	0	6	0	4
POC	64	1	6	0	0
RLM	118	0	4	0	1
TRM	258	0	11	0	0
URN	27	0	0	0	0
TOTAL	2787	12	138	4	30

Annual Checklist Changes: Why…

- **Scientific updates**
  - Emerging technologies
  - Advancement in technology
- **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
- **Expert recommendations**
  - Committees

Policy/Procedure (P/P) Icon: Reminder

- Added new icon to the 2022 edition to indicate when a policy or procedure is necessary
- Made understanding compliance simpler and improved consistency in inspections
- Removed or revised wording relating to policies and procedures to reduce redundancy
  - Modified requirement stems to be more direct and action oriented
  - Deleted evidence of compliance specifying policies/procedures

Laboratory General Checklist Changes

Calculated Test Results: Definition

A reportable patient test result that is not directly measured but rather calculated from one or more directly measured results.

Verification of Calculations

GEN.43450 **~~Calculated Patient Data~~ Verification of Calculations Producing Patient Results** **Phase II**

~~Calculated values~~Calculations that use patient results to produce other reported ~~with patient~~ results are reviewed every two years or when a system change is made that may affect the calculations.

NOTE: This checklist requirement applies ~~only to~~to laboratory information systems, middleware, and analyzer calculations ~~based on formulas~~ modifiable by the user~~.~~

~~Errors can be inadvertently introduced into established computer programs. Calculations involving reportable patient results must be rechecked to ensure accuracy and records retained.~~ (eg, estimated glomerular filtration rate [eGFR] or interpretive table for female reproductive cycle hormonal levels). This checklist requirement ~~applies to laboratory information systems, middleware, and analyzers.~~ does not apply to preset calculations provided by instruments as results (eg, oxygen saturation [so2]) or to age/sex stratified reference intervals that are routinely implemented, such as by an LIS.

LIS Testing

GEN.43022 LIS Testing **Phase II**

Programs are adequately tested for proper functioning when first installed and after any modifications, and the laboratory director or designee has approved the use of all new programs and modifications.

NOTE: Computer programs must be checked for proper performance when first installed and after any changes or modifications, including assessment after implementation in the live (production) system. Any changes or modifications to the system must be recorded, and the laboratory director or designee must approve all changes, additions and deletions in programs, the test library, and major computer functions before they are released. This applies both to locally installed and remotely hosted software. Testing should include reference intervals, critical values and/or verification limits, and operational rules/algorithms. Rules producing reported patient results or result interpretation are addressed in GEN.43450. Records must be retained for at least two years beyond the service life of the system.

Competency Assessments: Waived Testing

GEN.55499 **Competency Assessment - Waived Testing** **Phase II**
POC.06875

The competency of personnel performing waived testing is assessed for each test system at the required frequency.

GEN.55510 **Competency Assessment - Assessor Qualifications** **Phase II**
POC.06920

Individuals responsible for competency assessments have the education and experience to evaluate the complexity of the testing being assessed.

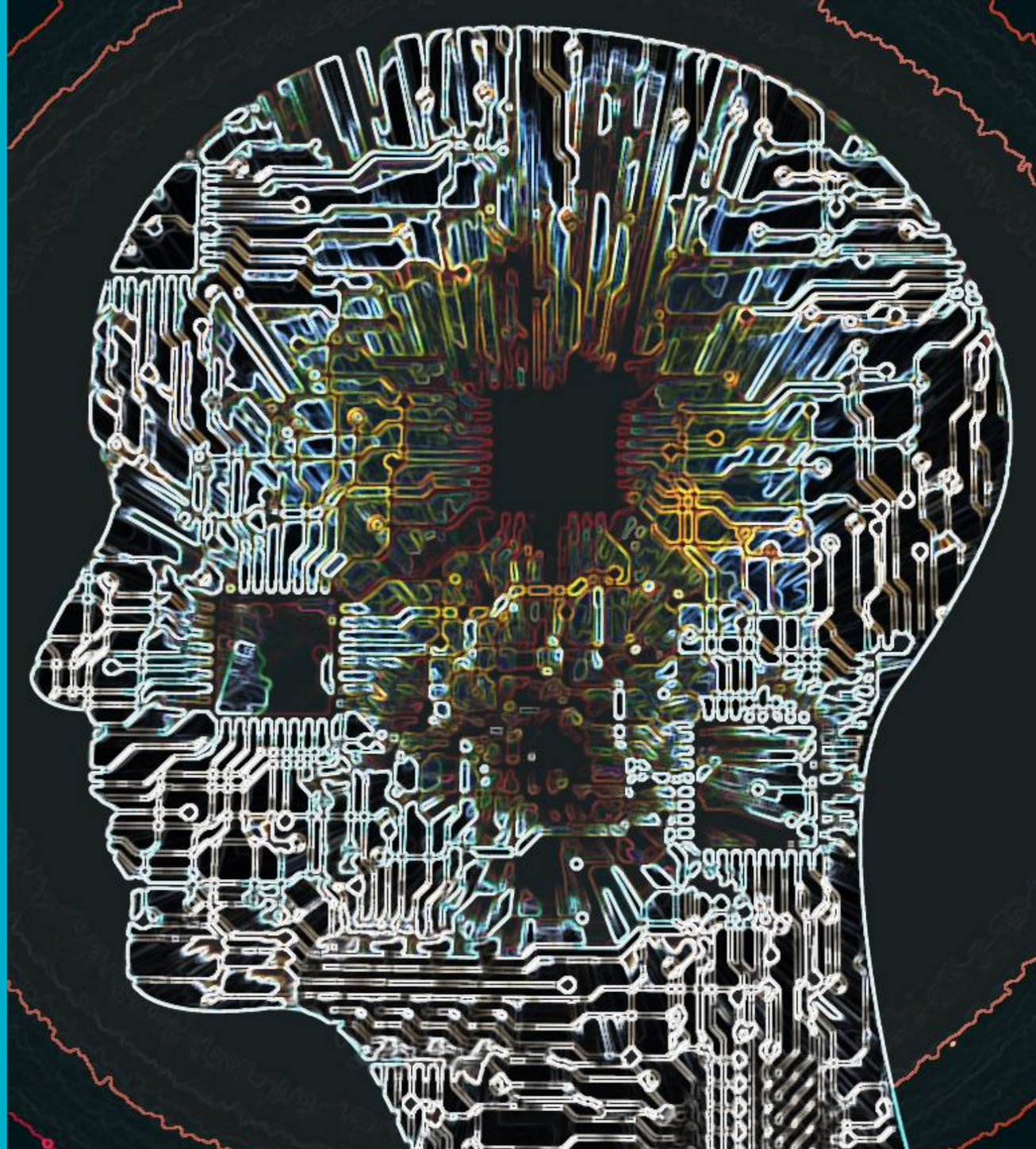
- **Added clarification on more stringent requirements for laboratories with California Clinical Laboratory licensure for waived testing.**

Competency Assessments: Waived Testing, cont'd

Competency Requirements for Waived Testing	Additional California Requirements
Assess competency at one year and at least annually thereafter	Assess competency semiannually during the first year and then annually thereafter
May select which elements of competency to assess	Must assess elements 1,2,3,4, and 6 of competency
Qualifications of the assessor may be determined by the laboratory director	Assessors must meet California waived laboratory supervisor qualifications (GEN.78250)

Knowledge Check

What do you think?



Competency Assessment Scenario

During an inspection of a laboratory in California, you see that competency of waived point-of-care testing personnel is being assessed by an RN with an associate's of nursing.

Should you cite a deficiency?

A. No. It's waived testing so the laboratory director may determine the qualifications of the assessor.

B. No. The person is qualified as a waived laboratory supervisor.

C. Yes. The person does not qualify as a waived laboratory supervisor.

Climate Control

GEN.61300 Climate Control **Phase I**

The room temperature and humidity are adequately controlled in all seasons.

NOTE: Laboratories must follow manufacturer's instructions for temperature and humidity for proper functioning of instruments, equipment, and test systems.

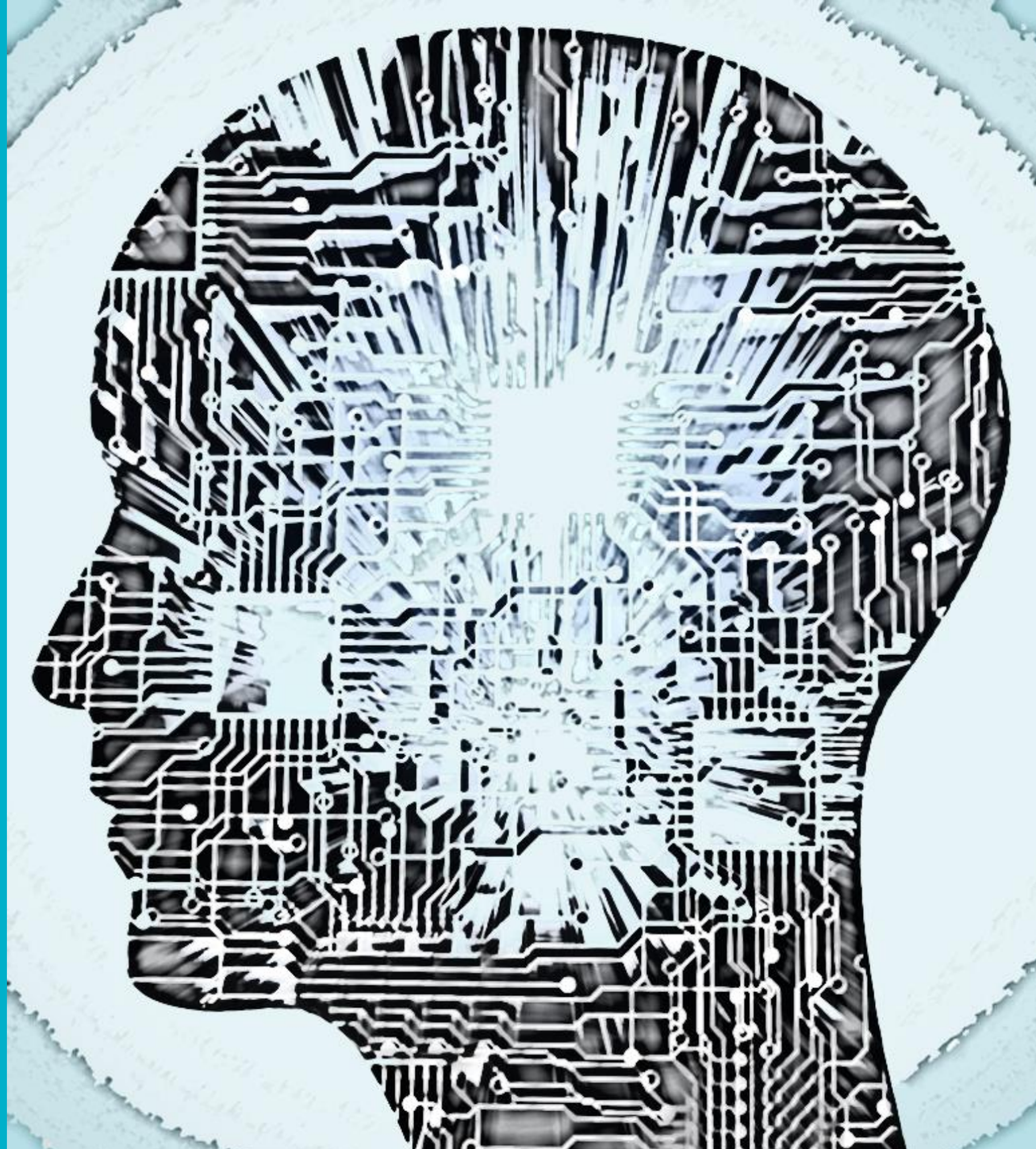
Evidence of Compliance:

✓ Temperature and humidity records, if specific ranges are required for instrument and/or reagent use

✓ Records of corrective action when specific ranges are exceeded

Knowledge Check

What do you think?



Humidity Scenario

During an inspection, you observe that the lab is not monitoring humidity but is using an instrument that has specific performance specifications for humidity defined in the manufacturer's instructions as 15%-80% relative humidity, noncondensing.

What do you do?

A. Move on. The range is broad, so no monitoring is indicated.

B. Give a recommendation for the laboratory to start monitoring humidity.

C. Cite a deficiency.

Chemical Hazard Emergencies

GEN.76400 Chemical Hazard Emergencies **Phase II**

Explicit instructions are posted, and appropriate supplies available, for the emergency treatment of chemical splashes and injuries and the control of chemical spills wherever major chemical hazards exist.

NOTE: Spill kits must be handled in accordance with manufacturer's instructions. If no expiration date is assigned, the spill kit must indicate the date it was put into service and the laboratory director or designee must ~~periodically~~ assess its usability at least annually.

New GEN Requirement: Fume Hood

GEN.76710 Fume Hood **Phase II**

A properly functioning fume hood (or chemical filtration unit) is available for any procedures using volatile chemicals.

- **Replaces separate requirements HSC.24446 and MOL.52760.**

Infectious Disease Reporting

GEN.41316 Infectious Disease Reporting **Phase II**

The laboratory communicates diagnoses of infectious diseases of particular significance (eg, human immunodeficiency virus, ~~SARS-CoV-2 coronavirus*,~~ and tuberculosis) in a timely manner, and retains records of the communication.

NOTE: The laboratory must have a policy to ensure that diagnoses of human immunodeficiency virus infection and other serious infections (for example, tuberculosis ~~or SARS-CoV-2 coronavirus~~) are communicated to the responsible clinician in a timely manner.

The intent of this checklist item is NOT to require that these diagnoses be treated as critical results (this decision is up to the laboratory director); rather, the intent is that the laboratory assures that its reporting system is effective.

~~Laboratories subject to US regulations performing testing intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report COVID-19 molecular, antigen, and antibody test results, when required, to local or state health authorities in a standardized format and at a frequency specified by the Secretary of Health and Human Services (HHS). Refer to the current HHS guidance, "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115" for specific information on which types of test~~

- **Revised in the 2022 edition (effective May 12, 2023) due to the end of the COVID-19 public health emergency.**

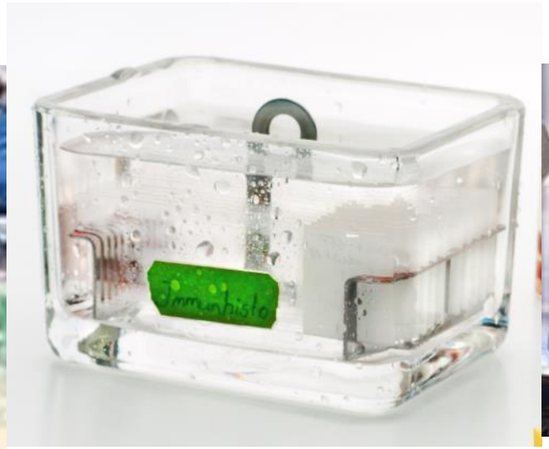
Glassware Cleaning

GEN.41770 Glassware Cleaning **Phase II**

When detergent is used for cleaning glassware, the laboratory tests for detergent removal and takes action if detergent residue is detected.

NOTE: Special instructions for micropipettes, cuvettes, acid washing, etc. must be included.

~~A simple procedure~~The test to detect detergent removal should be appropriate for the method of washing (eg, glassware washing machine, manual washing). Simple procedures to check for detergent residue ~~uses~~include the use of pH paper or bromcresol purple (0.1 g bromcresol purple in 50 mL ethyl alcohol). ~~Pipette~~To use bromcresol purple, pipette approximately 5 cm (2 inches) distilled water into a representative, washed, glassware item. Add two to three drops bromcresol solution. A purple color (high pH) reveals residual detergent. A yellow color indicates satisfactory rinsing.



UV Light Exposure

GEN.77600 UV Light Exposure **Phase II**

The laboratory follows written policies and procedures to prevent or reduce ultraviolet light exposure from instrument sources.

NOTE: UV light may cause corneal or skin burns from direct or deflected light sources. Wherever UV light sources are used~~,~~ (eg, in biological safety cabinets, cryostats, or for gel visualization), suitable and adequate personal protective equipment must be provided, and appropriate approved signage displayed. Laboratories may obtain information on safety from manufacturers of devices that emit UV light.

A suggested sign for display is: Warning: This device produces potentially harmful ultraviolet (UV) light. Protect eyes and skin from exposure.

- **Replaced separate requirements BAP.07620 and MOL.54580.**

All Common Checklist Changes

Alternative Performance Assessment

COM.01500 Alternative Performance Assessment **Phase II**

For tests for which 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 2: For in situ hybridization testing other than predictive marker testing, and other complex molecular and sequencing-based tests (including but not limited to microarray-based tests, multiplex PCR-based tests, and next generation sequencing-based tests), alternative performance assessment may be performed by method or specimen type rather than for each analyte or tested abnormality. For tests such as allergen testing, alternative performance assessment may be performed ~~in batches~~ using a rotating subset of ~~analogous~~ tests in the menu provided that the subset reflects the handling and testing procedure for the entire menu.

Predictive Marker PT and Alternative Performance Assessments

COM.01520 **PT and Alternative Performance Assessment for IHC, ICC, and ISH Predictive Markers** **Phase II**

The laboratory participates in the appropriate required proficiency testing (PT) program/external quality assessment (EQA) program accepted by CAP or performs alternative performance assessment for all predictive markers performed using immunohistochemistry (IHC), immunocytochemistry (ICC), and in situ hybridization (ISH) methods, as required in the note.

Extent of Service	Requirement
Predictive marker IHC stain and interpretation performed at the same laboratory	*The laboratory must participate in CAP-accepted PT when required (refer to the Activity Menu).*
Predictive marker IHC stain and interpretation performed at different laboratories	*Both the stain only and interpretation only laboratories must perform alternative performance assessment at least semiannually~~.~~, which may be satisfied by participation in a PT program.*

Predictive Marker PT and Alternative Performance Assessments, cont'd

Predictive marker hybridization and ISH interpretation performed at the same laboratory	*The laboratory must participate in CAP-accepted PT when required (refer to the Activity Menu).*
Predictive marker hybridization and ISH interpretation performed at different laboratories	*Both hybridization only and interpretation only laboratories must perform alternative performance assessment at least semiannually.* *The laboratory must not participate in formal (external) PT if the hybridization and interpretation are performed at different laboratories. Participation in formal PT would constitute PT referral.*
Other predictive marker testing performed by IHC, ICC, and ISH for which the CAP does not require proficiency testing (eg, PD-L1.	*The laboratory must perform alternative performance assessment at least semiannually.*

PT and Alternative Performance Assessment Specimen Testing

COM.01600 PT and Alternative Performance Assessment Specimen Testing Phase II

The laboratory integrates all proficiency testing (PT) and alternative performance assessment specimens within the routine laboratory workload, where applicable, and those specimens are analyzed by personnel who routinely test patient/client specimens, using the same primary method systems as for patient/client ~~/donor~~ specimens.

NOTE: Repetitive analysis of any proficiency specimen by one or more individuals is acceptable only if patient/client specimens are routinely analyzed in the same manner. ~~With respect to~~ An individual may seek assistance from other on-site personnel for morphologic examinations (identification of cell types and microorganisms~~;~~) or data review ~~of~~ (eg, for electrophoretic patterns~~, etc.), group review and consensus identifications are permitted only for unknown~~) for proficiency testing specimens ~~that would ordinarily be reviewed by more than one person on an actual~~ only if patient ~~specimen~~ specimens are handled in the same manner, as defined by the laboratory's policies and procedures.

Knowledge Check

What do you think?

PT Specimen Handling Scenario

While reviewing proficiency testing images included for blood cell identification, you are not sure how to classify one of the images and your supervisor is at a different lab site.

Which of the following are acceptable options for handling the PT challenge?

A. Give it your best guess.

B. Ask another hematology tech for assistance.

C. Ask the pathologist for assistance.

D. Send the image to the hematology supervisor at the other lab site.

E. Report the result as “unable to analyze.”

Comparability Criteria: Nonwaived Testing

COM.04250 **Comparability of Instruments and Methods - Nonwaived Testing** **Phase II**

If the laboratory uses more than one nonwaived instrument/method to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results.

COM.04300 **Comparability Criteria - Nonwaived Testing** **Phase II**

Acceptability criteria are defined for comparability of nonwaived instruments and methods used to test the same analyte ~~and action~~. Corrective action is taken when the criteria are not met.

Comparability Criteria: Nonwaived Testing, cont'd

COM.04300

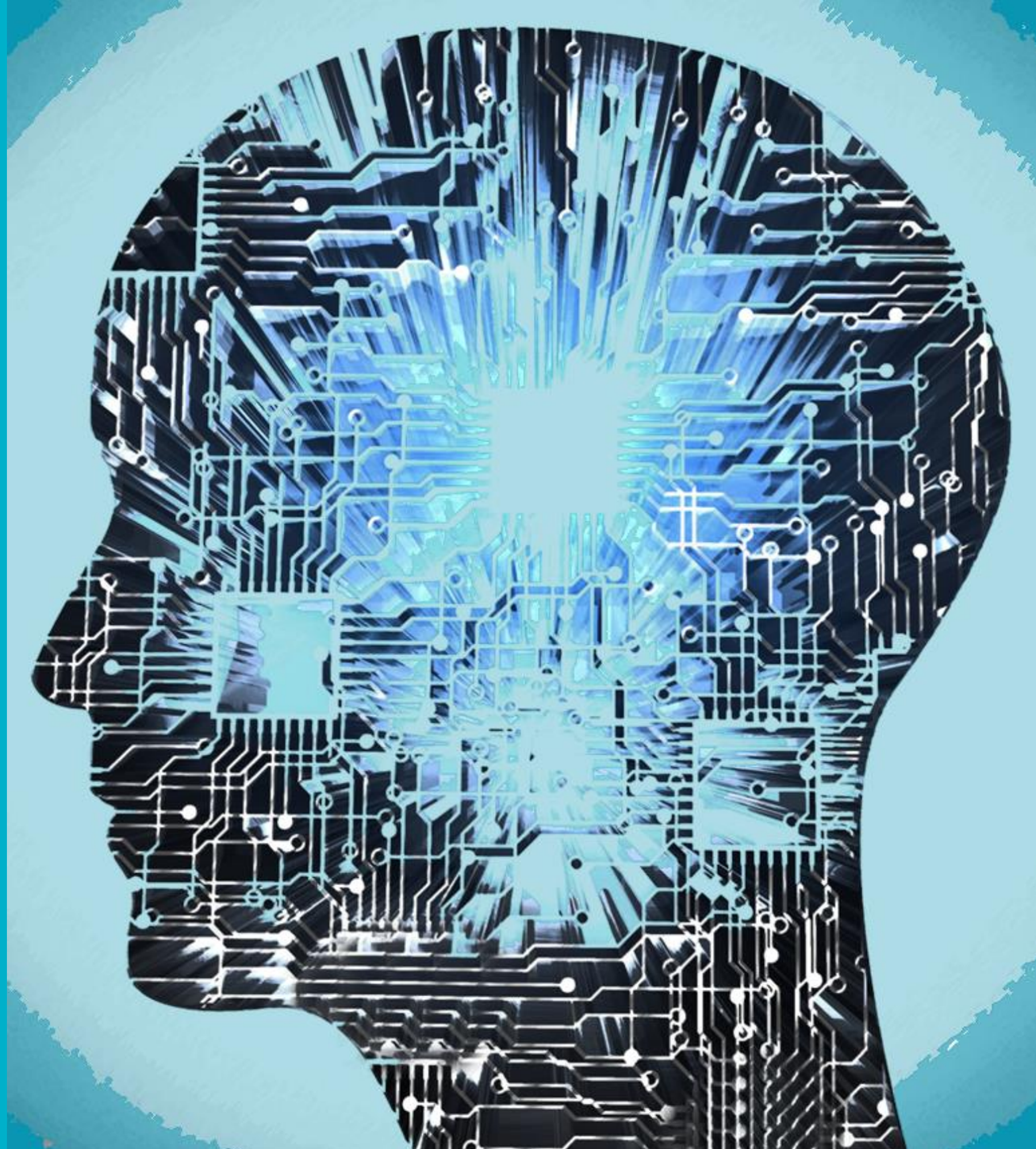
NOTE: The acceptability criteria are determined by the laboratory and can vary based on the specific analyte and clinical impact of its measurement variation. Examples of data that can be useful to establish these criteria include, but are not limited to:

- *Method validation or verification data*
- *Clinical significance of the variation between methods*
- *Biologic variation data*
- *Data from external proficiency testing providers.*

These criteria may be developed from in-house data or published literature and must be vetted by the laboratory director to ensure that they are appropriate for the clinical application of the test.

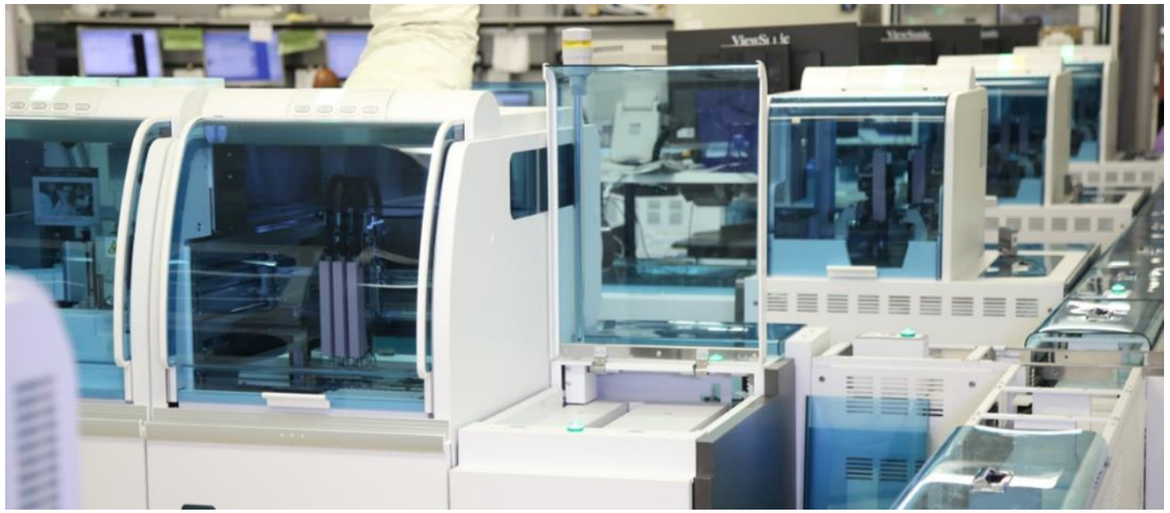
Knowledge Check

What do you think?



Instrument/Method Comparability Criteria Scenario

Is using the CLIA acceptance limits for proficiency testing as criteria for assessing comparability between methods considered a best practice?



New COM Requirement: Biological Safety Cabinet

COM.30695 Biological Safety Cabinet **Phase II**

A certified biological safety cabinet (BSC) is available and used when appropriate.

NOTE: The biological safety cabinet must be certified when installed, whenever moved, and at least annually to ensure that filters are functioning properly and that airflow rates meet specifications.

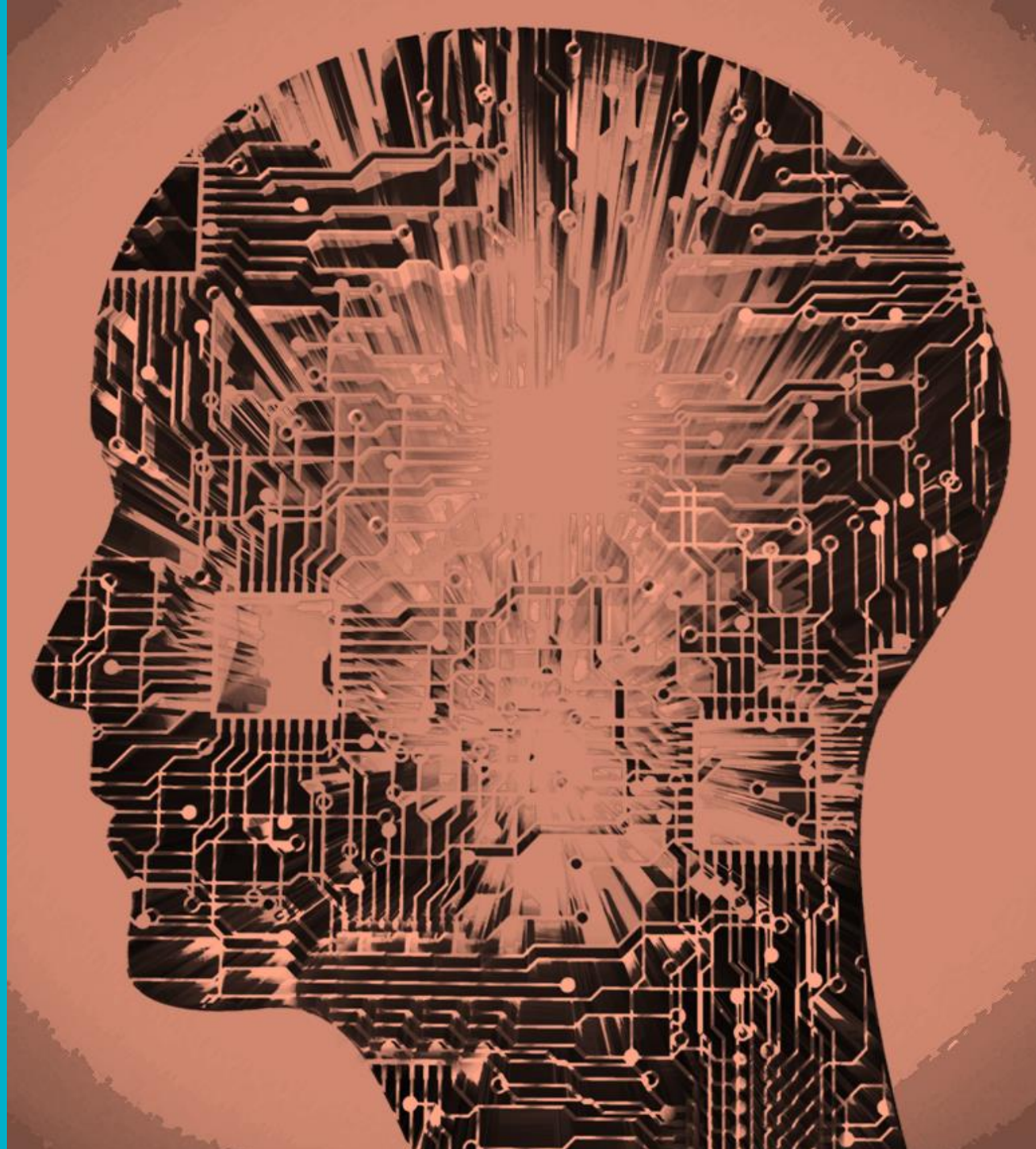
A BSC is used when protection of personnel, product, and/or the environment is needed for certain types of testing or procedures, including:

- *Handling specimens potentially containing infectious pathogens considered highly transmissible by airborne routes or with potential for aerosolization or risk of splashes*
- *Prevention of DNA/RNA contamination for molecular testing procedures*
- *Maintaining sterility of cell cultures.*

- **Replaced BAP.07610, CYG.33900, HSC.24633, LSV.46003, LSV.46066, MIC.19840, MIC.20520, and MOL.54570.**

Knowledge Check

What do you think?



Biological Safety Cabinet

My laboratory performs routine chemistry testing. Are we required to have a biological safety cabinet?

Biological Safety Cabinet, cont’d

Risk assessment conducted

Define work practice controls

6th edition of *Biosafety in Microbiological and Biomedical Laboratories* provides guidance

LDT Reporting

COM.40850 LDT ~~and Class I ASR~~ Reporting **Phase II**

Reports for laboratory-developed tests (LDTs~~), including those performed using class I analyte-specific reagents (ASRs),~~) contain the following:

- **A statement that the assay was developed by the laboratory AND**
- **A brief description of the method and performance characteristics needed for clinical use, unless the information is readily available to the clinician in another format (eg, test catalog, policy to provide upon request).**

NOTE: For laboratories subject to US regulations, the following disclaimer statement must be included on the patient report: "This test was developed and its performance characteristics determined by <insert laboratory/company name>. It has not been cleared or approved by the US Food and Drug Administration."

A test that uses a class I ASR (analytic-specific reagent) is by definition an LDT.

Analytic Measurement Ranges Changes

Impacted Checklists: CHM, CBG, HEM, IMM, POC

AMR Verification Materials

- **CHM.13550, CBG.12250, HEM.37373, IMM.33800, POC.08500**

Verification of the analytical measurement range (AMR) is performed with matrix-appropriate materials which, at a minimum, include the low, mid and high range of the AMR, and appropriate acceptance criteria are defined.

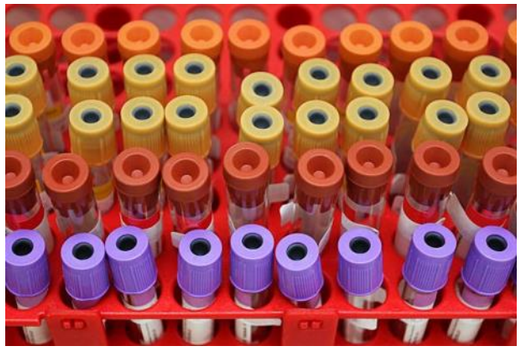
Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations and activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion.

AMR Verification

- **CHM.13600, CBG.12300, HEM.37375, IMM.33818, POC.08600**

Verification of the analytical measurement range (AMR) is performed at least every six months and following defined criteria. Records are retained.

AMR verification is not required for calculated test results as long as the individual results contributing to the calculation have AMR verification.



Mass Spectrometry (MS)

Checklists Impacted: CHM, CBG, FDT

Mass Spectrometry Changes

- **MS tuning**
  - Revised CHM.18600, FDT.24630, and CBG.17100 to include provisions for defining tune frequency
  - Deleted CBG.17200 and merged content on tandem MS tuning into CBG.17100
- **Extracted calibrators**
  - Added new requirement CHM.18610 for analysis of an extracted calibrator or appropriate calibration verification with each batch of samples
- **Analytical performance monitoring of MS assays**
  - Added new requirement CHM.18620 for using defined performance criteria and quality metrics
- **Validation, monitoring, and annual verification of MS data analysis tools**
  - Added new requirements CHM.18640, FDT. 24950, and CBG.17150 to evaluate software tools used for compound identification and quantification

Mass Spectrometry Changes, cont'd

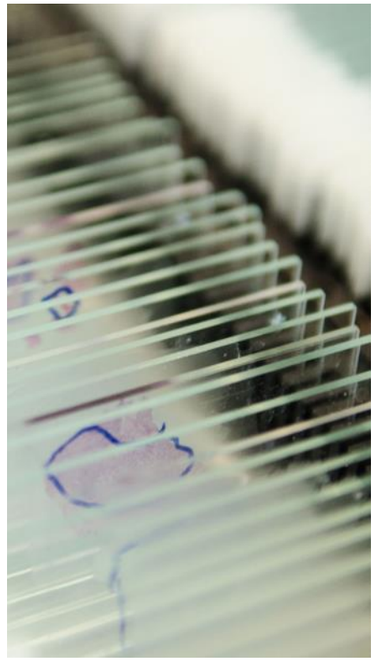
- **Identification criteria – MS**
  - Revised CHM.18700 and FDT.25130 to update the note for single-stage and tandem MS ID criteria
  - Deleted CHM.18800 and FDT.25180 and merged content on tandem MS ID into CHM.18700 and FDT.25130
- **Matrix effect assessment of MS assays – validation**
  - Revised CHM.18825 and CBG.17500 to provide more guidance on validation protocols
  - Added new requirement FDT.25150 to provide guidance and consistency across checklists
- **Matrix effect assessment of MS assays – routine monitoring**
  - Revised CHM.18850, FDT.25210, and CBG.17600 for consistency across checklists

Anatomic Pathology and Cytopathology Checklist Changes

Cancer Protocols

ANP.12350 Cancer Protocols **Phase II**

All required data elements in applicable CAP Cancer Protocols are included with appropriate responses using a synoptic format in surgical pathology reports from definitive resection specimens for primary invasive malignancies, as well as cases of ductal carcinoma in situ of the breast (DCIS~~).~~) and biopsies of pediatric tumor types listed in the CAP Cancer Protocols.



Record & Material Retention: Surgical Pathology

ANP.12500 Record and Material Retention - Surgical Pathology Phase II

Surgical pathology records and materials are retained for an appropriate period.

NOTE 1: The retention policy must address protecting and preserving the integrity and retrieval of surgical pathology materials and records.

Type of Record/Material	Retention Period
Accession log records	2 years
Wet tissue (stock bottle)	2 weeks after final report
Paraffin blocks (including cell blocks)	10 years ~~(subject~~ Refer to ~~Notes~~Note 2 ~~and 3~~ below~~)~~, paragraphs #2 and #3, for deceased patient material

ANP.12500: *Note 2*

NOTE 2: Paraffin blocks used for patient diagnostic, prognostic and/or predictive purposes must be kept for at least 10 years and be stored in a manner that preserves their identity and integrity. Tissue blocks must be stored in a temperature-controlled, pest-free environment to maintain tissue integrity. The CAP recommends (but does not require) ambient temperatures in block storage areas to be less than 27°C.

Paraffin blocks may be released for research purposes if all of the following criteria are met:

1. *For laboratories subject to US regulations, formal written authorization is obtained in accordance with the requirements of HIPAA if identifiable patient information is released.*
2. *The laboratory retains sufficient blocks to support the diagnosis for the full 10-year period. After a patient has been deceased for two years, only one block containing normal tissue (if it exists) needs to be retained for the full 10-year period.*
3. *Provision is made for retrieval by the laboratory of any blocks or material that remain after use in research, if the blocks or material are needed for diagnostic, legal, or other legitimate purposes. After a patient has been deceased for two years, only one block containing normal tissue (if it exists) must be retrievable for the full 10-year period.*

Gynecologic Cytopathology Statistical Records

CYP.07600 Statistical Records - Gynecologic Cytopathology **Phase II**

For gynecologic cytopathology cases, 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.

CYP.07600, cont'd

CONVENTIONAL*
Laboratory Percentile-Reporting Rate

CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.0	0.~~1~~0	0.~~2~~4	1.~~1~~3	2.~~9~~2	~~4.4~~5.2	~~5.0~~7.1
LSIL (%)	0.0	0.0	0.~~2~~3	0.8	1.~~5~~6	2.40	~~3.7~~2.8
HSIL (%)	0.0	0.0	0.~~0~~1	0.~~2~~3	0.5	~~1.~~0.9	1.~~2~~1
ASC-US (%)	0.~~2~~1						
ASC-H (%)	0.0						
AGC (%)	0.0						
ASC/SIL	0.~~5~~4						

ThinPrep**
Laboratory Percentile-Reporting Rate

CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.~~3~~2	0.4	0.9	1.~~6~~7	2.~~7~~9	4.~~7~~8	~~6.3~~5.7
LSIL (%)	0.~~5~~4	0.9	1.7	2.4	3.~~4~~3	4.~~5~~8	6.~~0~~6
HSIL (%)	0.1	0.1					
ASC-US (%)	1.0	~~2.~~1.					
ASC-H (%)	0.0	0.1					
AGC (%)	0.0	0.0					
ASC/SIL	0.~~8~~7	1.1					

SurePath**
Laboratory Percentile-Reporting Rate

CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.0	0.0	0.~~1~~2	0.~~3~~4	0.~~7~~8	1.2	1.6
LSIL (%)	0.~~5~~2	0.~~7~~5	1.40	2.2	3.40	~~5.0~~4.3	~~6~~5.9
HSIL (%)	0.0	0.~~1~~0	0.2	0.3	0.5	1.0~~.8~~	1.~~3~~4
ASC-US (%)	0.~~8~~3	~~1.5~~0.7	~~3.~~2.1	4.~~7~~2	~~7.1~~6.6	~~10.6~~9.2	~~15.2~~10.6
ASC-H (%)	0.0	0.~~0~~1	0.1	0.3	0.5	0.~~9~~8	1.~~4~~3
AGC (%)	0.0	0.~~1~~0	0.1	0.2	0.~~4~~5	0.~~8~~7	1.6
ASC/SIL	0.5	~~1.~~0.9	1.~~3~~2	~~2.0~~1.8	2.~~6~~9	3.~~5~~6	4.~~5~~2

CYP.07600: *Note*

NOTE: The data must be evaluated by the laboratory director or designee and included in the annual cytopathology statistical report. Inclusion of AGC data is optional. Separate statistics for conventional and each type of liquid-based preparations are required.

The benchmarking data listed in the table below are based on ~~2019~~2021 case volumes. These benchmarking data may not be applicable for laboratories that utilize primary HPV screening for a significant portion of cervical cancer screening. Results were excluded for laboratories that included primary HPV screening results in the interpretive totals when more than 25% of their cervical/gynecologic cytology slides were from positive primary HPV screening.

Discipline-Specific Checklist Changes

- Coagulation
- Point-of-Care
- Transfusion Medicine

Coagulation Specimen Quality

HEM.36920 **Specimen Quality Assessment - Coagulation** **Phase II**

Coagulation specimens are checked for clots ~~(eg, applicator sticks) or by analysis of testing results (eg, wave form analysis, delta checks)~~ before reporting results.

NOTE: Specimens with grossly visible clots may have extremely low levels of fibrinogen and variably decreased levels of other coagulation proteins, causing PT, aPTT, fibrinogen and other coagulation assays results to be inaccurate or unobtainable. Checking for clots may be done before or after testing:

- *With applicator sticks, where appropriate (should not be used with viscoelastic testing)*
- *By visual inspection of whole blood samples for large clots or centrifuged plasma for small clots*
- *By analysis of results including waveform analysis or delta checks as applicable*

Coagulation Testing

HEM.37165 Coagulation Testing and Therapeutic Anticoagulant Recommendations Phase I

Recommendations are available to clinicians on the following:

- **Laboratory tests used for monitoring heparin, low molecular weight heparin, direct thrombin inhibitors (eg, lepirudin, bivalirudin, argatroban) and/or oral anticoagulant therapy**
- **Utility and limitations of viscoelastic testing**
- **The therapeutic range for the tests, if available**
- **Information about potential interferences of anticoagulant medications on coagulation testing.**

For viscoelastic testing, recommendations on the utility of testing in clinically meaningful situations must be available, including the following as applicable:

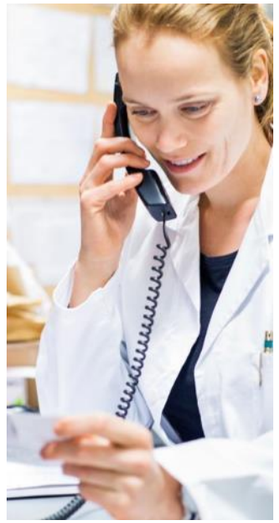
- *Proper test selection*
- *Instrument comparability and/or*
- *Recommendations for viscoelastic testing-based monitoring of antiplatelet or anticoagulant medications.*

New Requirement Viscoelastic Testing Errors

HEM.38700 Viscoelastic Testing - Error Communication Phase II

If viscoelastic testing for hemostasis analysis is performed in the laboratory and the results are viewable remotely by clinical personnel in real-time, the laboratory promptly communicates analytic errors to the responsible clinical personnel.

NOTE: Because real-time laboratory data is viewable by clinical personnel prior to reporting the final test results, the laboratory must ensure that there is training of staff for prompt notification to the responsible clinical personnel when analytic errors are detected. Communication must be recorded.



Provider Performed Microscopy (PPM) - Competency

POC.09600 Competency Assessment Elements - PPM **Phase II**

The competency of physicians and mid-level practitioners performing provider-performed microscopy (PPM) is assessed by the laboratory director or a qualified designee for each test system.

NOTE: ~~This requirement does not apply to waived testing. The laboratory director may determine how competency of waived testing is determined.~~

Competency for PPM procedures must be assessed by the laboratory director or be delegated to an individual meeting technical consultant qualifications (GEN.53625). If PPM is performed under a CLIA Certificate of Provider-Performed Microscopy Procedures, the laboratory director may only delegate competency assessment to another individual qualified as a PPM laboratory director (DRA.10100).

TRM Revisions: Not Subject to US Regulations

TRM.30950
Biologic Product Deviations

TRM.33300
License/Registration of Laboratories

TRM.42120
Blood Component Recall and Quarantine

TRM.44955
Bacterial Contamination in Platelets

TRM.44957
Bacterial Contamination in Platelets Notification

TRM.45267
Donor Arm Preparation

TRM.45270
Directed Donation Requirements

TRM.47450
Result Review

Microbiology Checklist Changes

Antimicrobial Susceptibility Breakpoints

MIC.11385 Current Antimicrobial Susceptibility Test Interpretation Breakpoints **Phase I**

Effective January 1, 2024, the laboratory uses current breakpoints for interpretation of antimicrobial minimum inhibitory concentration (MIC) and disk diffusion test results. New breakpoints are implemented within three years of the date of publication by the FDA for laboratories subject to US regulations, or within three years of publication by CLSI, EUCAST or other standards development organization (SDO) for laboratories not subject to US regulations.

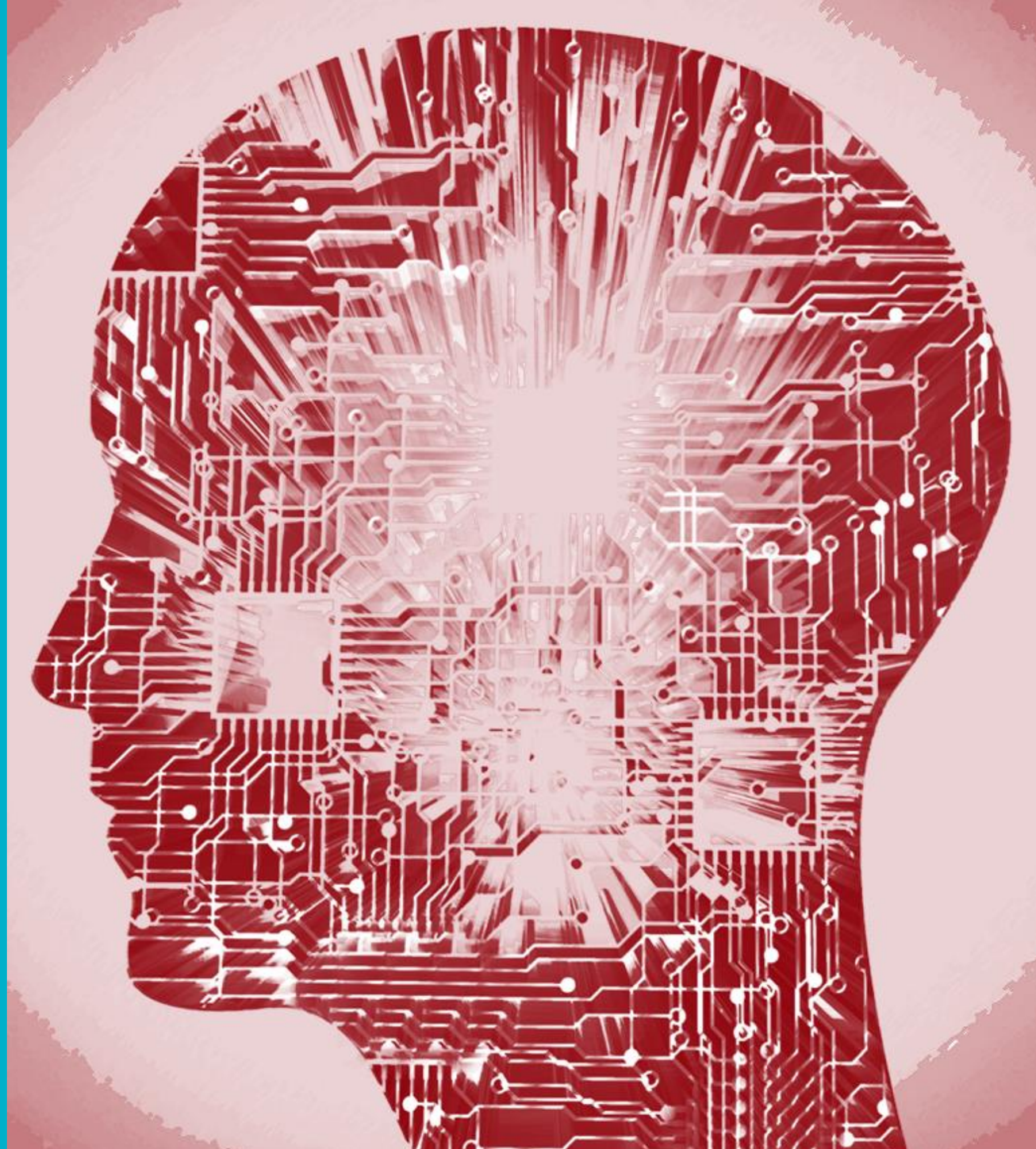
Laboratories may use CLSI, EUCAST, or FDA breakpoints. At minimum:

- Labs subject to US regulations must implement updated breakpoints within three years of publication by the FDA.
- Labs not subject to US regulations must implement updated breakpoints within three years after publication by the SDO used.

Listen to the CAP's webinar on microbiology breakpoints to learn more:
https://documents-cloud.cap.org/appdocs/learning/LAP/FFoC/MicroBreakpoints/index.html#/

Knowledge Check

What do you think?



Updated Breakpoints

Most of the breakpoints used in our laboratory are current. What if my laboratory is unable to validate a specific updated breakpoint (drug/bug combo) in our automated system?

Morphologic Observation Evaluation

MIC.11350 Morphologic Observation Evaluation **Phase II**

The laboratory evaluates consistency of morphologic observation among personnel performing ~~Gram, trichrome and other organism~~microscopic analysis (eg, stains or wet preparations) from direct specimens and cultured organisms at least annually.

NOTE: The laboratory must ensure the description and quantitation (if applicable) of ~~bacteria and other organisms is~~microorganisms and human cells are reported consistently amongst all personnel performing the microscopic analysis.

MS Controls

MIC.16605 Mass Spectrometer Controls Phase II

The laboratory tests appropriate control organisms on each day of patient testing.

NOTE: The ~~laboratory must analyze appropriate~~same protein extraction method(s) used for clinical testing must be used when testing microorganism(s) for quality control ~~organisms~~assessment on ~~a schedule determined by the manufacturer and relevant regulatory guidelines. Appropriate controls would include at least one representative organism for~~ each ~~class~~day of ~~organism tested (eg, a bacterium, a yeast, a filamentous fungi, an aerobic actinomycete, and a mycobacteria).~~ ~~For~~patient testing. At minimum, for FDA-cleared/approved ~~platforms~~test systems, the organisms or calibrator(s) required by the manufacturer must be used~~.~~

as described in the instructions for use. For laboratory developed tests, choice and use of control organisms is at the ~~Laboratory Director's~~laboratory director's discretion~~. Control~~, so long as control organisms ~~must be subjected to~~are treated in the same ~~testing conditions throughout the testing procedure as~~ manner as those derived from patient specimens ~~and an extraction control must be included if any of the organisms being tested are run with extraction~~.

C. difficile

MIC.22330 ***Clostridioides (formerly Clostridium) difficile*** **Phase II**
IMM.41820

The laboratory ~~follows a defined process~~defines criteria for the ~~detection and reporting~~rejection of specimens for *C. difficile* and/or ~~its toxins~~*C. difficile* toxin testing in stool.

NOTE: The laboratory, in collaboration with institutional stake holders (eg, infection prevention and control, antimicrobial stewardship, infectious diseases), must develop criteria for rejection of inappropriate specimens submitted to the laboratory for C. difficile testing. For example, these criteria may include stool consistency (eg, test only unformed stool), repeat testing (eg, do not perform repeat testing during the same episode of diarrhea), and any exceptions. Reference or commercial laboratories may not have the ability to collaborate with stakeholders, but still need to define rejection criteria.

Histocompatibility Checklist Changes

Section Director/Technical Supervisor Qualifications

HSC.40000 Section Director/Technical Supervisor Qualifications Phase II

The section director (technical supervisor) of the histocompatibility section has the following qualifications.

1. **MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located, or doctoral degree in chemical, physical, biological or clinical laboratory science from an accredited institution, AND**
2. **Laboratory training and experience: four years training and experience in histocompatibility, or two years training and experience in general immunology plus two years in histocompatibility. For section director/technical supervisors supporting solid organ and/or hematopoietic progenitor cell transplantation, records of training or relevant experience in histocompatibility appropriate to the supported transplant program(s)**

Section Director/Technical Supervisor Qualifications, cont'd

- **Submit records of qualifications to the CAP when there is a section director change**
  - Curriculum vitae
  - Education
  - Training
  - Experience
- **Submit a portfolio of cases if requested**
  - 20 solid organ cases including 10 detailed
  - UNOS/OPTN members* = 50 solid organ cases including 10 detailed
  - 20 hematopoietic progenitor cases including 10 detailed
  - 10 cases for all other histocompatibility testing

OR

- **Submit evidence of portfolio review from a certifying board**

**** Submission of additional records may also be required for UNOS/OPTN members based on qualifications***

Changes in Key Personnel

HSC.40100 Notification of Change in Key Personnel **Phase II**

~~If the histocompatibility laboratory participates as a member of the United Network for Organ Sharing (UNOS), the~~The laboratory notifies the CAP's Laboratory Accreditation Program when there is a change in the histocompatibility director (technical supervisor) and other key personnel, as applicable.

NOTE: All laboratories must notify the CAP when there is a change of histocompatibility section director and submit records for review by the CAP as requested.

Histocompatibility testing laboratories that participate as a member of the United Network for Organ Sharing (UNOS) must also notify the CAP when there is a change in other key personnel, including the ~~section director/technical supervisor,~~ general supervisor~~,~~ and/or clinical consultant.

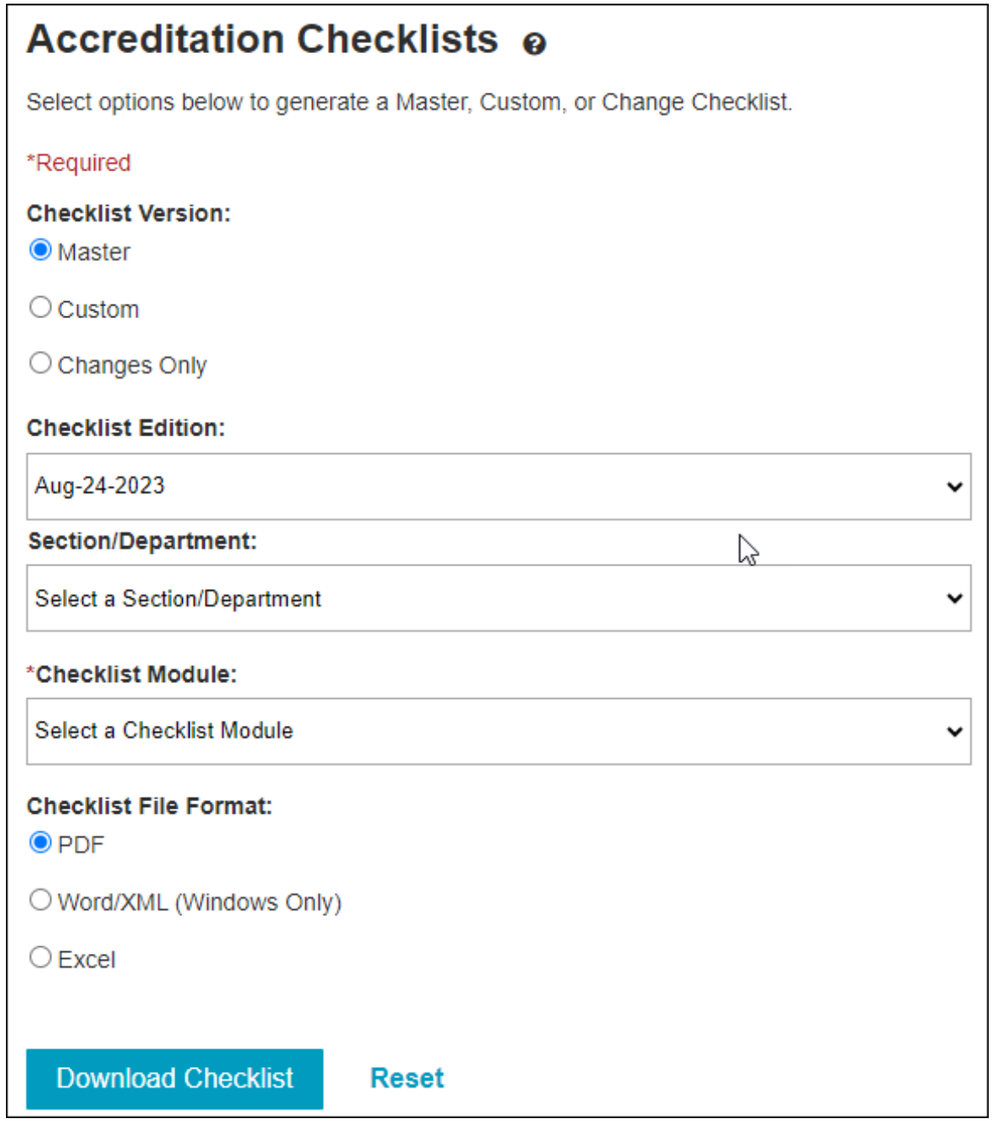
- **Update section director and key personnel roles in organization profile on cap.org.**

Using CAP Resources to Identify and Implement Changes

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.



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**

Top 10 Deficiencies

Checklist Requirement		CAP-Wide Ranking
GEN.55500	Competency Assessment	1
COM.04250	Comparability of Instruments and Methods – Nonwaived Testing	2
COM.01200	Activity Menu	3
COM.10000	Policy and Procedure Manual	4
COM.01700	PT and Alternative Assessment Result Evaluation	5
COM.30600	Maintenance/Function Checks	6
COM.04200	Instrument/Equipment Record Review	7
COM.01400	PT Attestation Statement	8
COM.30750	Temperature Checks	9
GEN.20450	Correction of Laboratory Records	10

Toolbox

- **For CAP accredited labs, a toolbox, which includes the following, is available on the CAP website (cap.org):**
  - **Predictive Marker PT Decision Tree**
  - **AMR Decision Tree**
  - **Instructions for Downloading a Checklist**
  - **Top 10 Deficiencies**
  - **Deleted, Merged, Moved Requirement Table**

Questions?

Email questions to accred@cap.org

Thank you