COLLEGE of AMERICAN PATHOLOGISTS

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

CAP Webinar

June 27, 2024

Regulatory Changes Impacting Laboratories

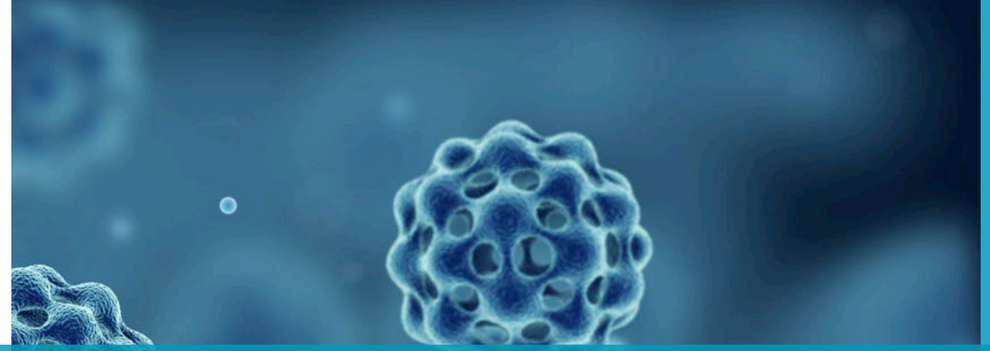
- Webinar Focus: CLIA Proficiency Testing (PT) Changes
  - Changes go into effect Jan. 1, 2025

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**
  - **Changes go into effect Jan. 1, 2025**

- **Impacted Specialties:**
  - **Microbiology**
  - **Chemistry**
  - **Diagnostic Immunology**
  - **Hematology (including routine hematology and coagulation)**
  - **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

PT Changes: Specialty and Subspecialty (Continued)

§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

CLIA regulation	New analytes
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)

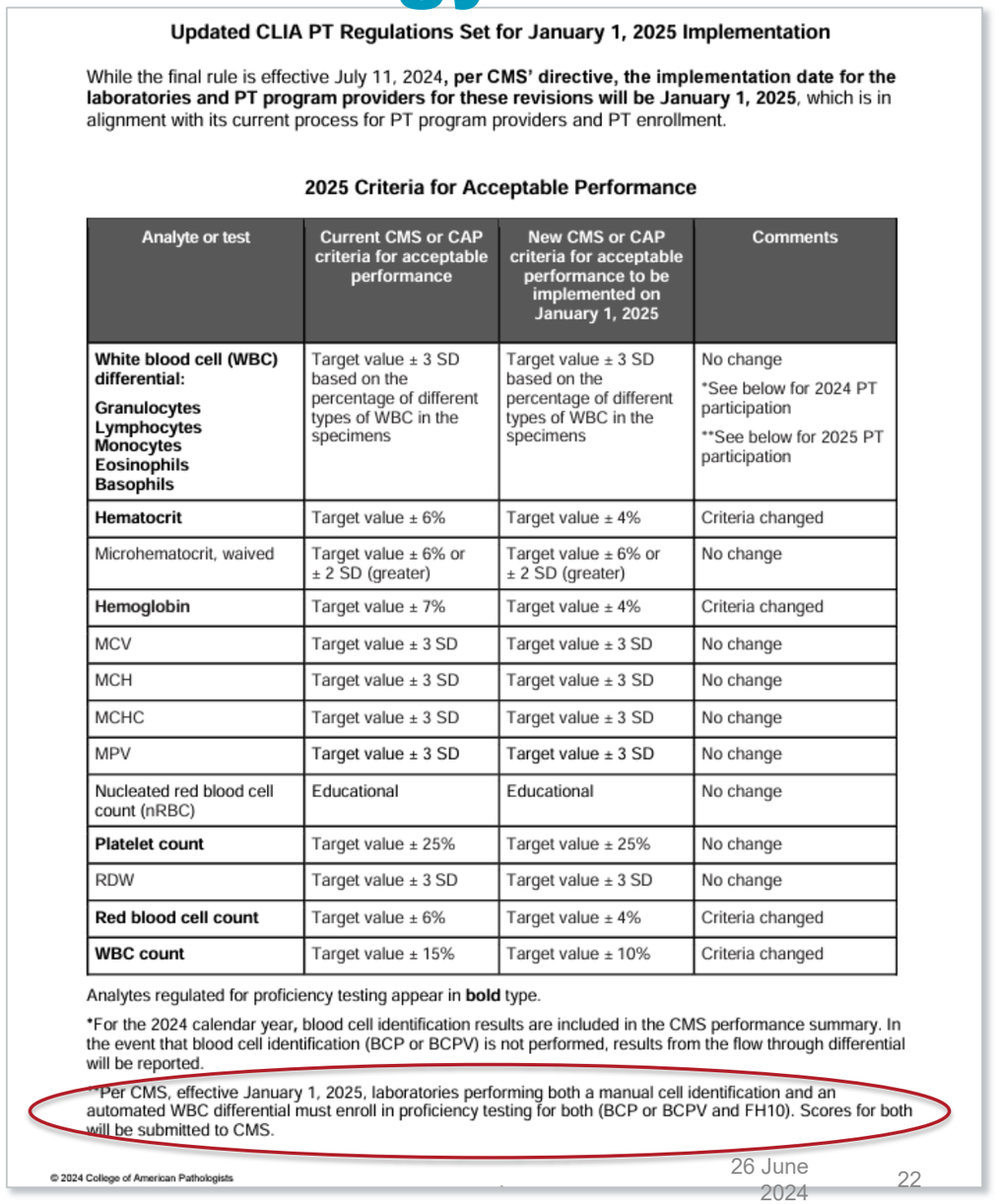
- **Per CMS: tightening limits may increase miss rates per challenge**
  - **High unsuccessful rates not expected based on the data simulations provided by the PT programs**
- **As in the past, laboratories must get 4/5 challenges correct (80%) or the event will be considered unsatisfactory, except for immunohematology**

A Few Notable Grading Changes

Analyte/Test	Current CMS criteria	New Criteria	Change
Hematocrit (Excluding spun hematocrit)	Target value ±6%	Target value ±4%	33.3%
Hemoglobin	Target value ±7%	Target value ±4%	~ 43%
Uric acid	Target value ±17%	Target value ±10%	41.1%
Magnesium	Target value ±25%	Target value ±15%	40%
Potassium	Target value ±0.5 mmol/L	Target value ±0.3 mmol/L	40%
Alpha-fetoprotein (AFP)	Target value ± 3 SD	Target value ± 20%	
pO2	Target value ± 3SD	Target value ± 15% or 15 mmHg (greater)	

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

Analyte or test	Current CMS or CAP criteria for acceptable performance	New CMS or CAP criteria for acceptable performance to be implemented on January 1, 2025	Comments
White blood cell (WBC) differential: **Granulocytes** **Lymphocytes** **Monocytes** **Eosinophils** **Basophils**	Target value ± 3 SD based on the percentage of different types of WBC in the specimens	Target value ± 3 SD based on the percentage of different types of WBC in the specimens	No change *See below for 2024 PT participation **See below for 2025 PT participation
Hematocrit	Target value ± 6%	Target value ± 4%	Criteria changed
Microhematocrit, waived	Target value ± 6% or ± 2 SD (greater)	Target value ± 6% or ± 2 SD (greater)	No change
Hemoglobin	Target value ± 7%	Target value ± 4%	Criteria changed
MCV	Target value ± 3 SD	Target value ± 3 SD	No change
MCH	Target value ± 3 SD	Target value ± 3 SD	No change
MCHC	Target value ± 3 SD	Target value ± 3 SD	No change
MPV	Target value ± 3 SD	Target value ± 3 SD	No change
Nucleated red blood cell count (nRBC)	Educational	Educational	No change
Platelet count	Target value ± 25%	Target value ± 25%	No change
RDW	Target value ± 3 SD	Target value ± 3 SD	No change
Red blood cell count	Target value ± 6%	Target value ± 4%	Criteria changed
WBC count	Target value ± 15%	Target value ± 10%	Criteria changed

Analytes regulated for proficiency testing appear in **bold** type.

*For the 2024 calendar year, blood cell identification results are included in the CMS performance summary. In the event that blood cell identification (BCP or BCPV) is not performed, results from the flow through differential will be reported.

**Per 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**

2025 Criteria for Acceptable Performance

Analyte or test	Current CMS or CAP criteria for acceptable performance	New CMS or CAP criteria for acceptable performance to be implemented on January 1, 2025	Comments
Activated partial thromboplastin time	Target value ± 15%	Target value ± 15%	No change
D-dimer, quant	Target value ± 3 SD	Target value ± 3 SD	No change
Fibrinogen	Target value ± 20%	Target value ± 20%	No change
Prothrombin time (seconds or international normalized ratio [INR])	Prothrombin time target value ± 15% (CMS)	Prothrombin time target value ± 15% (CMS)	No change
	INR target value ± 20% (CAP)	INR target value ± 15% (CMS)	Criteria changed for INR, see below for reporting*

Analytes regulated for proficiency testing appear in **bold** type.

*Per CMS, "If a laboratory reports a prothrombin time in both INR and seconds, the INR should be reported to the PT provider program."[1]

For the 2024 calendar year, CAP criteria will be used for INR at target value ± 20%.

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

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.**
  - **CAP will continue to provide this information throughout 2024**

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

Analyte or test	Current CMS or CAP criteria for acceptable performance	New CMS or CAP criteria for acceptable performance to be implemented on January 1, 2025	Comments
Whole blood cell (WBC) differential: **Basophils** **Eosinophils** **Granulocytes** **Lymphocytes** **Monocytes**	Target value ± 3 SD based on the percentage of different types of WBC in the specimens	Target value ± 3 SD based on the percentage of different types of WBC in the specimens	No change *See below for 2024 PT participation **See below for 2025 PT participation
Hematocrit	Target value ± 6%	Target value ± 4%	Criteria changed
Microhematocrit, waived	Target value ± 6% or ± 2 SD (greater)	Target value ± 6% or ± 2 SD (greater)	No change
Hemoglobin	Target value ± 7%	Target value ± 4%	Criteria changed
Immature granulocyte (IG)	Educational	Educational	No change

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).**

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CAP Number:
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City / State:

Kit ID:
Kit Mailed: 9/27/2021
Original Evaluation: 11/3/2021

EVALUATION
ORIGINAL

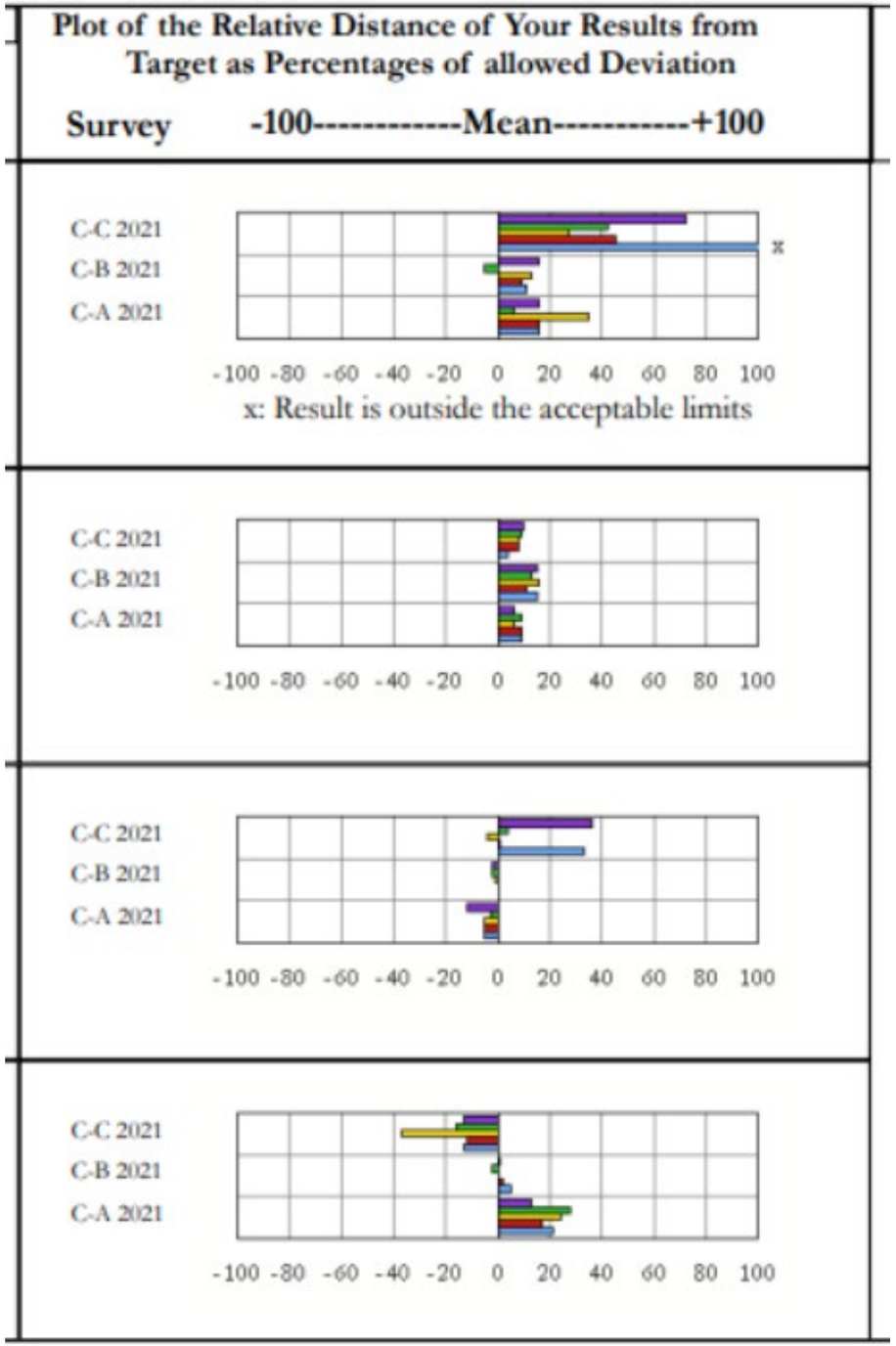
C-C 2021 General Chemistry/Therapeutic Drugs

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade	Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation
Albumin	**CHM-11**	3.7	3.44	0.09	109	+3.0	3.0	3.8	Acceptable	
g/dL	**CHM-12**	3.1	2.95	0.09	110	+1.6	2.6	3.3	Acceptable	
DYE BINDING-BCG	**CHM-13**	5.0	4.85	0.09	107	+1.7	4.3	5.4	Acceptable	
ROCHE COBAS c311	**CHM-14**	3.1	2.93	0.08	109	+2.0	2.6	3.3	Acceptable	
	CHM-15	2.0	1.65	0.06	106	+5.7	1.4	1.9	Unacceptable	
Alkaline Phosphatase	**CHM-11**	377	365.8	14.6	118	+0.8	256	476	Acceptable	
U/L	**CHM-12**	178	173.1	7.1	118	+0.7	121	226	Acceptable	
ROCHE COBAS c311	**CHM-13**	241	235.2	9.2	118	+0.6	164	306	Acceptable	
ROCHE	**CHM-14**	177	172.7	7.3	118	+0.6	120	225	Acceptable	
	CHM-15	51	50.3	2.2	118	+0.3	35	66	Acceptable	
Amylase, serum	**CHM-11**	371	334.0	5.9	58	+6.2	233	435	Acceptable	
U/L	**CHM-12**	161	158.8	2.1	57	+1.1	111	207	Acceptable	
ROCHE COBAS c311	**CHM-13**	229	232.3	3.6	58	-0.9	162	302	Acceptable	
ROCHE	**CHM-14**	159	158.4	2.3	58	+0.3	110	206	Acceptable	
	CHM-15	33	30.0	0.7	57	+4.2	20	39	Acceptable	
AST (SGOT)	**CHM-11**	235	241.3	9.0	107	-0.7	193	290	Acceptable	
U/L	**CHM-12**	103	106.6	4.5	107	-0.8	85	128	Acceptable	
ROCHE COBAS c311	**CHM-13**	148	160.2	7.2	106	-1.7	128	193	Acceptable	
ROCHE	**CHM-14**	105	107.8	5.0	108	-0.6	86	130	Acceptable	
	CHM-15	9	9.3	0.6	107	-0.5	7	12	Acceptable	

Survey -100----------Mean----------+100
C-C 2021
C-B 2021
C-A 2021
-100 -80 -60 -40 -20 0 20 40 60 80 100
x: Result is outside the acceptable limits

PT Participant Summary & Evaluation Reports (Continued)

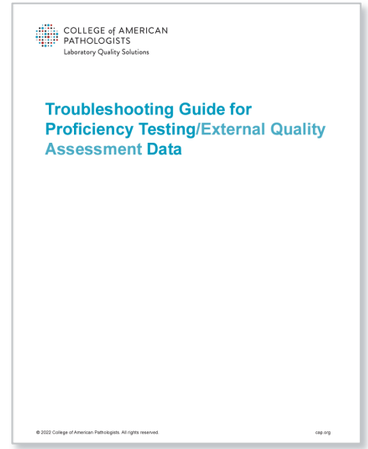
- Graph lists three consecutive mailings of each analyte
  - Could help identify bias, shifts, or trends
  - May be used to troubleshoot and evaluate whether results will be within or outside the limits of acceptability with new (tighter) grading criteria



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



4. Learn

Review and interpret reports and implement and document corrective action for issues.

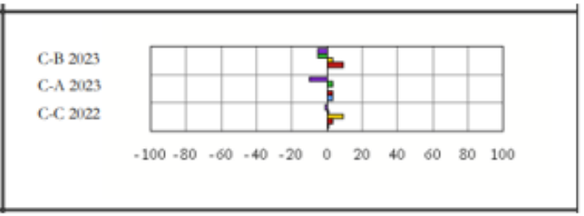
- Troubleshooting Guide for PT/EQA Data
- PT/EQA Exception Investigation Worksheet
- Performing a Self-Evaluation When PT is Not Graded
- Root Cause Analysis Poster
- Root Cause Analysis Check Sheet
- Why Proficiency Testing, Education and Insights (video)
- Proficiency Testing Participant Summary and Evaluation Resource

Examples Illustrating Criteria Changes

Potassium: Current vs. New Criteria

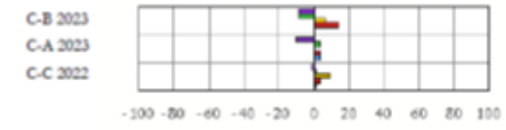
Potassium evaluated at target value +/- 0.5 mmol/L (current criteria)

Potassium, serum mmol/L ION SELECT ELECT DIL SIEMENS DIMENSION	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
	CHM-06	6.3	6.33	0.07	274	-0.5	5.8	6.9	Acceptable
	CHM-07	3.3	3.33	0.05	275	-0.7	2.8	3.9	Acceptable
	CHM-08	5.2	5.18	0.05	272	+0.4	4.6	5.7	Acceptable
	CHM-09	5.0	4.95	0.06	274	+0.8	4.4	5.5	Acceptable
	CHM-10	6.8	6.80	0.07	273	-0.1	6.3	7.4	Acceptable



Same laboratory – C-B 2023 evaluated at target value +/- 0.3 mmol/L (new criteria)

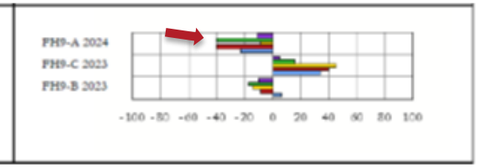
Test Unit of Measure Peer Group	Evaluation and Comparative Method Statistics Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade	Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation Survey -100----------Mean----------+100
Potassium, serum mmol/L ION SELECT ELECT DIL SIEMENS DIMENSION	CHM-06	6.3	6.33	0.07	274	-0.5	6.0	6.7	Acceptable	
	CHM-07	3.3	3.33	0.05	275	-0.7	3.0	3.7	Acceptable	
	CHM-08	5.2	5.18	0.05	272	+0.4	4.8	5.5	Acceptable	
	CHM-09	5.0	4.95	0.06	274	+0.8	4.6	5.3	Acceptable	
	CHM-10	6.8	6.80	0.07	273	-0.1	6.5	7.2	Acceptable	



Hemoglobin & Hematocrit: Current vs. New Criteria

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

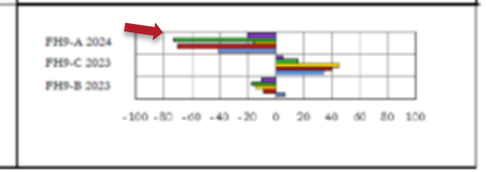
Hemoglobin g/dL SYSMEX XN-SERIES RL AP	FH9-01	5.7	5.75	0.08	98	-0.7	5.3	6.2	Acceptable
	FH9-02	17.9	18.45	0.21	98	-2.6	17.1	19.8	Acceptable
	FH9-03	5.9	5.94	0.08	99	-0.5	5.5	6.4	Acceptable
	FH9-04	15.7	16.17	0.19	98	-2.5	15.0	17.4	Acceptable
	FH9-05	12.2	12.41	0.13	97	-1.5	11.5	13.3	Acceptable



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

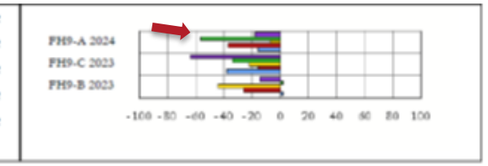
Test Unit of Measure Peer Group	Evaluation and Comparative Method Statistics								
	Specimen	Your Result	Mean	S.D.	No. of Labs	Limits of Acceptability S.D.I	Lower	Upper	Your Grade
Hemoglobin g/dL SYSMEX XN-SERIES RL AP	FH9-01	5.7	5.75	0.08	98	-0.7	5.5	6.0	Acceptable
	FH9-02	17.9	18.45	0.21	98	-2.6	17.7	19.2	Acceptable
	FH9-03	5.9	5.94	0.08	99	-0.5	5.7	6.2	Acceptable
	FH9-04	15.7	16.17	0.19	98	-2.5	15.5	16.9	Acceptable
	FH9-05	12.2	12.41	0.13	97	-1.5	11.9	13.0	Acceptable

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation



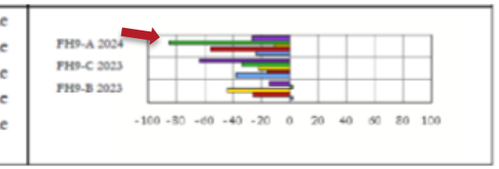
Hematocrit evaluated at target value +/- 6% (current criteria)

Hematocrit % SYSMEX XN-SERIES RL AP	FH9-01	16.70	16.887	0.350	97	-0.5	15.87	17.90	Acceptable
	FH9-02	50.10	51.878	0.877	98	-2.0	48.76	55.00	Acceptable
	FH9-03	16.90	16.980	0.319	99	-0.3	15.96	18.00	Acceptable
	FH9-04	43.90	44.908	0.705	98	-1.4	42.21	47.61	Acceptable
	FH9-05	34.80	35.153	0.615	98	-0.6	33.04	37.27	Acceptable



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

Hematocrit % SYSMEX XN-SERIES RL AP	FH9-01	16.70	16.887	0.350	97	-0.5	16.21	17.57	Acceptable
	FH9-02	50.10	51.878	0.877	98	-2.0	49.80	53.96	Acceptable
	FH9-03	16.90	16.980	0.319	99	-0.3	16.30	17.66	Acceptable
	FH9-04	43.90	44.908	0.705	98	-1.4	43.11	46.71	Acceptable
	FH9-05	34.80	35.153	0.615	98	-0.6	33.74	36.56	Acceptable



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 ± 6% in 2025. Therefore, the CAP will provide two evaluations starting with the GH5-A 2025 mailing to meet CLIA (Target value ± 8%) and CAP checklist (Target value ± 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

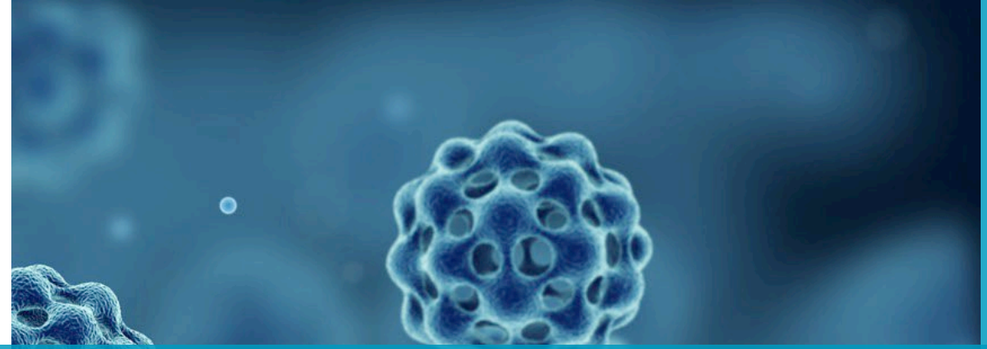
Impact on CAP Customers: PT Enrollment

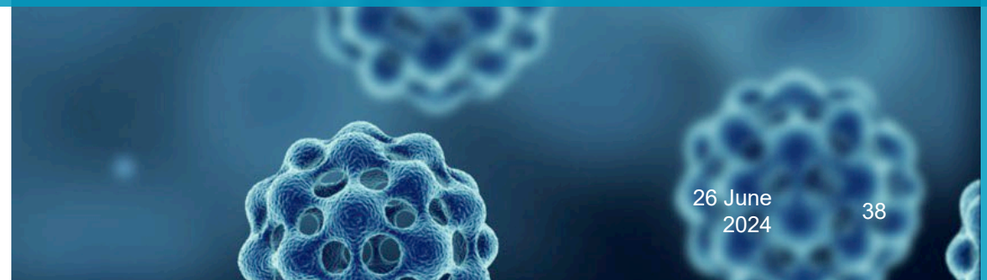
- CAP will pre-populate customer order forms with the recommended program during the order renewal process, based on order history
- Review your 2025 order renewal form carefully
- CAP accredited laboratories: PT enrollment will be audited in early 2025 for analytes that require enrollment and participation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

2025 Criteria for Acceptable Performance

Analyte or test	New CMS criteria for acceptable performance to be implemented on January 1, 2025	Comments
Antimicrobial susceptibility testing	80% participant or referee consensus and CLSI guidelines for 2 graded challenges	Number of challenges increased to 2 **graded** per mailing; ungraded educational challenge will not be offered
Bacterial antigen detection	80% participant or referee consensus	No change
Bacterial toxin detection	80% participant or referee consensus	New CMS regulated analyte
Bacterial identification	80% participant or referee consensus	No change
Gram stain reaction	80% participant or referee consensus	No change
Gram stain morphology	80% participant or referee consensus	New CMS regulated analyte, see below*

Analytes regulated for proficiency testing appear in **bold** type.

*Effective January 1, 2025, Gram stain result reporting to CMS will include both reaction and morphology.

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

Analyte or test	New CMS criteria for acceptable performance to be implemented on January 1, 2025	Comments
Antimycobacterial susceptibility testing (AST)	80% participant consensus	See below*
Mycobacteria identification	80% participant or referee consensus	No change
Acid-fast smear	80% participant or referee consensus	No change

Analytes regulated for proficiency testing appear in **bold** type.

*Effective January 1, 2025, 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

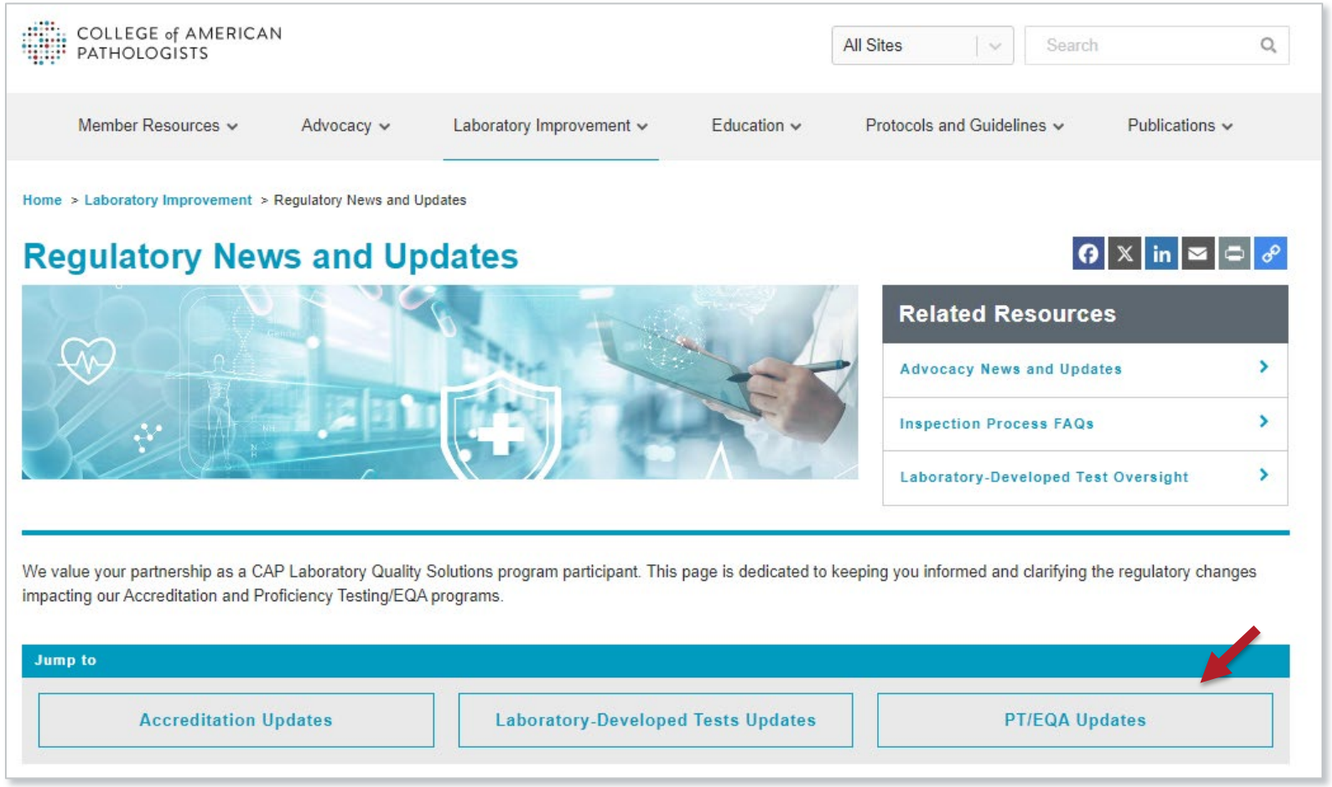
Virology

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

Resources

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



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