Important Notice - Updates to Recorded Webinar

- The CAP modified checklist content in the 2021 Checklist Edition relating to slides #14 and #46 after this webinar was recorded.
- The following includes updates to this presentation:
  - Slide #14 – GEN.40115 – removed content in the checklist note for provisions on cold ischemia time and time in fixative for specimens clinically suspected or otherwise known to contain malignancy that are likely to be submitted for ancillary testing.
  - Slide #46 – ANP.10039 – withdrew the requirement for laboratories to have a process to ensure an optimal total fixation time in formalin for specimens clinically suspected or otherwise known to contain malignancy that are likely to be submitted for ancillary testing.
- Please see the Questions and Answers document for more information (#30).

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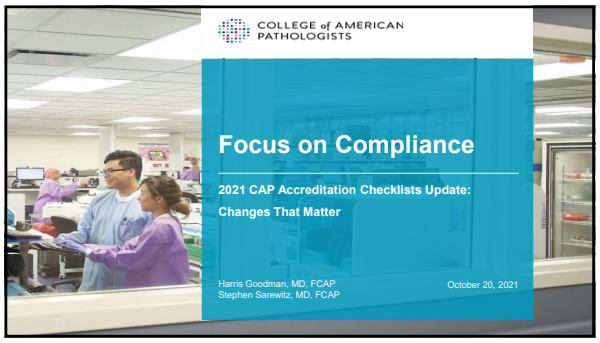

1

Disclosure

The following authors/planners/reviewers have financial interests/relationships to disclose:
None

The following authors/planners/reviewers have no financial interests/relationships to disclose:
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2

Accreditation

The College of American Pathologists (CAP) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

CE (Continuing Education for Nonphysicians)
The CAP designates this educational activity for a **maximum of 1.00** credit/hour of continuing education. Each participant should only claim those credits/hours he/she spent in the activity.

ASCP Statement
The American Society for Clinical Pathology (ASCP) Board of Certification (BOC) Certification Maintenance Program (CMP) accepts this activity to meet the continuing education requirements.

California and Florida Statement
This activity is approved for continuing education credit in the states of California and Florida.

 3

3

Today's Presenter

Dr. Goodman is a compulsive ultramarathoner with a love of pathology. He attended the University of California at San Francisco for medical school and residency in pathology and laboratory medicine. Dr. Goodman is board certified in anatomic pathology, clinical pathology, and cytopathology.

He is currently the CAP commissioner for central California and the chair of the CAP Checklists Committee.

Harris Goodman, MD, FCAP

4

Today's Presenter

Dr. Sarewitz is board certified in anatomic and clinical pathology with over 30 years experience in community pathology practice in the Seattle area, in both hospital and independent laboratory settings. He received his MD from Columbia University, New York, New York; completed residency training in anatomic and clinical pathology and laboratory hematology at Hartford Hospital, Hartford, Connecticut; and completed a fellowship in tumor pathology at Memorial Sloan Kettering Cancer Center, New York, New York. Dr. Sarewitz was a member of the CAP Board of Governors and has served on numerous councils and committees for the CAP in addition to serving as a CAP commissioner. He is vice chair of the Checklists Committee and Commission on Laboratory Accreditation.

Stephen Sarewitz, MD, FCAP

5

Objectives

- Describe key changes and the rationale for the changes in the 2021 version of the CAP Accreditation Program requirements.
- Use CAP resources to identify changes.
- Implement any necessary changes to ensure compliance with new accreditation requirements.

6

Summary of Changes in 2021

Checklist	Requirements	New	Significant Changes	Deleted	Moved/Merged
ANP	187	2	16	0	2
BAP	178	0	4	0	2
CBG	73	0	2	0	0
CHM	160	1	2	0	1
COM	85	3	29	0	0
CYG	68	0	6	0	1
CYP	86	6	12	0	1
DRA	20	0	8	0	0
FDT	108	0	4	0	10
FLO	49	1	3	0	1
GEN	252	8	38	1	0
HEM	181	2	8	0	1
HSC	147	0	9	0	0
IMM	66	3	7	0	3
LSV	281	6	24	1	6
MIC	242	3	28	0	27
MOL	161	0	35	0	9
POC	64	2	10	0	0
RLM	118	2	7	0	0
TRM	259	2	25	0	5
URN	27	0	5	0	0
TOTAL	2812	41	282	2	69

7

Topics for 2021 Checklists Update

- Laboratory General Checklist (GEN)
  - Quality Management System (QMS)
  - Specimen Collection and Handling
  - Autoverification (Laboratory Computer System)
  - Competency Assessment
- Director Assessment Checklist (DRA)
  - New Director Policy and Procedure Approval

8

Topics for 2021 Checklists Update, cont'd

- All Common Checklist (COM)
  - Proficiency Testing
  - Aliquoting
  - Specimen Rejection Criteria
  - New Reagent Lots and Shipments
  - Test Method Verification/Validation
- Discipline-specific checklist changes (CHM, IMM, HEM, MIC, TRM, ANP, CYP)
- CAP resources to identify changes

 9

9

Webinar Toolkit

The following materials are available in the toolkit:

- Summary of the Discipline-Specific Checklist Changes
- Instructions for Downloading the Checklists in Different Formats
- Quality Management System (QMS) Resources
- Competency Assessor Qualifications Tool

http://appsuite.cap.org/appsuite/learning/LAP/FoC_Webinars/2021Toolkit.zip

 10

10

Laboratory General Checklist

 11

11

Quality Management Systems (QMS)

- **GEN.13806 Quality Management System (QMS)**

The laboratory has a document that describes the overall QMS.

- Expanded concept of a quality management program to a QMS

Register for the November 17, 2021, Focus on Compliance webinar: Building a Quality Management System (QMS) for Your Laboratory: Moving on Up to the QMS Side (at learn.cap.org/lms/compliance)

- **GEN.13820 Scope of Service**

There is a document that describes the patient care and client services offered by the laboratory (eg, tests offered, hours of operation, turnaround times).

- New Phase I requirement

Refer to webinar toolkit for QMS resources.

 12

12

Specimen Collection and Handling

- **GEN.40050 Distribution of Specimen Collection Manuals**

The specimen collection manual is available at all locations where specimens are collected.

- Added new collection location examples – interventional radiology and endoscopy

- **GEN.40100 Specimen Collection Manual Elements – Clinical Pathology Specimens**

The specimen collection manual for clinical pathology specimens includes instructions for all the following elements, as applicable…

- Added content for phlebotomy draw order, instructions for fill volume, and proper mixing
- Moved content for surgical pathology and cytopathology specimens into a separate checklist requirement (GEN.40115)

 13

13

Specimen Collection and Handling, cont'd

- **GEN.40115 Specimen Collection Manual Elements – Surgical Pathology and Cytopathology Specimens**

The specimen collection manual for pathology specimens includes instructions for all the following elements, as applicable…

- New Phase II requirement (split from GEN.40100)
- Requires instructions for the types and amounts of fixatives (eg, 10% neutral phosphate-buffered formalin) or special media (eg, RPMI for flow cytometry)
- Provides guidelines for formalin fixation
  - Fully submerged with the optimal formalin to approximate specimen volume of 10:1 or higher, or if not feasible (eg, large specimens) at least 4:1
- Includes provisions for cold ischemia time and time in fixative for specimens clinically suspected or otherwise known to contain malignancy that are likely to be submitted for ancillary testing
  - Examples: breast carcinoma, gastroesophageal carcinoma

 14

14

Autoverification (Laboratory Computer System)

- **GEN.43876 Current Autoverification Rules**

Current autoverification rules are recorded.

- New Phase II requirement
- Current autoverification rules must be recorded
  - Have adequate detail in case of system failure
  - Can be placed in a single procedure or record, or be in the procedures for each method
- You can ensure compliance by:
  - ✓ Maintaining records of the autoverification rules when initiated
  - ✓ Implementing a process to keep them current (change control)

 15

15

Competency Assessment Elements

- **GEN.55500 Competency Assessment Elements – Nonwaived Testing**

The competency of personnel performing nonwaived testing is assessed using all six elements (as applicable) on each test system.

- **Revised to focus on assessing all six elements for each test system**
  - You can ensure compliance by:
    - ✓ Identifying the test systems that testing personnel use to generate test results
    - ✓ Including primary and back-up methods used for testing
    - ✓ Outlining practices and processes used to evaluate competency in a written procedure
    - ✓ Recording and tracking each element assessed and maintaining the supporting records

A test system is the process that includes preanalytic, analytic, and postanalytic steps used to produce a test result or set of results.

 16

16

GEN.55500 Scenario

- **We perform the following tests/methods in my laboratory section:**
  - Automated CBC with five-part differential (primary and back-up instruments – same make/different models)
  - Manual WBC differentials
  - General chemistry profile on ABC brand analyzer
  - Lipid profile on ABC brand analyzer
  - Cardiac panel on XYZ brand analyzer
  - Blood gas testing on ABG analyzer
  - Rapid serum hCG test kit
  - Infectious mono rapid test kit, nonwaived
- **How many test systems does this include?**

 17

17

Competency Assessment Frequency

- **GEN.55505 Competency Assessment Frequency – Nonwaived Testing**

The competency of personnel performing nonwaived testing is assessed at the required frequency at each laboratory (CAP/CLIA) number where testing is performed.

- **New Phase II requirement (split out of GEN.55500)**

Competency Assessment Frequency – Nonwaived Testing
At least semiannually (**first assessment within seven months from initiation of testing and second assessment no later than 12 months from the start of testing)** during the first year an individual tests patient specimens (new employees)
At least annually after an individual has performed assigned duties for one year *
When problems are identified with an individual's performance

**** The annual competency assessment may be performed throughout the entire year to minimize the impact on workload.***

 18

18

Competency Assessment: Waived Testing

- **GEN.55499 Competency Assessment – Waived Testing**

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

- **Must follow more stringent state and local regulations where applicable (eg, California)**

Competency Assessment Frequency – Waived Testing
After an individual has performed assigned duties for one year, and at least annually thereafter *
When problems are identified with an individual's performance

**** The annual competency assessment may be performed throughout the entire year to minimize the impact on workload.***

- **You can ensure compliance by:**
  - ✓ **Identifying the test systems that testing personnel use to generate test results**
  - ✓ **Outlining practices and processes used to evaluate competency in a written procedure**
  - ✓ **Recording and tracking each element assessed and maintaining the supporting records**

 19

19

Competency Assessment: Assessor Qualifications

- **GEN.55510 Competency Assessment – Assessor Qualifications**

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

- **Meet minimum qualifications and be knowledgeable about the test system**
- **Follow more stringent state or local regulations (including state licensure requirements) where applicable**

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

**** A technical consultant must have a bachelors degree in a chemical, physical, biological, clinical laboratory science, or medical technology and have at least two years of training/experience in nonwaived testing in the designated specialty/subspecialty supervised.***

 20

20

Competency Assessment: California Assessor Qualifications

- California qualifications for technical consultants and general supervisors
  - Individual licensed to perform high-complexity testing in California **or** to practice medicine **and**
  - Have at least two years of experience in moderate or high-complexity testing for specialty(ies) supervised
  - Exceptions:
    - Laboratories located outside of the state of California with a California clinical laboratory license – personnel may meet equivalent qualifications in lieu of obtaining a license. Records demonstrating equivalence must be retained.
    - Physician office laboratories (with five or fewer physicians that perform tests only on their own patients) – personnel are except from personnel licensure requirements but need to meet CLIA regulations for the complexity of testing.

Reference: Title 17, Article 2.3 Clinical Laboratory Supervisors. §036.2 & §036.1

 21

21

Case Study

When inspecting a blood gas laboratory, you see that the supervisor is assessing competency of the respiratory therapists. The supervisor doesn't work the bench, but has an associate degree, 25 years of experience performing blood gas testing, and has a state license as a respiratory therapist. The laboratory medical director signs the bottom of each competency assessment form.

Is this laboratory in compliance with GEN.55510?

A. Yes, the supervisor's experience and state license qualifies the supervisor to assess competency for blood gas testing
B. Yes, the laboratory medical director meets the qualifications of a technical consultant
C. No, the supervisor does not meet technical consultant qualifications
D. Need more information – need to confirm if the supervisor has a current competency assessment to perform this testing

For more information, refer to the webinar toolkit for the Competency Assessor Qualifications tool.

 22

22

Director Assessment Checklist

 23

23

Director Assessment, cont'd

- **DRA.11485 New Director Policy and Procedure Approval**

Following a change in laboratory directorship, the new laboratory director approves the technical policies and procedures within three months of the change of directorship.

- Approval to occur within three months of directorship change for most laboratories
- For larger, more complex laboratories, additional time may be given if the laboratory:
  - Records an explanation of why more time is needed
  - Creates a schedule for completion
  - Completes approval as scheduled

 24

24

New Director Policy/Procedure Approval FAQs

1. What is considered a technical policy or procedure?
2. Do new section directors (technical supervisors) need to review and reapprove technical policies and procedures for that section?
3. Will my laboratory be cited with a deficiency if the review process extends beyond three months?

 25

25

All Common Checklist

 26

26

Proficiency Testing: COM.01100

- **COM.01100 Ungraded PT Challenges**

The laboratory director or designee assesses its performance on PT challenges that are ungraded.

- Requires the laboratory director or designee to assess performance on ungraded PT challenges
- Includes educational PT challenges (added in the 2020 edition)
- Defines minimum records of assessment to include notation of acceptability of the ungraded result **and** investigation and corrective action for unacceptable results

- **You can ensure compliance by:**
  - ✓ Defining the policy on how to record assessment of ungraded PT challenges
  - ✓ Maintaining records of the assessment

 27

27

Proficiency Testing: COM.01400

- **COM.01400 PT Attestation Statement**

The PT attestation statement is signed (physical or electronic signature) by the laboratory director or qualified designee and all individuals involved in the testing process.

- Revised to allow the use of **physical or electronic signatures**

Electronic Signatures

Show that it is traceable to the event (eg, date/time stamp)

Only used by the authorized person (eg, password protected account)

Reference: CMS Guidance QSO-21-10-CLIA, released on January 8, 2021

 28

28

Proficiency Testing: COM.01600

- **COM.01600 PT and Alternative Performance Assessment Specimen Testing**

The laboratory integrates all PT and alternative performance assessment specimens within the routine laboratory workload, where applicable…

- Clarifies the need to integrate both PT **and alternative performance assessment** specimen testing into the routine workload

- **You can ensure compliance by:**
  - ✓ Defining proper handling of PT and alternative performance assessment specimens in your laboratory policy
  - ✓ Training personnel on how to properly handle these specimens
  - ✓ Rotating the specimens to different personnel that routinely perform patient testing
  - ✓ Retaining complete records showing who tested the specimens and how the testing was performed

 29

29

Specimen Aliquoting

- **COM.06250 Specimen Aliquoting**

The laboratory follows a written procedure for aliquoting of specimens to prevent cross-contamination and mix-up of specimens and aliquots.

- **New Phase II requirement**
- **Prohibits returning specimens into the original container for certain types of testing (eg, molecular-based testing, forensic drug testing, and biorepository storage)**
- **Cautions laboratories to consider contamination and potential for mix-up when defining procedures**
- **Replaces similar requirements from other checklists (CHM.12133, LSV.39875, MIC.63322, MOL.32385, FDT.05080, BAP.01723)**

 30

30

Specimen Rejection Criteria

- **COM.06300 Specimen Rejection Criteria**

The laboratory defines and follows criteria for the rejection or special handling of specimens that do not meet established laboratory criteria for the requested test(s). The laboratory retains records of these specimens in the patient/client report and/or QM records.

- **Reinforces the need to record preanalytic problems with specimens deviating from collection instructions**
- **Supports communication between the laboratory and clinical personnel when testing is requested on specimens not meeting the defined preanalytic parameters**

 31

31

Specimen Rejection Criteria: COM.06300

- **Examples of specimens not meeting established preanalytic parameters include:**
  - **Improperly collected, handled (eg, specimen leakage), or stored specimens**
  - **Desiccated specimens, if appropriate**
  - **Specimens submitted beyond their stability time limits**
  - **Insufficient quality/quantity of specimen**
  - **Inadequate specimen labeling or requisition information**
  - **Broken slides**
  - **Hemolyzed, lipemic, or grossly contaminated specimens**
  - **Tissue specimens with inadequate or inappropriate fixation or processing for the specific test(s) ordered (eg, frozen section specimen submitted for IHC HER2 testing)**

 32

32

New Reagent Lots and Shipments

- **COM.30450 New Reagent Lot and Shipment Confirmation of Acceptability – Nonwaived Tests**

New reagent lots and shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service.

- Revised to address frequently asked questions, such as:
  - Which materials does this requirement apply to? Are stains or saline considered a reagent?

    This requirement applies to reagents that provide a chemical or biological reaction to detect and/or measure a target analyte and would not apply to inert ingredients (eg, reagent water, saline) or materials used for specimen preparation.
  - How many specimens do I need to use to check new reagent lots?

    The laboratory director may determine the number of specimens tested.

 33

33

Test Method Validation/Verification: EUA

- **Emergency use authorization (EUA)**
  - Must verify the test performance specifications based on the test's FDA-designated authorized setting (found in the EUA letter of authorization)

Authorized Setting	Requirement	Actions
Authorized for use in a patient care setting	COM.30980	• Deemed by FDA to be CLIA waived • Follow manufacturer's instructions for introduction • Have records of laboratory director/qualified designee approval of test prior to use
Authorized for use in moderate or high-complexity testing laboratories	COM.40300	• Verify analytical accuracy, precision, reportable range, and reference intervals

CAP Resource: Frequently asked questions on www.cap.org/covid-19

 34

34

Test Method Validation/Verification

- **COM.40625 Clinical Claims Validation – FDA-Cleared/Approved Tests**

For FDA-cleared/approved tests, the laboratory validates clinical claims not included in the manufacturer's instructions.

- New Phase II requirement split out of COM.40640
- Requires validation of clinical claims not included in the manufacturer's instructions by
  - Performing a study using at least 20 samples (representing both positive and negative cases) or
  - Referencing peer-reviewed literature or textbooks for clinical validity of the test

- **COM.40640 Clinical Performance Characteristics Validation – Laboratory-Developed Tests (LDTs)**

The laboratory validates clinical performance characteristics for LDTs.

- Requires establishment of the clinical performance characteristics for LDTs by:
  - Performing a study using at least 20 samples (representing both positive and negative cases) or
  - Referencing peer-reviewed literature or textbooks for clinical validity of the test

 35

35

Scenario

My laboratory is performing a D-dimer test that has been FDA approved for monitoring patients with DIC. We read a study in a peer-reviewed journal in which that test was validated for use in evaluation of venous thromboembolism (VTE). Can we reference that study and use it for that purpose?

 36

36

Discipline-Specific Checklist Changes

Review the Summary of the Discipline-Specific Checklist Changes in the webinar toolkit

 37

37

Tumor Marker Reporting

- **Tumor Marker Result Reporting – CHM.29050, IMM.39800, LSV.41344, LSV.46245**

The following information is available to clinicians for the reporting of tumor marker results…

- New Phase II requirement
- Requires the following information to be available to the clinician for the reporting of tumor marker results:
  - Manufacturer and methodology of the tumor marker assay
  - A statement indicating that patient results determined by assays using different manufacturers or methods may not be comparable
- Allows the information to be reported with the test result or be readily available, such as in the test reference guide

As used within this checklist requirement, a tumor marker is any analyte that is serially measured over time primarily as an indicator of tumor burden.

 38

38

Body Fluid Reporting of Nucleated Cells

- **Body Fluid Result Reporting of Nucleated Cells – HEM.35650, LSV.43771**

When absolute total cell counting methods cannot reliably distinguish white blood cells from other nucleated cells, body fluid cell counts and differential results are reported with the total nucleated cell count and a differential with all nucleated cell types observed.

- New Phase I requirement
- Applies to methods that cannot reliably distinguish WBCs from other nucleated cells (eg, mesothelial cells, synovial lining cells, squamous epithelial cells)
  - Examples:
    - Manual cell count performed on unstained cells using a hemocytometer counting chamber
    - Automated cell count performed using instruments that can't reliably distinguish the nucleated cell types in the total count

 39

39

Directly Measured Coagulation Testing

- **Quantitative Cut-Off Values – HEM.37390, LSV.38757**

For qualitative tests that use a quantitative cut-off value to distinguish positive from negative results, the analytic performance around the cut-off value is verified or established initially, and reverified at least every six months thereafter.

- New Phase II requirement
- Applies to qualitative tests that use a quantitative cut-off value to distinguish positive from negative (eg, heparin-induced thrombocytopenia screening assay)
- May be satisfied by:
  - Calibration or calibration verification processes if the calibrator or calibration material is at or near the cut off
  - The use of suitable QC materials near the cut-off value

 40

40

Microbiology

- **Blood culture collection requirements added to the Laboratory General Checklist**
  - **Applicable to laboratories that:**
    - Collect blood cultures using media provided/QC'd by another laboratory **and**
    - Send the cultures back to that laboratory for testing
  - **Not applicable to laboratories that:**
    - Receive media directly from the manufacturer
    - Test blood cultures on-site and report any findings, including "no growth"

GEN.40560	Inspection of blood culture media shipments received from the referral laboratory and retention of referral laboratory media QC records
GEN.40570	Use of sterile techniques for drawing and handling blood cultures
GEN.40580	Monitoring of blood culture contamination rates against an acceptable threshold
GEN.40590	Monitoring of blood culture volumes collected on adults and providing feedback for unacceptable volumes

 41

41

Microbiology

- **Laboratory Safety**
  - Merged and modified safety requirements across the checklist into one section
  - Streamlined content for more consistent application throughout the microbiology laboratory

MIC.19035	Safe Specimen Processing
MIC.19060	Biosafety Levels – Occupational Risk
MIC.19160	Biosafety Levels – Engineering Work Practice Controls
MIC.19840	Biological Safety Cabinet (use for handling highly contagious specimens by airborne routes)
MIC.20520	Biological Safety Cabinet (annual certification)

Reference: CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition

 42

42

Microbiology

- **MIC.11380 Antimicrobial Susceptibility Test Interpretation Criteria**

For antimicrobial susceptibility testing systems, there are written criteria for determining and interpreting MIC or zone diameter sizes…

  - Significantly revised and moved (previously MIC.21930) to apply to bacterial, fungal, and mycobacterial susceptibility testing
  - Requires interpretive criteria used for interpreting MIC or zone diameter sizes to be documented and evaluated annually

- **MIC.11385 Current Antimicrobial Susceptibility Test Interpretation Breakpoints**

Effective January 1, 2024, the laboratory uses current breakpoints for interpretation of antimicrobial MIC and disk diffusion test results…

  - New Phase I requirement
  - Use current interpretive breakpoints and implement new breakpoints within three years of the date of publication from the FDA or standards development organizations (ie, CLSI, EUCAST)
  - Phase-in date will help you prepare for and implement changes to use current breakpoints

 43

43

Microbiology

- **MIC.21855 Antimicrobial Resistance Markers by Molecular Analysis – Clinical Validity**

Detection of genotypic antimicrobial resistance markers (eg, vanA, mecA, bla_{KPC}) is linked or attributed to a corresponding organism in the final laboratory report when molecular analysis is performed directly on patient specimens…

  - New Phase I requirement
  - Requires linking of genotypic antimicrobial resistance markers reported to a corresponding organism when molecular analysis is performed directly on specimens
  - Does not apply to screening or surveillance testing

 44

44

Transfusion Medicine

- **TRM.41550 Intraoperative/Perioperative Safety and Efficacy**

The intraoperative and perioperative blood recovery program ensures the safety and efficacy of the recovered blood components.

  - You can measure the safety and efficacy of recovered blood components through review of data by institutional committees and monitoring of intraoperative and perioperative transfusion practices

- **TRM.41600 Intraoperative/Perioperative Program Involvement**

The transfusion service medial director is involved in establishing standard operating policies and procedures related to intra- and perioperative collection and reinfusion procedures.

  - The transfusion service medical director involvement is required even when the service is not under the direct responsibility of the laboratory
    - Can be demonstrated through review of procedures or through meeting minutes of institutional transfusion committee meetings

 45

45

Anatomic Pathology

- **ANP.10039 Total Fixation Time**

The laboratory has a process to ensure an optimal total fixation time in formalin for specimens clinically suspected (as stated on the requisition) or otherwise known to contain malignancy that are likely to be submitted for ancillary testing, such as breast and gastroesophageal carcinomas.

  - New Phase I requirement

- **ANP.10041 Quality of Formalin**

The quality of formalin provided for fixation of specimens to be submitted for pathology and for use as a fixative in the laboratory is monitored (eg, spot check or other processes).

  - New Phase I requirement

- **ANP.23700 Slide and Block Storage**

Slides and paraffin blocks are properly stored in a temperature-controlled, pest-free, organized manner…

  - Revised to specify monitoring of storage temperature conditions (on-site and off-site locations)

 46

46

Anatomic Pathology, cont'd

- **ANP.12155 Gross Description Report Elements**
  - Previously ANP.12200
  - Requires processing information to be included on grossing report for type of specimen fixation and processing (cold ischemia time, length of time in fixative, as applicable)

- **ANP.22969 Report Elements**
  - Requires the following for patient reports for predictive marker testing:
    - Cold ischemia time and length of time in fixative
    - Limitations relating to suboptimal preanalytical factors (eg, prolonged cold ischemia time or over or under-fixation on reports

Reference: Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimen for Precision Medicine, Archives of Pathology and Laboratory Medicine (2019)

 47

47

Cytopathology

- Updated statistical record keeping requirements to clearly define required elements
  - CYP.07600 Statistical Records – Gynecologic Cytopathology
    - Contains updated benchmarking data
  - CYP.07692 Statistical Records – Nongynecologic Cytopathology
    - Renumbered from CYP.07400
- Added content for written criteria for identification and reporting of unsatisfactory specimens
  - CYP.07452 Unsatisfactory Specimens – Gynecologic Cytopathology
  - CYP.07666 Unsatisfactory Specimens – Nongynecologic Cytopathology
    - New Phase II requirement
- Added a new Predictive Markers section for immunochemical testing on cytology specimens

 48

48

Using CAP Resources to Identify and Implement Changes

- Accreditation resources available on cap.org in e-LAB Solutions Suite (log-in required)
  - Checklist download – instructions for download included in the webinar toolkit

Checklist Type
Master ✓
Custom
Changes Only

  - Checklist requirement Q&A
  - Templates
  - Quality management
  - Proficiency testing/external quality assurance toolbox
  - IQCP toolbox
  - CAP laboratory director education, information, and resources

 49

49

Using CAP Resources to Identify and Implement Changes, cont'd

- Educational resources on cap.org:
  - Focus on Compliance webinar series
  - Fast Focus on Compliance: bite-size learning
- *CAP Today* articles: view or subscribe on cap.org

 50

50

Top 10 Deficiencies for 2020

Checklist Requirement	CAP-Wide *
COM.01200 Activity Menu	1
GEN.55500 Competency Assessment – Nonwaived Testing	2
COM.10000 Procedure Manual	3
COM.30600 Maintenance/Function Checks	4
COM.04250 Comparability of Instruments and Methods – Nonwaived Testing	5
COM.01700 PT and Alternative Performance Assessment Result Evaluation	6
COM.01400 PT Attestation Statement	7
COM.04200 Instrument/Equipment Record Review	8
COM.30300 Reagent Labeling	9
COM.10100 Procedure Manual Review	10

** Based on 2020 CAP inspection data*

 51

51

Summary

- Summarized significant checklist changes
- Provided a brief overview of changes to discipline-specific checklists
- Provided a toolkit for you to review on your own

 52

52

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53