Focus on Compliance

2022 CAP Accreditation Checklist Updates: Changes that Matter

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December 14, 2022

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 2022 version of the CAP Accreditation Program requirements.
- Use the CAP resources to identify changes.
- Implement any necessary changes to ensure compliance with new accreditation requirements.

A Blueprint for Running a High-Quality Laboratory

CAP Accreditation Checklists

21 accreditation program checklists

- Simplify compliance
- Provide best-in-class standards
- Guided by expertise from all laboratory participants
- Incorporate best practices
- Written in straightforward language
- Updated annually
- Suitable for all staff

Summary of Changes in 2022

Checklist	Requirements	New	Significant Changes	Deleted	Moved/Merged
ANP	186	0	14	1	0
BAP	178	0	4	0	0
CBG	73	0	7	0	0
CHM	160	0	8	0	0
COM	84	0	4	1	0
CYG	68	0	1	0	0
CYP	86	0	13	0	0
DRA	20	0	3	0	0
FDT	108	0	7	0	0
FLO	49	0	6	0	0
GEN	256	4	19	0	0
HEM	180	0	19	0	1
HSC	148	1	8	0	0
IMM	66	0	8	0	0
LSV	279	0	39	0	2
MIC	231	1	32	0	17
MOL	167	6	24	0	5
POC	63	1	5	2	0
RLM	118	0	11	0	0
TRM	258	0	12	0	3
URN	27	0	3	0	0
Total	2,805	13	247	4	28

Topics for 2022 Checklists Update

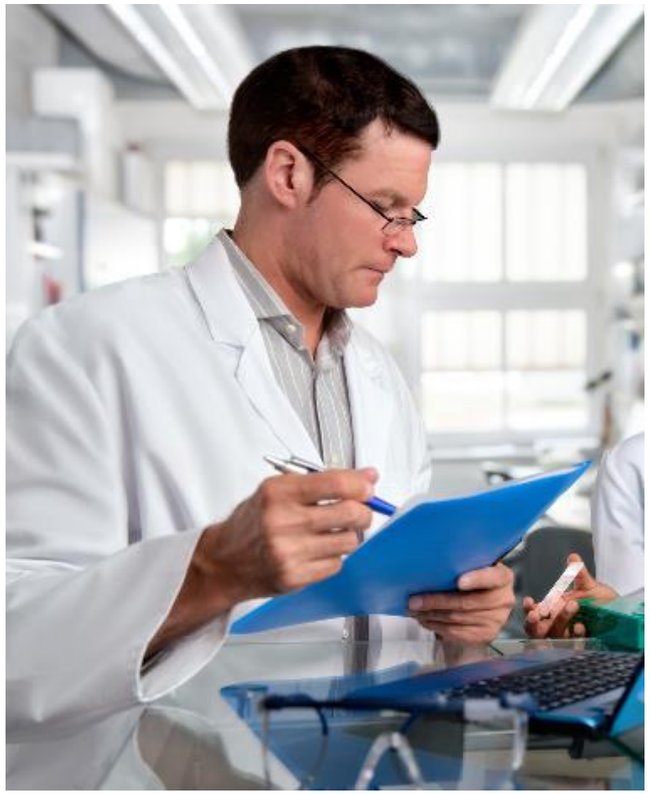
Checklist enhancements for 2022

- **Policy/Procedure Icon**
- **Waived Testing Laboratories – Laboratory General Customization**
- **Next-Generation Sequencing (NGS) – Enhanced Customization**

Topics for 2022 Checklists Update, cont’d

Checklist Changes

- Laboratory General
  - Reporting Outside Test Results
  - Patient Data Accessibility
  - Safe Work Practices Review



Topics for 2022 Checklists Update, cont’d

Checklist Changes

- Director Assessment
  - Director Responsibilities – New Method Validation/Verification
- All Common
  - Waived Test Implementation and Approval
  - Critical Result Notification

Topics for 2022 Checklists Update, cont’d

Checklist Changes

- **Discipline-specific**
  - **ANP**
  - **CYP**
  - **HEM**
  - **MIC**
  - **TRM**
  - **HSC**

Policy/Procedure Icon

Policy/Procedure (P/P) Icon

How have the requirements changed?

- **New** icon to indicate when a policy or procedure is necessary
- 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

P/P Icon: Example Requirement in 2022

If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.

Evidence of Compliance:

- ✓ Records of alternative control procedures

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1256(h)].

P/P Icon: What Does This Mean for my Laboratory?

All laboratory testing, functions, and processes must be defined in written policies and/or procedures.

- **A single P/P may be used to address multiple requirements**
- **Checklist requirements without the icon do not require review of P/P by the inspector to determine compliance**

P/P Icon: When is it *Applicable*

- **The P/P icon was applied to requirements that:**
  - **Are complex**
  - **Address technical testing processes**
  - **Have significant regulatory impact**
  - **Have significant patient or personnel safety impact**
  - **Have the potential for significant variation if not well defined**

P/P Icon: When is it *not* Applicable

- **The P/P icon was not applied to requirements that:**
  - **Are self-evident**
    - **Examples:**
      - **URN.30750 – Availability of reference materials**
      - **COM.01200 – Activity menu that reflects testing performed**
  - **Are covered under a broader requirement**

P/P Icon: Examples

COM.40300 **Verification of Test Performance Specifications - FDA-cleared/approved Tests** **Phase II**

Prior to clinical use of each unmodified FDA-cleared or approved test, the laboratory has performed a verification study and prepared a written assessment of each of the following test method performance specifications, as applicable, using a sufficient number of characterized samples:

1. Analytical accuracy
2. Analytical precision
3. Reportable range

COM.40475 **Method Validation and Verification Approval - Nonwaived Tests** **Phase II**

Prior to clinical use of each nonwaived test, the laboratory director, or designee meeting CAP director qualifications, has signed the laboratory's written assessment of the validation or verification study (accuracy, precision, etc.) to confirm the acceptance of the study data and written assessment, and to approve each nonwaived test for clinical use.

COM.40300 has the P/P icon because the verification of the test method performance specifications is a complex process and general guidance needs to be defined. COM.40475 does not have the P/P icon because the inspector can verify compliance through review of the written assessment alone.

P/P Icon: Examples, cont'd

COM.30700 Thermometric Standard Device **Phase II**

An appropriate thermometric standard device of known accuracy (certified to meet National Institute of Standards and Technology (NIST) Standards or traceable to NIST Standards) is available.

Evidence of Compliance:

- ✓ Thermometer certificate of accuracy

COM.30725 Non-certified Thermometers **Phase II**

All non-certified thermometers are checked against an appropriate thermometric standard device before initial use and as defined by laboratory policy.

Evidence of Compliance:

- ✓ Records of verification

COM.30700 does not have the P/P icon because the inspector can confirm compliance through review of the certificates alone. COM.30725 has the P/P icon because this requires an ongoing process that needs to be defined.

P/P Icon: How do we Comply

- **CAP-accredited laboratories can download customized checklists to identify requirements with the P/P icon**
  - **Word and PDF checklists display the P/P icon next to requirements**
  - **Excel checklists have a column to indicate a P/P is required instead of an icon**

Requirement (ID)	Policy/ Procedure	Phase	Subject Header	Requirement	Note	Evidence of Compliance
GEN.40825	X	2	Specimen ID	There is a system to positively identify all patient specimens, specimen types, and aliquots at all times.	NOTE: Each specimen container must identify the patient uniquely. This may be text-based, numeric, bar-coded, etc. The form of this system is entirely at the discretion of each laboratory, so long as all primary collection containers and their aliquots have a unique label which one can audit back to full particulars of patient identification, collection date, specimen type, etc. Practical considerations of container size may limit the extent of such details. There must be an appropriate, consistently applied accessioning system.	
GEN.40900		2	Specimen Date Received	The date (and time, if appropriate) that the specimen was received by the laboratory is recorded.		

P/P Icon: How do we Comply

****Important considerations****

- **A separate policy or procedure is not needed for each separate requirement.**
- **Broad or overarching policies and procedures may cover multiple related requirements.**
- **The policy/procedure must match laboratory practice.**

Waived Only Testing Laboratories

Laboratory General Checklist Customization

What's Different about GEN Waived Customization

- **Added four new requirements for waived only laboratories replacing the need for various more complex GEN requirements on:**
  - **Quality management systems**
  - **Record retention**
  - **Test orders**
  - **Safety program**
- **Reduced the overall number of applicable requirements to better reflect the waived setting.**

Changes provide a better fit for laboratories that do less complex testing, while still ensuring high quality.

Waived Only Requirement: Example

Quality Management System (QMS) - Laboratories Only Performing Waived Testing **Phase II**

The laboratory has a QMS that includes processes for the following:

- **Monitoring the quality of the testing performed**
- **Recording and investigating non-conforming events**
- **Mechanism for employees and patients to report quality and safety concerns**
- **Recording corrective and preventive actions taken to address problems**
- **Managing recalls and notifications from vendors for reagents, supplies, instruments, equipment, or software that may impact patient/client services**
- **Ensuring compliance with applicable national, federal, state (or provincial), and local laws and regulations.**

*NOTE: This requirement is applicable to laboratories that **only offer waived testing services**. Laboratories that perform any nonwaived testing are subject to the additional requirements in the Quality Management System section.*

The quality manual must describe processes used to investigate non-conforming events. For serious non-conforming events that result in death, permanent harm or severe temporary harm (eg, sentinel event), the laboratory must perform a root cause analysis (RCA). Methods used to perform RCAs may vary. Helpful tools on RCA can be found on cap.org on the CAP15189 Accreditation Program landing page and behind e-LAB Solutions Suite under Accreditation Resources-Quality Management.

Which Laboratories Qualify as Waived Only Laboratories

- Laboratories with CAP activity menus limited to only waived activities
  - Test complexity can be found in the FDA database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
  - Modifications made to a waived test would not be considered a waived-only laboratory
  - Applies to laboratories that have a CLIA Certificate of Waiver
- If a laboratory performs even one nonwaived test, it does not qualify

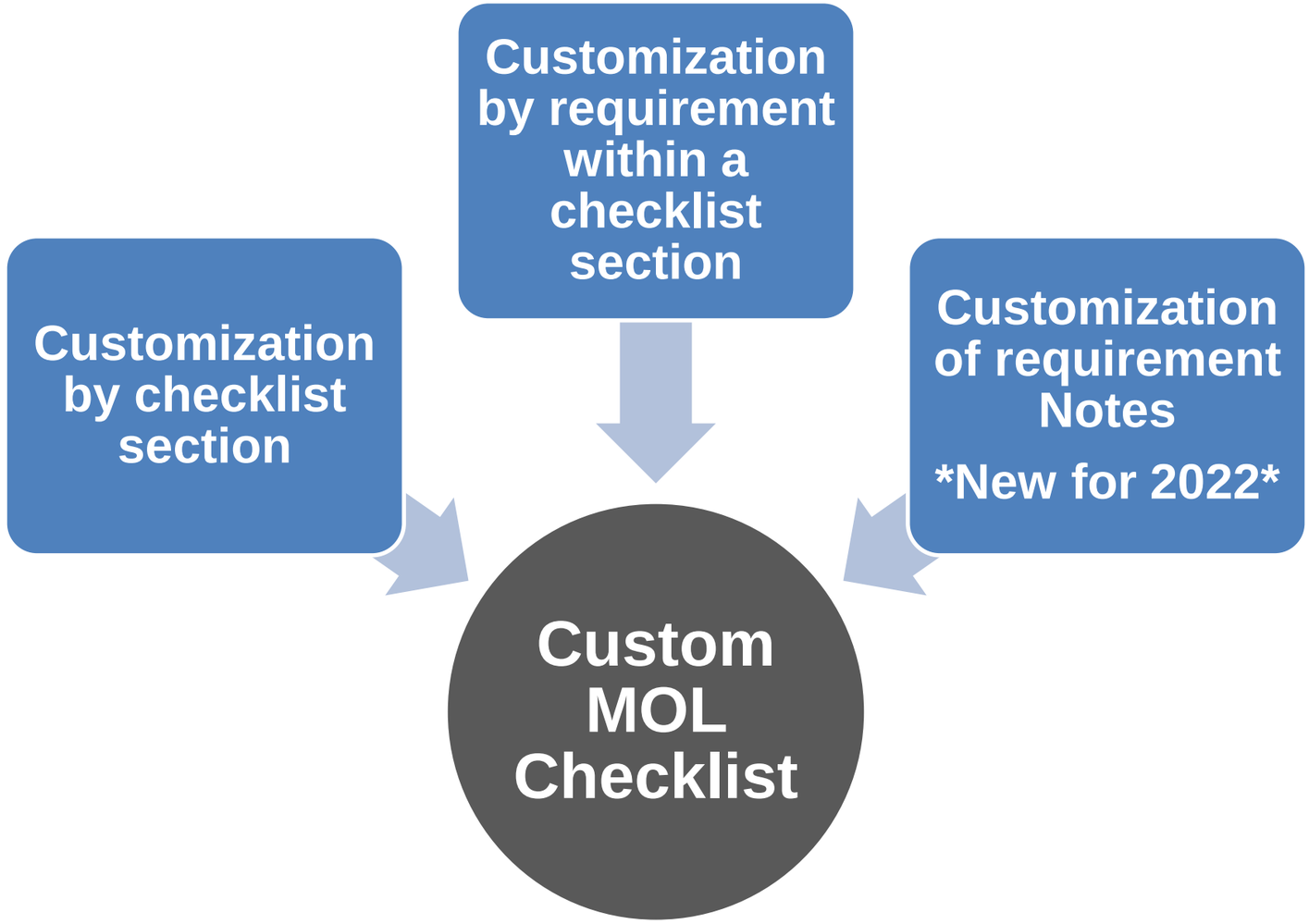
Next-Generation Sequencing (NGS)

Enhanced Customization

NGS Enhanced Customization

- **New level of checklist customization for Molecular Pathology Checklist**
  - Includes the complex technical details needed for different applications of NGS
  - Excludes NGS content not applicable to specific applications
  - Examples of customization for the following NGS applications:
    - Inherited disease testing
    - Oncology testing
    - Infectious disease testing
    - Histocompatibility testing

NGS Enhanced Customization, cont'd



NGS Note Customization

All NGS laboratories will receive this NOTE paragraph

NGS labs performing Oncology and Inherited Disease testing will receive this paragraph

NGS labs performing Infectious Disease testing will receive this paragraph

NGS labs performing HLA testing will receive this paragraph

All NGS laboratories will receive this NOTE paragraph

The laboratory follows written procedures defining all of the essential elements for performing the analytical next generation sequencing wet bench component.

NOTE: The written procedure must include a description of the analytical targets that are evaluated, specimen requirements, and acceptable validated sample types (eg, primary specimens, such as plasma, whole blood, body fluids, stool, tissue, saliva, buccal swabs, and FFPE). The targets selected for analysis and interpretation in an individual NGS test must be based on the diagnostic purpose of the test and their relevance must be substantiated by evidence in the scientific literature and/or as established by expert consensus guidelines.

For oncologic and inherited disease testing applications, the description must include genes in a panel, exome, genome, or other targeted regions, such as introns or promotor sites. A description of the evidence supporting the inclusion of the genes or targets analyzed and interpreted in an individual NGS test must also be included. An evidence-based method to establish the strength of gene-disease associations is critical to facilitate an informed approach to the interpretation of genomic variants in panels, as well as exomes/genomes.

For infectious disease testing, the description must include the genes or organisms in a panel, or whether the procedure utilizes a metagenomic approach. Accepted sample types may also include cultured isolates, such as viruses, bacteria, mycobacteria, fungi, or positive broth cultures.

For HLA and/or chimerism testing, the description must include the genomic region or nucleic acid to be characterized (eg, whole or part of an HLA gene, KIR, mRNA).

NOTE: The written procedure must also include the following elements, as applicable:

- *Methods and reagents used for the enrichment of target regions*

Checklist Changes

Laboratory General

Reporting Outside Test Results

There is a policy for laboratory director (or designee meeting CAP director qualifications) input regarding the integration of outside test results into the institution's patient data systems (eg, laboratory information system (LIS), institutional electronic medical record).

Patient self-testing

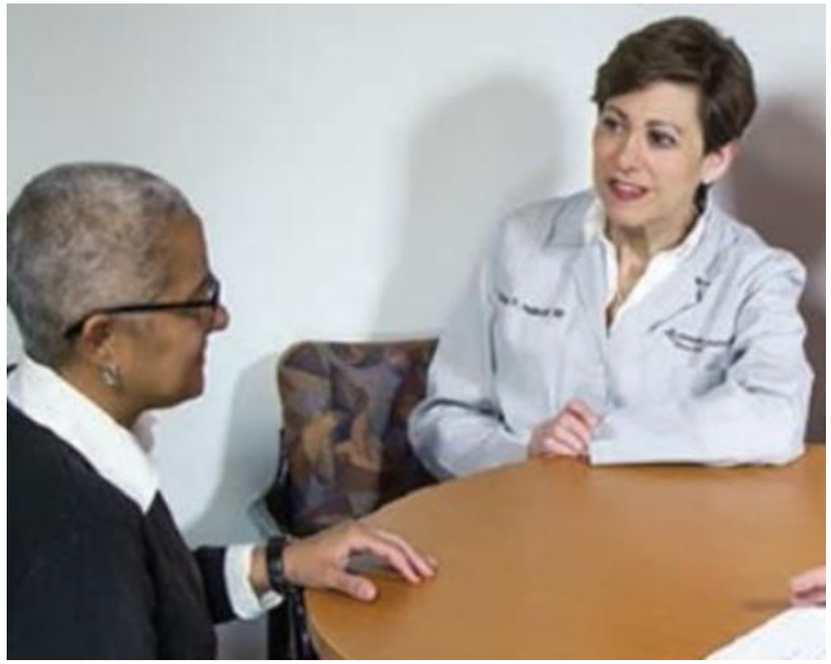
Tests performed by an outside laboratory, not referred by the primary lab

- **Revised requirement to clarify the following:**
  - **Need for laboratory director awareness and involvement**
  - **Clear reporting of the origin of outside results**
  - **Applies to test results provided by a patient or clinician**

Knowledge Check

Our laboratory is getting more requests for different types of outside results or patient self-testing results to be entered into the EMR (eg, COVID antigen, glucose monitoring from continuous glucose or home monitors).

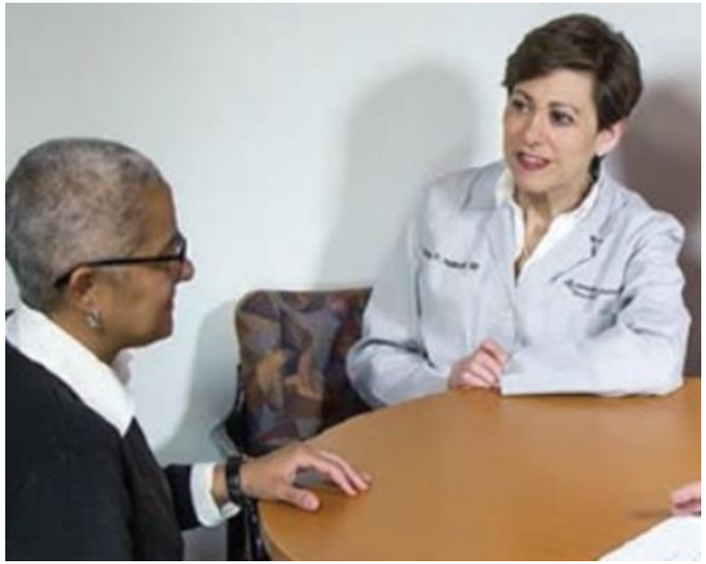
- **What should we do?**
- **How can we comply?**



Knowledge Check

- **What should we do?**
  - **LD awareness**

- **How can we comply with reporting of outside results?**
  - **Policy**



Patient Data Accessibility

The laboratory ensures that patient data are accessible in a timely manner only to those individuals who are authorized to review test results.

NOTE: Only those healthcare personnel authorized to review a patient's test results should have access to those results. Laboratories subject to US regulations must provide final test results to the patient or the patient's personal representative upon request. For completed tests, these results must generally be provided no later than 30 days after such a request. Laboratories must also comply with other federal and state laws on patient access to laboratory and pathology results.

- **21st Century CURES Act**
  - **Aimed at providing easier access to health information and prevent information blocking.**
  - **Laboratories must follow the CURES Act and the HIPAA privacy rule for patient access to test reports.**

CURES Act fact sheet: https://documents.cap.org/documents/sharing-test-results-cures-act-fact-sheet.pdf

Safe Work Practices

The laboratory evaluates safe work practices at least annually to identify hazards, investigate problems, and take actions to prevent recurrence or mitigate potential risks, as appropriate.

NOTE: Review must include assessment of work practices for infection control (eg, bloodborne pathogens, highly infectious pathogens), fire prevention and control, electrical safety, chemical safety, radiation safety, personnel and patient security incidents, and environmental safety.

Appropriate risk assessment processes must include the following steps, as applicable:

- *Identifying risks*
- *Planning for prevention and mitigation of safety risks*
- *Implementing risk mitigation plans*
- *Assessing incidents and incorporating those assessments into goals and plans*
- *Evaluating the effectiveness of the plan either annually, or when risks change significantly*
- *Communicating the findings of assessments with the institutional safety committee and/or other stakeholders.*

Revised and expanded NOTE to detail risk assessment processes

Checklist Changes

Director Assessment

Director Responsibility: New Method Val/Ver

The laboratory director ensures that the performance specifications for new tests, instruments, and methods introduced to the laboratory have been properly validated or verified prior to being used for patient testing.

NOTE: Specific requirements are in the All Common Checklist (Instruments & Equipment, Test Method Validation/Verification, and Method Performance Specifications sections) and in other checklists.

Artificial intelligence and machine learning algorithms implemented by the laboratory for patient testing are subject to this requirement.

- **Added validating/verifying artificial intelligence or machine learning algorithms implemented by the laboratory for patient testing**

Examples

What types of tests involve artificial intelligence and machine learning?

Checklist Changes

All Common

Critical Result Notification

The laboratory immediately notifies physicians or other clinical personnel responsible for patient care when results of designated tests exceed established "critical" values. Records of notification are retained.

NOTE: Alert or critical results are those results that may require prompt clinical attention to avert significant patient morbidity or mortality. The laboratory director, in consultation with the clinicians served, must define the critical values and critical results that pertain to its patient population. The laboratory may establish different critical results for specific patient subpopulations (for example, dialysis clinic patients).

An appropriate notification includes a direct dialog with the responsible individual or an electronic communication (eg, secure email or fax) with confirmation of receipt by the responsible individual.

For communication of significant and unexpected surgical pathology and cytopathology findings, refer to ANP.12175 and CYP.06450 instead.

Allowing clinicians to "opt out" of receiving critical results is strongly discouraged.

Records must show prompt notification of critical results to the appropriate clinical individual and include the following:

- *Date of communication*
- *Time of communication*
- *Responsible individual communicating the result*
- *Person notified using identifiers traceable to that person (a first name alone is inadequate)*
- *Test results.*

Waived Test Implementation and Approval

The laboratory director or designee meeting CAP director qualifications approves the introduction of new waived tests.

NOTE: After initial approval, the introduction of additional identical waived instruments performing identical previously approved waived tests does not require approval by the director or designee, providing manufacturer instructions for instrument verification are followed and recorded.

Knowledge Check

My institution's point-of-care testing program uses large numbers of waived glucose meters. Due to our high volume, we receive replacement instruments that need to be put into service each month. It's been a burden to have our laboratory director approve each replacement instrument prior to use.

What does my laboratory need to do to put a waived replacement instrument into service?

Knowledge Check, cont’d

What does my laboratory need to do to put a waived replacement instrument into service?

- **Follow manufacturer’s instructions for implementation of the instrument**
- **Ensure that the instrument is identical and performing the same tests as those already approved for use (the same make and model)**

Discipline-Specific Changes

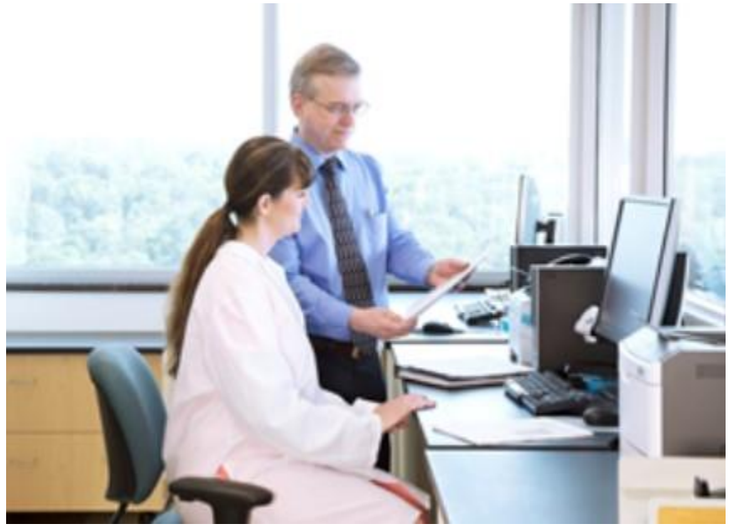
Cancer Protocols

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).

- Removed the requirement for an annual self audit of reports
- Revised to require processes to ensure compliance with reporting of all required data elements
  - LIS built-in check
  - Use of templates for reporting
  - LIS generated reports
- Added a recommendation to use the CAP's pediatric cancer protocols

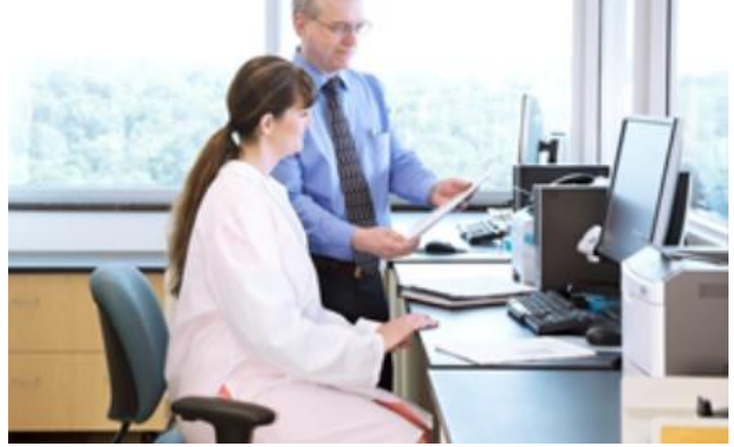
Knowledge Check

My laboratory has been performing an annual 10% self audit of cancer reports for the required data elements and plans to move to the use of standardizing report templates within the next year. Our inspection is not due until the beginning of the following year. The self-audit is a big undertaking. Can we discontinue the self-audit now?



What do you do think?

Knowledge Check



What do you think?

A. Yes. You can discontinue the audit as long as the standardized templates are implemented prior to your next inspection.

B. No. You must continue the annual audit until the standardized templates are implemented.

C. Maybe. Check to see if other processes are in use that would ensure reporting of the required data elements.

Statistical Records for Gynecologic Cytopathology

- **Laboratories are required to evaluate statistical records at least annually for the categories of ASC-US, ASC-H, AGC, LSIL, HSIL, and Unsatisfactory.**
- **The CAP provides benchmarking data in the requirement to compare reporting rates with other laboratories.**
- **A NOTE was added to both requirements to clarify that benchmarking data may not be applicable for laboratories that utilize primary HPV screening for a significant portion of cervical cancer screening.**

Consistency of Morphologic Observations

The laboratory evaluates consistency of morphologic observation among personnel performing blood cell microscopy at least annually.

NOTE: The laboratory must ensure the identification and morphology of blood cells is reported consistently amongst all personnel performing the microscopic analysis.

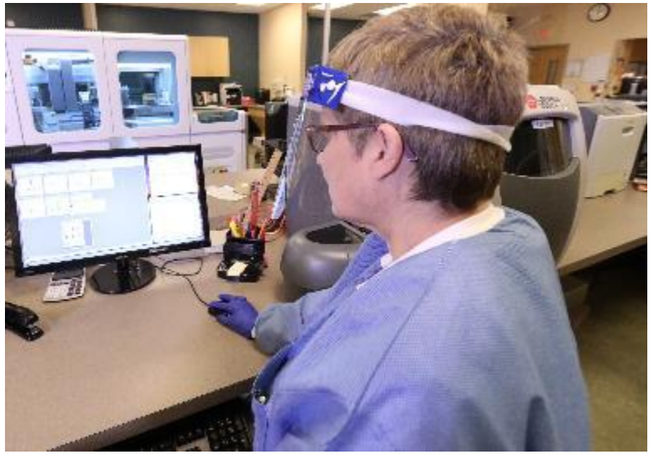
Added option #5 as an additional suggested method to accomplish the evaluation:

1. ***Circulation of a pregraded set of blood files/body fluid smears/semen smears/urine sediments/organisms with defined criteria***
2. ***Multi-headed microscopy***
3. ***Use of photomicrographs with referee and consensus identifications (eg, former CAP Surveys)***
4. ***Use of digital images***
5. ***Enrollment and participation of all personnel in an external assessment program for morphologic observation of peripheral blood smear morphology, body fluid differentials, semen smears, urine sediment microscopy, Gram stains***

Consistency of Morphologic Observation: Knowledge Check

Your laboratory is enrolled in proficiency testing for morphologic observation and has a schedule to rotate the PT to different staff each mailing. According to the schedule, all staff will be included in the rotation over a one-year period unless someone is out on leave.

Is your laboratory in compliance?



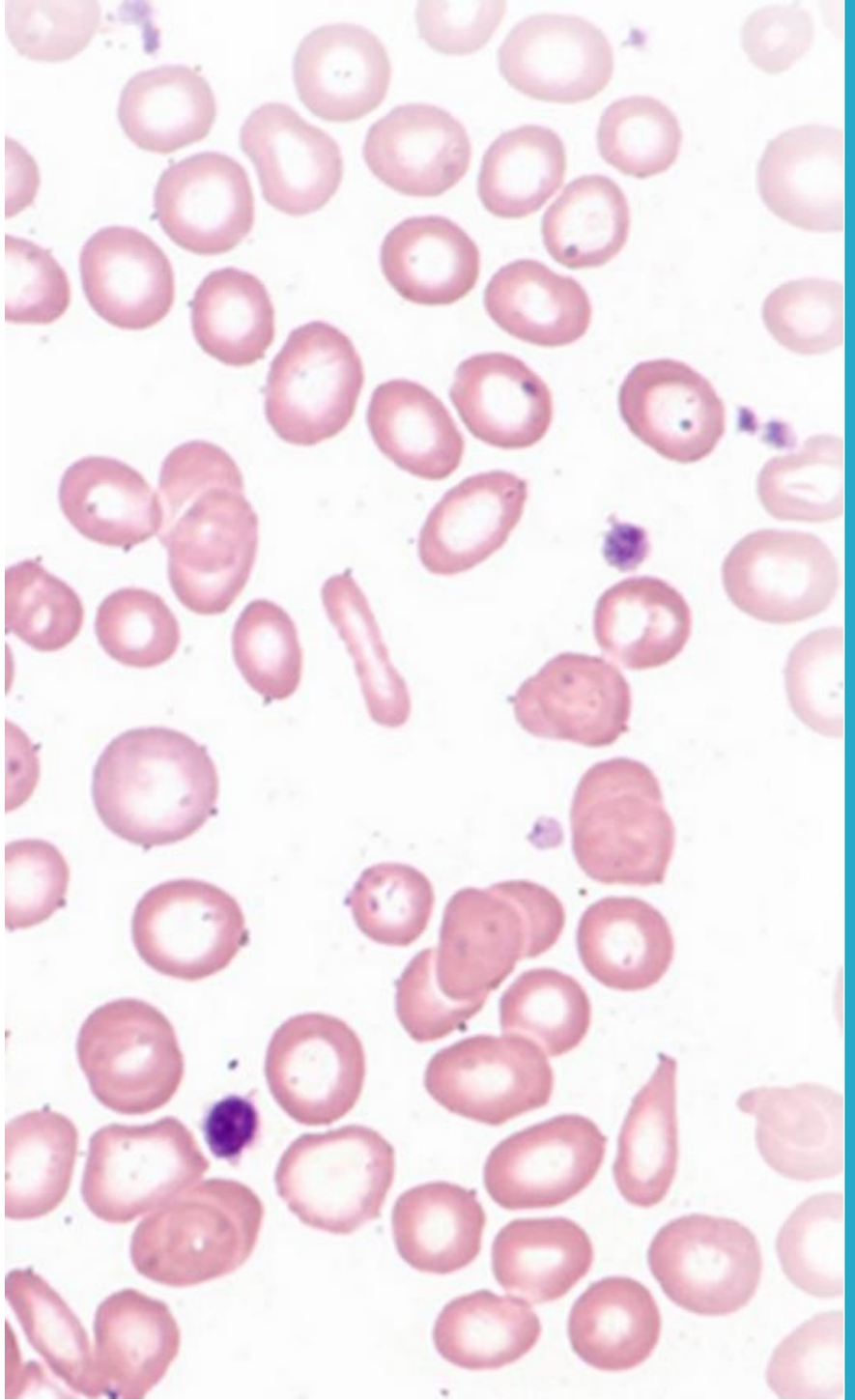
Knowledge Check: Answer

Is your laboratory in compliance?

A. No. It is deficient.

B. Yes. The lab is in compliance because it is enrolled in PT.

C. Yes. The lab is in compliance because everyone participates at least once a year.



Antimicrobial Susceptibility Testing

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#/

M. tuberculosis Molecular Testing

Laboratories performing molecular testing for the detection of *M. tuberculosis* directly from specimens clinically suspicious for tuberculosis perform culture on all specimens or include a recommendation for mycobacterial culture.

NOTE: Mycobacterial culture is a more sensitive method than molecular testing for the diagnosis of tuberculosis and is still considered the gold standard. When possible, a culture must be performed regardless of the molecular test result to aid in clinical diagnosis. Isolates may be required for susceptibility testing, genotyping, or to ascertain the presence of viable organisms in patients currently being treated. In the absence of a culture, a comment must be added to the report recommending culture.

This checklist item does not apply to broad multiplex or metagenomic panels that are able to detect M. tuberculosis, but in which the clinical suspicion for tuberculosis is absent.

Requirement revised to clarify the importance of culture when there is a clinical suspicion of tuberculosis.

Fetomaternal Hemorrhage

Identified Rh immune globulin candidates are tested after delivery to detect fetomaternal hemorrhages greater than 30 mL of whole blood.

Modified the NOTE for neonates with a weak-D phenotype:

- Fetal rosette testing is contraindicated
- A quantification method (Kleihauer-Braun-Betke or flow cytometry) must be performed

Histocompatability Virtual Crossmatch

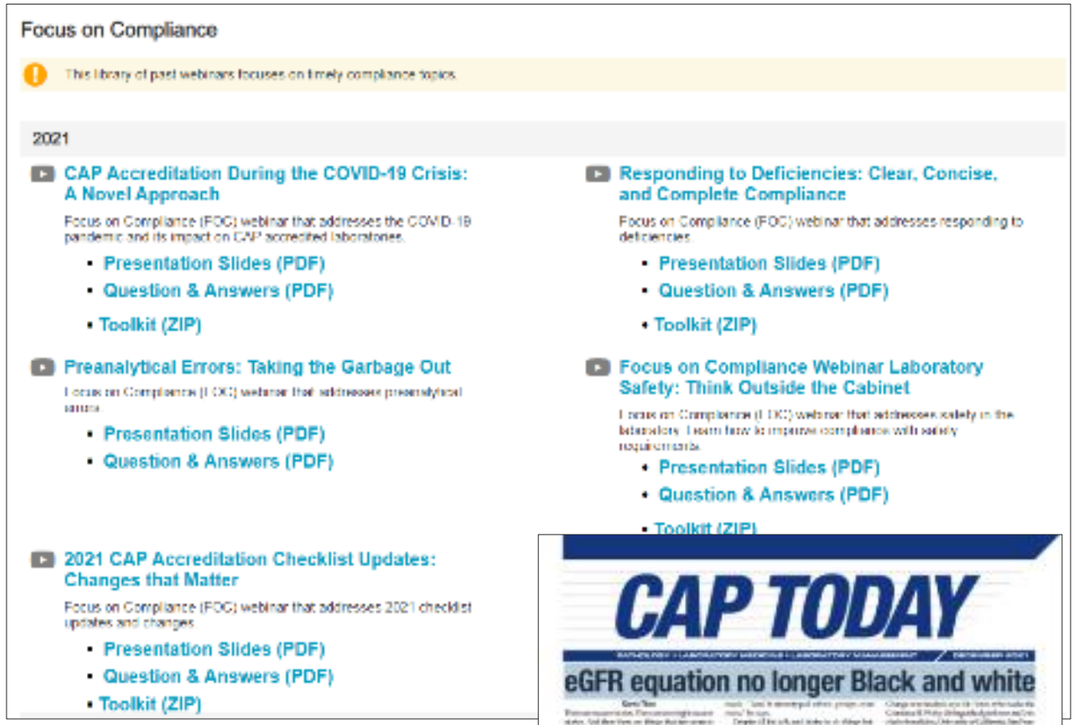
The eligibility criteria and process used to perform a prospective virtual crossmatch are defined for each transplant program the laboratory serves.

- New requirement to define the eligibility criteria and process for use of a prospective virtual crossmatch
- NOTE section contains specific items that must be defined
- Transplant program agreements must address the use of virtual crossmatch

CAP Resources

CAP Resources to Keep Up-to-Date

- *CAP Today*
- e-Alerts
- Online Inspector Training: Team Member/Team Leader
- CAP Accreditation Resources Repository
- Educational webinars: Focus on Compliance Series



Top 10 Deficiencies

Checklist Requirement		CAP-Wide Ranking
COM.01200	Activity Menu	1
GEN.55500	Competency Assessment	2
COM.10000	Procedure Manual	3
COM.04250	Comparability of Instruments and Methods – Nonwaived Testing	4
COM.04200	Instrument/Equipment Record Review	5
COM.30600	Maintenance/Function Checks	6
COM.01700	PT and Alternative Assessment Result Evaluation	7
COM.30750	Temperature Checks	8
COM.01400	PT Attestation Statement	9
COM.30450	New Lot/Shipment Confirmation of Acceptability	10

Resources

Checklist interpretation questions?

- **Contact the CAP at:**
  - **Email: accred@cap.org**
  - **Phone: 800-323-4040, option 1**

Summary

- Provided an overview of enhancements for the 2022 edition.
- Summarized significant changes to the checklists.
- Discussed resources for your laboratory.