Get Ready for the PT CLIA Changes: Stay Ahead, Stay Compliant

CAP Webinar

June 27, 2024
Regulatory Changes Impacting Laboratories

- Webinar Focus: CLIA Proficiency Testing (PT) Changes
  - Changes go into effect Jan. 1, 2025
Today’s Presenters

- Jonathan Genzen, MD, PhD, FCAP
  - Chair, CAP Clinical Chemistry Committee

- Christi Wojewoda, MD, FCAP
  - Chair, CAP Microbiology Committee
Overview

• Upcoming Regulatory Changes
• Background: CLIA PT Updates
• High Level Overview of Non-Microbiology Changes
• Tools to Prepare for Changes: PT Participation/Evaluation Reports
• Examples
• Impact on CAP PT Enrollment
Upcoming Regulatory Changes
Regulatory Changes Impacting Laboratories

• Today’s Focus: CLIA Proficiency Testing (PT) Changes
  o Changes go into effect Jan. 1, 2025

• Impacted Specialties:
  o Microbiology
  o Chemistry
  o Diagnostic Immunology
  o Hematology (including routine hematology and coagulation)
  o Immunohematology
Other Regulatory Changes Impacting Laboratories (Continued)

- Final Rule - CLIA Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326-F)
  - Effective Dec. 28, 2024
  - 2024 CAP checklist edition expected to publish in October/November to incorporate CLIA changes
  - Laboratories must continue to follow their current checklist edition until that time
  - Learn about 2024 checklist changes: Nov. 20th Focus on Compliance webinar, "Staying in Sync: CAP Accreditation Checklist Changes for 2024"
Other Regulatory Changes Impacting Laboratories (Continued)

• Final FDA Oversight of Laboratory Developed Test (LDT) Regulation
  ○ Follow CAP Advocacy updates (cap.org/advocacy)
Background: CLIA PT Updates
Background: Update Rationale

- CLIA ’88 regulations were published in subpart I of the Federal Register on February 28, 1992
- Since 1992, the testing has evolved significantly; current technology is more accurate and precise
- The HHS solicited input from the Clinical Laboratory Improvement Advisory Committee (CLIAC), the official federal advisory committee responsible for advising HHS on regulatory standards for ensuring accuracy and reliability of laboratory testing.
Background: Update Rationale (Continued)

• CMS and the CDC collaborated in revising the required analytes and published a proposed rule on February 4, 2019

• PT changes: whether addition of new analytes, deletion of analytes, or changes in acceptance limits, apply to analytes listed in subpart I of the Federal Register.
PT Changes: Specialty and Subspecialty

- CMS finalized the 29 non-micro analytes based on factors:
  - Current availability of PT materials
  - Number of PT programs currently offering PT
  - Volume of patient testing performed nationwide
  - Impact on patient health, cost, and feasibility of implementation

- Some potential analytes for inclusion were not pursued:
  - Too unstable for PT development or shipping, or
  - Methodology was not sufficiently standardized to support PT (ex: Vitamin D testing)
PT Changes: Specialty and Subspecialty

§493.909 Microbiology
- §493.911 Bacteriology
- §493.913 Mycobacteriology
- §493.915 Mycology
- §493.917 Parasitology
- §493.919 Virology

§493.921 Diagnostic Immunology
- §493.923 Syphilis serology
- §493.927 General immunology
§493.929 Chemistry
- §493.931 Routine chemistry
- §493.933 Endocrinology
- §493.937 Toxicology

§493.941 Hematology (including routine Hematology and Coagulation)

§493.959 Immunohematology
High Level Non-Microbiology Changes
New Regulated Analytes

- 29 new analytes/tests for which PT will be required
- Many analytes for which PT was not required are now in routine clinical use, (e.g.) Hemoglobin A1c, troponins
  - High sensitivity troponins are preferred, but are not CMS regulated

<table>
<thead>
<tr>
<th>CLIA regulation</th>
<th>New analytes</th>
</tr>
</thead>
</table>
| General Immunology §493.927 | Anti-HBs  
Anti-HCV  
C-reactive protein (high sensitivity) |
| Routine chemistry §493.931 | B-natriuretic peptide (BNP)  
ProBNP  
Cancer antigen (CA) 125  
Carbon dioxide  
Carcinoembryonic antigen  
Cholesterol, low density lipoprotein, direct measurement  
Ferritin  
Gamma glutamyl transferase  
Hemoglobin A1c  
Phosphorus  
Prostate specific antigen, total  
Total iron binding capacity (TIBC), direct measurement  
Troponin I  
Troponin T |
| Endocrinology §493.933 | Estradiol  
Folate, serum  
Follicle stimulating hormone  
Luteinizing hormone  
Progesterone  
Prolactin  
Parathyroid hormone  
Testosterone  
Vitamin B12 |
| Toxicology §493.937 | Acetaminophen, serum  
Salicylate  
Vancomycin |
Removed Analytes From Subpart I

- Five analytes/tests are removed from Subpart I of the Federal Register
  - Lactate dehydrogenase (LDH) isoenzymes
  - Ethosuximide
  - Primidone
  - Quinidine
  - Procainamide (and its metabolite N-acetyl procainamide)
Alternative Performance Assessment

- At least 2x/year, laboratories must verify the accuracy of any test or procedure it performs that is not included in subpart I of the Federal Register

- The CAP will continue to offer the deleted, non-CMS regulated analytes in its current PT programs as participation in PT is one of the ways to meet this regulatory requirement
Grading Changes

• 53 analytes/tests (existing or new) for which percentage-based acceptance limits are published

• White blood cell differential is the only test with standard deviation, as there were no biological variability data available

• See tables with all grading changes at cap.org.
  • Search: regulatory news and updates
Grading Changes (Continued)

• Per CMS: tightening limits may increase miss rates per challenge
  o High unsuccessful rates not expected based on the data simulations provided by the PT programs

• As in the past, laboratories must get 4/5 challenges correct (80%) or the event will be considered unsatisfactory, except for immunohematology
<table>
<thead>
<tr>
<th>Analyte/Test</th>
<th>Current CMS criteria</th>
<th>New Criteria</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematocrit (Excluding spun hematocrit)</td>
<td>Target value ±6%</td>
<td>Target value ±4%</td>
<td>33.3%</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Target value ±7%</td>
<td>Target value ±4%</td>
<td>~ 43%</td>
</tr>
<tr>
<td>Uric acid</td>
<td>Target value ±17%</td>
<td>Target value ±10%</td>
<td>41.1%</td>
</tr>
<tr>
<td>Magnesium</td>
<td>Target value ±25%</td>
<td>Target value ±15%</td>
<td>40%</td>
</tr>
<tr>
<td>Potassium</td>
<td>Target value ±0.5 mmol/L</td>
<td>Target value ±0.3 mmol/L</td>
<td>40%</td>
</tr>
<tr>
<td>Alpha-fetoprotein (AFP)</td>
<td>Target value + 3 SD</td>
<td>Target value ± 20%</td>
<td></td>
</tr>
<tr>
<td>pO2</td>
<td>Target value ± 3SD</td>
<td>Target value ± 15% or 15 mmHg or greater</td>
<td></td>
</tr>
</tbody>
</table>
Discipline-Specific Changes: Hematology

- Hematology: laboratories performing manual cell identification and an automated WBC differential must enroll in PT for both
  - The CAP will submit both scores to the CMS
  - For example, BCP or BCPV and FH10 will both be submitted to CMS.

Updated CLIA PT Regulations Set for January 1, 2025 Implementation

While the final rule is effective July 11, 2024, per CMS’ directive, the implementation date for the laboratories and PT program providers for these revisions will be January 1, 2025, which is in alignment with its current process for PT program providers and PT enrollment.

2025 Criteria for Acceptable Performance

<table>
<thead>
<tr>
<th>Analyte or test</th>
<th>Current CMS or CAP criteria for acceptable performance</th>
<th>New CMS or CAP criteria for acceptable performance to be implemented on January 1, 2025</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>White blood cell (WBC) differential:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granulocytes</td>
<td>Target value ± 3 SD based on the percentage of different types of WBC in the specimens</td>
<td>Target value ± 3 SD based on the percentage of different types of WBC in the specimens</td>
<td>No change</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monocytes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eosinophils</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basophils</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematocrit</td>
<td>Target value ± 6%</td>
<td>Target value ± 4%</td>
<td>Criteria changed</td>
</tr>
<tr>
<td>Micromethod, wired</td>
<td>Target value ± 6% or ± 2 SD (greater)</td>
<td>Target value ± 6% or ± 2 SD (greater)</td>
<td>No change</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Target value ± 7%</td>
<td>Target value ± 4%</td>
<td>Criteria changed</td>
</tr>
<tr>
<td>MCV</td>
<td>Target value ± 3 SD</td>
<td>Target value ± 3 SD</td>
<td>No change</td>
</tr>
<tr>
<td>MCH</td>
<td>Target value ± 3 SD</td>
<td>Target value ± 3 SD</td>
<td>No change</td>
</tr>
<tr>
<td>MCHC</td>
<td>Target value ± 3 SD</td>
<td>Target value ± 3 SD</td>
<td>No change</td>
</tr>
<tr>
<td>MPV</td>
<td>Target value ± 3 SD</td>
<td>Target value ± 3 SD</td>
<td>No change</td>
</tr>
<tr>
<td>Nucleated red blood cell count (NRBC)</td>
<td>Educational</td>
<td>Educational</td>
<td>No change</td>
</tr>
<tr>
<td>Platelet count</td>
<td>Target value ± 25%</td>
<td>Target value ± 25%</td>
<td>No change</td>
</tr>
<tr>
<td>MPV</td>
<td>Target value ± 3 SD</td>
<td>Target value ± 3 SD</td>
<td>No change</td>
</tr>
<tr>
<td>Red blood cell count</td>
<td>Target value ± 6%</td>
<td>Target value ± 4%</td>
<td>Criteria changed</td>
</tr>
<tr>
<td>WBC count</td>
<td>Target value ± 15%</td>
<td>Target value ± 10%</td>
<td>Criteria changed</td>
</tr>
</tbody>
</table>

Analysis regulated for proficiency testing appear in bold type.

*CMS, effective January 1, 2025, laboratories performing both a manual cell identification and an automated WBC differential must enroll in proficiency testing for both (BCP or BCPV and FH10). Scores for both will be submitted to CMS.
Discipline-Specific Changes: Coagulation

- Coagulation: criterion for prothrombin time reporting units: seconds or the international normalized ratio (INR)
  - Laboratories must report PT the same way they report patient results
Discipline-Specific Changes: Transfusion Medicine

- Transfusion medicine: effective Jan. 1, 2025; unexpected antibody detection will no longer use 80% for satisfactory performance
  - Like ABO, Rh, and compatibility testing, 100% accuracy will be needed for unexpected antibody detection. Antibody identification will remain at 80%+ accuracy.
Tools to Prepare for Changes
PT Participant Summary & Evaluation Reports
• All new analytes, criteria changes by specialty/subspecialty are included in each PT Participant Summary (PS) of all 2024 A-Mailing CMS regulated programs.
  o CAP will continue to provide this information throughout 2024
PT Participant Summary & Evaluation Reports (Continued)

- Review Your PT Evaluation Reports for Quantitative PT Programs
  - Evaluation report lists laboratory’s result, statistics for peer group, and normalized results as the standard deviation index (SDI).

![Image of evaluation report]
• Graph lists three consecutive mailings of each analyte
  o Could help identify bias, shifts, or trends
  o May be used to troubleshoot and evaluate whether results will be within or outside the limits of acceptability with new (tighter) grading criteria
PT/EQA Troubleshooting Guide

- Accessible from the PT resources on cap.org
  - Includes guidelines for monitoring PT/EQA performance using the evaluation graphs.

https://www.cap.org/laboratory-improvement/proficiency-testing/pt-resources
Examples Illustrating Criteria Changes
Potassium: Current vs. New Criteria

Potassium evaluated at target value +/- 0.5 mmol/L (current criteria)

Same laboratory – C-B 2023 evaluated at target value +/- 0.3 mmol/L (new criteria)
Hemoglobin & Hematocrit: Current vs. New Criteria

Hemoglobin evaluated at target value +/- 7% (current criteria)

Same laboratory FH9-A 2024 evaluated at target value +/- 4% (new criteria)

Hematocrit evaluated at target value +/- 6% (current criteria)

Same laboratory FH9-A 2024 evaluated at target value +/- 4% (new criteria)
Impact on CAP Customers
Impact on CAP Customers: Accreditation

- CAP accredited laboratories that perform high-sensitivity cardiac troponin I or T testing are required to enroll in high sensitivity cardiac troponins PT to meet 2025 accreditation requirements.

- Laboratories that use accuracy-based proficiency testing for hemoglobin A1c will be required to evaluate results based on acceptable performance criteria of $\pm 6\%$ in 2025. Therefore, the CAP will provide two evaluations starting with the GH5-A 2025 mailing to meet CLIA (Target value $\pm 8\%$) and CAP checklist (Target value $\pm 6\%$) requirements.
Impact on CAP Customers: PT Enrollment

- Impact expected to be minimal
- Some programs reconfigured to meet CLIA requirements
  - Five specimens, three times/year
  - Exception: mycobacteriology, two events/year
Impact on CAP Customers: PT Enrollment

• CAP will pre-populate customer order forms with the recommended program during the order renewal process, based on order history
• Review your 2025 order renewal form carefully
• CAP accredited laboratories: PT enrollment will be audited in early 2025 for analytes that require enrollment and participation to ensure compliance
Microbiology Changes
Overview: Changes in Microbiology and Subspecialties

- Bacteriology
- Mycobacteriology
- Mycology
- Parasitology
- Virology
Bacteriology
Bacteriology

• Gram stain will now include bacterial morphology
  o Both stain and morphology results will be submitted to CMS
• Direct bacterial antigen detection and bacterial toxin detection will be reported to CMS
• Included as reporting option: Detection of the presence or absence of bacteria without identification
Bacteriology

- Laboratories must detect and identify organisms for PT to the highest level that the laboratory reports results on patient specimens
  - At least 25% of samples must be mixtures of the principal pathogen and appropriate normal flora
    (change from 50%)
- Two specimens/mailing will be included for antimicrobial susceptibility testing (AST)
  - Program will include gram-positive and gram-negative organisms that have a predetermined pattern of susceptibility to the common antimicrobial agents
Mycobacteriology
Mycobacteriology

- This subspecialty includes five specimens, two mailings per year
- Included as a reporting option: Detection of the presence or absence of mycobacteria without identification
- Laboratory must detect and identify organisms to the highest level that the laboratory reports results on patient specimens
- Molecular identification of mycobacteria is allowed
Mycobacteriology

- At least 25% of the samples must be mixtures of principal mycobacteria appropriate normal flora (change from 50%)
- The Antimicrobial Susceptibility Testing (AST) challenge is removed as a CMS-regulated test
  - However, CAP will continue to include two AST challenges as currently offered to meet the regulatory requirement for verifying test accuracy at least 2X per year.

### 2025 Criteria for Acceptable Performance

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</thead>
<tbody>
<tr>
<td>Antimycobacterial susceptibility testing (AST)</td>
<td>80% participant consensus</td>
<td>See below*</td>
</tr>
<tr>
<td>Mycobacteria identification</td>
<td>80% participant or referee consensus</td>
<td>No change</td>
</tr>
<tr>
<td>Acid-fast smear</td>
<td>80% participant or referee consensus</td>
<td>No change</td>
</tr>
</tbody>
</table>

*Effective January 1, 2026, AST will no longer be CMS regulated. The CAP will continue to offer AST challenges to meet alternative performance assessment requirements.
Mycology
Mycology

• Now included: fungal antigen detection category for CMS reporting
• Detection of the presence or absence of fungi and aerobic actinomycetes without identification
• Laboratory must detect and identify the organisms to highest level that the laboratory reports results on patient specimens
• At least 25% of samples must be mixtures of the principal pathogen and appropriate normal flora (change from 50%)
• Molecular identification of fungi is allowed
Mycology

- CMS will not require antifungal susceptibility testing for mycology as originally proposed.
- However, CAP will continue to offer antifungal susceptibility challenges in its mycology programs to meet the regulatory requirement for verifying test accuracy at least 2X per year.
  - Mycology and Aerobic Actinomycetes (F)
  - Yeast (F1)
Parasitology
Parasitology

• Direct parasite antigen detection category is now included for CMS reporting
• A laboratory must detect and identify parasites to the highest level
• Molecular identification of parasites is allowed
Virology
Virology

- Laboratory must detect and identify the viruses to the highest level that the laboratory reports results on patient specimens
- No other changes
Customer Resources

- Effective in the 2024 A mailings: detailed information regarding all the changes in each PT Participant Summary Report
- May 2024 CAP Today Q&A article
- Cap.org Regulatory News and Updates webpage