



## **2014 Continuing Compliance Master Series**

# **Best Practices in Alternative Assessment of Performance**

Brad S. Karon, MD, PhD, FCAP  
November 19, 2014

[www.cap.org](http://www.cap.org)

## Today's Presenter

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### **Brad S. Karon, MD, PhD, FCAP**

Dr. Karon is currently chair of the College of American Pathologists (CAP) Continuous Compliance Committee and a member of the Commission on Laboratory Accreditation. He is an Associate Professor of Laboratory Medicine and Pathology at Mayo Clinic Rochester.

# Disclosure

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- No disclosures
- Special thanks to Dr. Christina Wojewoda for some content

# Objectives

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- Define alternative performance assessment and the elements of an alternative performance assessment system.
- Identify tests or analytes performed in your laboratory that may be assessed using an alternative performance assessment system.
- Describe Laboratory Accreditation Program (LAP) requirements for alternative performance assessment systems.
- List best practices for alternative performance assessment that help laboratories improve the quality of testing while optimizing laboratory resources.

## What is Proficiency Testing (PT)?

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- The CAP checklists define PT as “the determination of laboratory testing performance by means of interlaboratory comparisons.”
- CMS defines PT as the “testing of unknown samples sent to a laboratory by a CMS approved PT program.” The PT program grades the results using CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed testing.

## What is Alternative Performance Assessment (APA)?

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- Determination of laboratory testing performance by means other than PT:
  - Split-sample testing with reference or other laboratory or by a different method.
  - Split samples with established in-house method, assayed samples or materials, etc.
  - Clinical validation by chart review.
  - Participation in graded/ungraded/educational PT challenges.
  - Also (previously) known as Alternative Assessment of Performance

## CMS PT Requirements

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- Clinical Laboratory Improvement Amendments (CLIA)
  - [http://www.cms.gov/CLIA/03\\_Interpretive\\_Guidelines\\_for\\_Laboratories.asp#TopOfPage](http://www.cms.gov/CLIA/03_Interpretive_Guidelines_for_Laboratories.asp#TopOfPage)
  - Appendix C, Interpretive Guidelines
    - *Subpart H, PT requirements for non-waived testing*
  - Regulated analytes defined by discipline (specialty)
  - Enrollment by analyte (chemistry, immunology, hematology, immunohematology)
  - Enrollment by subspecialty (microbiology)

## CMS PT Requirements - Regulated Analytes

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- Eighty-three analytes listed in the CLIA Regulations
- Criteria for evaluation described in CLIA regulations (% or SD from target or peer mean)
- Five Microbiology Subspecialties
  - *Bacteriology*
  - *Mycology*
  - *Mycobacteriology*
  - *Parasitology*
  - *Virology*



## CMS PT Requirements

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- CLIA PT rules, continued
  - Enrollment required for each “lab” (CLIA number)
  - Enrollment required for primary instrument/method each analyte
    - *Secondary instrument reporting eliminated 2014*
  - Regulated analyte PT 5 samples X 3/year
  - Must be CMS-approved PT provider
  - Passing score 80% (100% immunohematology)

## CMS PT Requirements

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- CLIA PT rules, continued
  - One failed PT test (< 80%) = unsatisfactory performance
    - *Must investigate cause*
    - *CMS can direct cease testing if patient danger*
  - 2 consecutive or 2/3 failed = unsuccessful performance
    - *CMS may permit technical assistance or retraining, or cease testing*
  - 3 consecutive or 3/4 failed (repeat unsuccessful) = cease testing (regulated analytes)

# CMS PT Requirements

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## CLIA PT rules, continued

- What about all other non-waived testing?
- Non-regulated, non-waived testing
  - *Twice annually verify accuracy of results*
- What about waived testing?
  - *No CLIA/CMS requirements for PT or accuracy verification*
- PT handling
  - *Handle as patient specimen*
  - *Incorporate PT into routine patient workload*

# Accrediting Agency PT Requirements

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- Accrediting agencies must at minimum meet CLIA
  - Frequency, scoring of *regulated* analyte PT
  - Each agency puts its own “spin” on PT
    - *Best practice*
    - *Focus of accrediting agency*
    - *Scientific/medical input on significance of testing*

## Accrediting Agency PT Requirements

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- Laboratory Accreditation Program (LAP)
  - College of American Pathologists (CAP)
- Key differences between LAP and CLIA PT
  - LAP does not distinguish waived vs. non-waived
    - *For enrollment, not necessarily scoring*
  - PT required for predictive markers (ER/PR, HER2)
  - Emphasis on evaluating ungraded or no consensus PT
  - PT Programs must be CAP-accepted
    - *Currently 9 CAP-accepted PT programs*

# Accrediting Agency PT Requirements

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- LAP vs. CLIA PT
  - Analytes with required PT enrollment (> 300)
    - *Waived and non-waived*
    - *Regulated and non-regulated*
  - Similar to CLIA by analyte
    - *Some analytes defined by matrix (serum vs. urine hCG)*
  - Frequency/number PT samples
    - *5 X 3 for regulated analytes*
    - *Varies for all other analytes (5X3, 3X2, 2X3)*

## CAP (LAP) Oversight of PT Performance

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- Continuous Compliance Committee (CCC)
  - Defines which nonregulated and waived analytes require PT
    - *Clinical relevance/significance of analytes*
    - *Availability of graded PT*
    - *Number labs performing test*
  - Audits and accepts PT providers
  - Monitors enrollment, participation, and performance in required PT by LAP laboratories
  - Sends out notification when a laboratory must **CEASE TESTING** due to non-enrollment, non-participation, or critical performance failure

# PT Terminology

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- Regulated analytes
- Non-regulated analytes
  
- Graded
- Non-graded
  
- Graded, Not-required
- PT, Not available



# PT Terminology

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- Non-graded PT
  - Intended as educational challenge
  - Lack of participant or referee consensus
  - Small number enrolled (< 10 quantitative or < 5 qualitative)
  - For both regulated and non-regulated analytes, laboratory must have policy/procedure for grading itself

## Example of PT Evaluation-Ungraded PT Challenges

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Blood Cell ID Ungraded	<a href="#">BCP-16</a>	PLASMODIUM SP (MALARIA)	[26]
	<a href="#">BCP-17</a>	NEUTROPHIL, SEG/BAND	[26]
	<a href="#">BCP-18</a>	MONOCYTE	[26]
	<a href="#">BCP-19</a>	POLYCHROMATOPHILIC RBC	[26]
	<a href="#">BCP-20</a>	PLASMODIUM SP (MALARIA)	[26]

# PT Terminology

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- Graded, not required
  - Laboratory enrolls in available PT product as an alternative performance assessment

## How to Find Out What or if PT is Required?

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- Master Activity Menu with PT Options (in *e-Lab* Solutions)
- Laboratory's Activity Menu (in *e-Lab* Solutions)  
[COM.01200 The laboratory's current CAP activity menu should accurately reflect the testing performed]
- Analyte/Procedure Index of the Surveys or EXCEL Catalog (on [www.cap.org](http://www.cap.org))

# Master Activity Menu with PT Options

Select or Change Laboratory

## Laboratory Accreditation Program









### Notifications

The College of American Pathologists has asked the Centers for Medicare & Medicaid (CMS) to investigate the apparent discrepancy regarding the process to verify staff credentials for nursing or other state allied health licensed personnel conducting moderate or high complexity laboratory testing as it appears on [The Joint Commission website](#). CAP accreditation requirements, as approved by CMS, do not allow for third-party services to verify staff credentials in the instance cited. The CAP will continue to work with CMS staff to resolve this matter for CAP-accredited laboratories.


- The Accreditation Application/Data Maintenance system is not available during the daily maintenance cycle: 1:30 am - 4:30 am (CDT); 6:30 am - 9:30 am (GMT).

The CAP apologizes for any inconveniences you may experience while using e-Labs. The CAP is undergoing a multi-year, enterprise-wide improvement program for its entire information services platform including Web site technology and design. In the short-term, you may experience some planned service outages and other performance issues as we continue to make improvements. Long term, you'll experience a new cap.org that is easier to navigate, faster, and responsive. Please refer [troubleshooting information](#) specific to e-Labs. Additional support is available from the CAP Customer Contact Center at 800-323-4040, option 1 or 847-832-7000 or [contactcenter@cap.org](mailto:contactcenter@cap.org).

Please select a laboratory using the button above in order to enable the links specific to your laboratory.

 <b>My Laboratory</b> <ul style="list-style-type: none"><li>Laboratory Data Maintenance</li><li>Master and Custom Checklists</li><li><b>Activity Menu with PT Options</b></li><li>Laboratory Data Report</li><li>Inspector's Summation Report</li><li>CAP LINKS Quarterly Reports</li><li>CAP Accreditation Certification Mark</li></ul>	 <b>Accreditation/Inspection Information</b> <ul style="list-style-type: none"><li>What's New</li><li>LAP Resources for Laboratories</li><li>Proficiency Testing Toolbox</li></ul>	 <b>Accreditation Application /Data Maintenance</b> <ul style="list-style-type: none"><li>System Requirements -Troubleshooting (PDF, 42 K)</li><li>FAQs (PDF, 22 K)</li></ul>
 <b>Using e-LAB Solutions</b> <ul style="list-style-type: none"><li>Opt In Your Lab or Organization</li></ul>	 <b>New to e-LAB Solutions?</b> <ul style="list-style-type: none"><li>Getting Started</li></ul>	 <b>Resources</b> <ul style="list-style-type: none"><li>About Accreditation Checklists</li><li>Master Activity Menu (PDF 500K, Excel 250K)</li><li>PT Enrollment Guide</li></ul>

**System Requirements**  
[VIEW DETAILS](#)



# Master Activity Menu with PT Options



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## Master Activity Menu With Proficiency Testing Options

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Program: LAP

Discipline	Subdiscipline	Test/Activity	Test/Activity ID	Scope of Service/Analytic Method	Surveys CAP PT Options	EXCEL CAP PT Options
Chemistry	Special Chemistry	Enzyme immunoassay	1789	Y		
Chemistry	Special Chemistry	Enzyme-linked immunosorbent assay (ELISA)	1788	Y		
Chemistry	Special Chemistry	Enzymology (Biochemical Genetics)	2876	Y		
Chemistry	Special Chemistry	Epinephrine	**1582		N, NX	
Chemistry	Special Chemistry	Erythropoietin, serum	1939			
Chemistry	Special Chemistry	Estradiol	**1744		Y, YY	L27
Chemistry	Special Chemistry	Estriol, total	1745			
Chemistry	Special Chemistry	Estriol, unconjugated	**1746		FP, FPX, Y, YY	
Chemistry	Special Chemistry	Estrogen receptors	1747			
Chemistry	Special Chemistry	Estrone-3-glucuronide, waived	2550			
Chemistry	Special Chemistry	Ethosuximide	**1748		CZ, CZ2, CZ2X, CZX, Z	
Chemistry	Special Chemistry	FSH, urine, non-waived	2554			
Chemistry	Special Chemistry	FSH, urine, waived	2552			
Chemistry	Special Chemistry	Fatty acids, free (non-esterified)	3140			
Chemistry	Special Chemistry	Fecal leukocytes, lactoferrin	3587			
Chemistry	Special Chemistry	Ferritin	**1749		C3, C3X, CZ, CZ2, CZ2X, CZX, K, KK	CH9
Chemistry	Special Chemistry	Fetal fibronectin	**3314		FF	
Chemistry	Special Chemistry	Fetal lung maturity by FPIA, amniotic fluid	**1932		LM, LM1	
Chemistry	Special Chemistry	Flame photometer	1779	Y		

\*\* CAP Accepted PT Required. For activities requiring alternative assessment, laboratories can use PT products supplied by the CAP or other providers. Laboratories should review the Surveys and EXCEL catalogs to determine which PT products are compatible with their specific methodologies.

NOTE: Activities noted as Scope of Service / Analytical Method do not require PT or alternative assessment.

# Laboratory's Activity Menu



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## Laboratory Accreditation Program Laboratory Activity Menu

SU: ALL

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CAP Number:

Laboratory:

City/State(Province)

Department /Section: Instrumental Analysis

Subdiscipline	Test/Activity	Test / Activity ID	PT Required	Alternative Assessment Required	Scope of Service/Analytic Method	2011 Missing PT Enrollment
Special Chemistry	Porphobilinogen	1861		Y		
Special Chemistry	Primidone	1654	Y			
Special Chemistry	Procainamide and metabolite (NAPA)	1655	Y			
Special Chemistry	Quinidine	1661	Y			
Special Chemistry	Salicylate	1662	Y			
Special Chemistry	Serotonin	1878		Y		
Special Chemistry	Stone analysis	1935		Y		
Special Chemistry	Theophylline	1668	Y			
Special Chemistry	Tobramycin	1670	Y			
Special Chemistry	Uroporphyrin	1598	Y			Y
Special Chemistry	Valproic acid	1673	Y			
Special Chemistry	Valproic acid, free	1674	Y			
Special Chemistry	Vancomycin	1675	Y			
Special Chemistry	Vanillylmandelic acid, urine	1599	Y			Y
Special Chemistry	Vitamin A	1924		Y		
Special Chemistry	Vitamin B1	1925		Y		
Special Chemistry	Vitamin B2	3586		Y		

For activities requiring alternative assessment, laboratories can use PT provided by the CAP or other providers.

NOTE: Activities noted as Scope of Service / Analytical Method do not require PT or alternative assessment.

# Analyte/Procedure Index of Surveys and EXCEL Catalogs



Analyte/Procedure	LAP ENR
Antigen detection, bacterial (cont.)	X
	X
Antigen detection, viral	X
	X
	X
Antigliadin antibody IgA, IgG, qualitative	X
Antigliadin antibody IgA, IgG, quantitative	
Antiglomerular basement membrane, qualitative	X



## What is Alternative Performance Assessment (APA)?

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- Determination of laboratory testing performance by means other than PT:
  - Split-sample testing with reference or other laboratory or by a different method.
  - Split samples with established in-house method, assayed materials, etc.
  - Clinical validation by chart review.
  - Participation in graded/ungraded/educational PT challenges.
- Alternative assessment must be performed semi-annually/evaluation criteria established.

## When Would You Need To Do APA?

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- For non-regulated, not required analytes
  - Porphobilinogen, antigliadin Ab (quant)
  - May use PT to satisfy APA requirement
- For analytes in which PT is not available
  - By definition not required analytes
  - Stone analysis
- For in vivo testing:
  - Bleeding time

# LAP AAP Requirements

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- Laboratory Accreditation Manual
- If enrollment in a CAP-accepted PT program is not required for a particular test, the laboratory must perform and document an alternative assessment method semiannually to assess its analytic performance for that test. Alternative assessment may include:
  - Participation in a PT program (graded or educational)
  - Split sample analysis with reference or other laboratories
  - Split samples with an established in-house method, assayed materials or regional pools
  - Clinical validation by chart review, or other suitable and documented means
- Alternative assessment that allows for comparison of results with external laboratories may provide more information than split sample analysis using internal methods. The laboratory must define acceptable criteria for alternative assessment (eg, results within 10% of a reference method)

# LAP APA Requirements

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- 2014 CAP Checklists
- COM.01500 Alternative Performance Assessment
  - For tests for which CAP does not require PT, the laboratory at least semi-annually exercises an alternative performance assessment system for determining the reliability of analytic testing.
  - *NOTE 1: Appropriate alternative performance assessment procedures include participation in an external PT program not required by CAP; participation in an ungraded/educational PT program; split sample analysis with reference or other laboratories, split samples with an established in-house method, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such alternative assessment procedures and the criteria for successful performance in accordance with good clinical and scientific laboratory practice.*

## What You Need To Do

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- Choose process for APA
- Procedure to document plan and acceptability limits before testing is performed
  - (+/- 2 or 3 SD or based on variation in the literature)
- Document performance
- Evaluate trends
- Corrective action if needed
- Performance and evaluation automatic if using graded PT
- Evaluation more robust if using ungraded PT, still must define performance required (SDI, % from target or mean)

# Example: PT Evaluation - Alternative Assessment

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## ALTERNATIVE PERFORMANCE ASSESSMENT

### Urine Myoglobin

<u>SAMPLE</u>	<u>XYZ LAB</u>	<u>REF LAB</u>	<u>CRITERIA</u>
12345	POS	POS	+/+ or -/-

Acceptable Y / N

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

## FAQ's

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- **If a laboratory is enrolled in a PT Program but the laboratory does not test the specimens for a shipment (testing event), is the laboratory required to perform an alternative assessment?**
- Yes. The laboratory should document why the PT specimens were not analyzed (ie, instrument not functioning or reagents not available, etc.). The laboratory should contact the PT program to determine if replacement specimens are available. If not, the laboratory should perform/document alternative assessment at the same number of challenges for the period(s) that the PT specimens were not tested.

# Split-Sample Testing

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- External – reference laboratory
- Internal – with a different established method or previously tested samples



## Split-Sample Testing: Quantitative

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- Determine type of statistical analysis to use
- Determine criteria for acceptability
- Test samples representing AMR, each side of cut-off
- Test enough samples
- Use patient samples
  - Avoids matrix effects, probes pre-analytic error
  - Storage, processing may still differ from routine patient testing

## Split-Sample testing: Quantitative

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- If only 2 of 3 match, the sample size must be increased to 6
- 5 of the 6 must match to achieve the same level of confidence
- 95% confidence

## Audit-Sample Procedure (Previously Tested Samples)

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- Can be used for stable analytes
- Aliquots of patient sample stored
- Analyzed periodically over time
- Assesses reproducibility and stability of calibration
- Does not assess trueness

# Direct Observation of Technique-Dependent Tests

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- Sweat test
- Bleeding time
- Observed by experienced senior analyst or supervisor
- Checklist with factors to be observed

# Clinical Correlation Studies

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- Limited application to routine test assessment
  - Imperfect correlation of clinical events to laboratory results
  - Test referral bias
  - Disease classification bias
- Can be used in certain circumstances
  - If the presence of the disorder can be independently determined at a reasonable point in time after testing

## Scenario 1

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- You are inspecting an anatomic pathology laboratory and you are told that they are performing HER2, brightfield in situ hybridization (CISH). You ask the staff what are they doing for AAP and they show you a binder of results from samples that were split with a local laboratory. You notice some discrepancies in the results between the laboratory you are in and the reference laboratory. When you ask how these results were evaluated, you are told “We think we were right and they were wrong” although no corrective action or evaluation was documented.

# Scenario 1

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This laboratory is:

- Meeting the requirement
- Not meeting the requirement
- Performing Best Practice AAP

# Scenario 1

Department /Section: Anatomic Pathology

Subdiscipline	Test/Activity	Test / Activity ID	PT Required	Alternative Assessment Required	Scope of Service/Analytic Method	2014 Missing PT Enrollment
All Common	Common (CAP Office use)	4334			Y	
Anatomic Pathology Processing	HER2, immunohistochemistry staining	2824			Y	
Anatomic Pathology Processing	Immunofluorescence staining, tissue biopsy	1399			Y	
Anatomic Pathology Processing	Immunohistochemistry staining	1393			Y	
Anatomic Pathology Processing	Routine processing (e.g., block prep, H&E stain)	1397			Y	
Anatomic Pathology Processing	Special stains, histochemistry	1398			Y	
Anatomic Pathology Processing	Tissue processing, Autopsy Pathology	1396			Y	
Autopsy Pathology	Dissection	13			Y	
Autopsy Pathology	Forensic pathology, Autopsy	11			Y	
Autopsy Pathology	Microscopic evaluation, Autopsy Pathology	16			Y	
Intraoperative Consultation	Intraoperative consultation (e.g. frozen sections)	2137			Y	
Molecular Anatomic Pathology	HER2, brightfield in situ hybridization (CISH)	2377		Y		
Surgical Pathology	Gross evaluation, non-pathologist	10			Y	
Surgical Pathology	Gross evaluation, pathologist	1			Y	
Surgical Pathology	HER2, IHC staining and path interpretation on-site	3210	Y			
Surgical Pathology	Microscopic evaluation, Surgical Pathology	4			Y	
Surgical Pathology	Oral pathology (oral specimen exam)	5			Y	

For activities requiring alternative assessment, laboratories can use PT provided by the CAP or other providers.  
 NOTE: Activities noted as Scope of Service / Analytical Method do not require PT or alternative assessment.



# Scenario 1

**\*\*REVISED\*\* 07/29/2013**

**COM.01500 Alternative Performance Assessment**

**Phase II**

**For tests for which CAP does not require PT, the laboratory at least semi-annually exercises an alternative performance assessment system for determining the reliability of analytic testing.**

*NOTE 1: Appropriate alternative performance assessment procedures include participation in an external PT program not required by CAP; participation in an ungraded/educational PT program; split sample analysis with reference or other laboratories, split samples with an established in-house method, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such alternative assessment procedures and the criteria for successful performance in accordance with good clinical and scientific laboratory practice.*

*NOTE 2: For FISH testing, alternative assessment may be performed by method and specimen type, rather than for each tested abnormality (i.e. one program for all FISH cytogenetics tests performed on cell suspensions). Additionally, for sequencing based testing such as Sanger, pyrosequencing and next generation, alternative assessment may be performed by method and specimen type. For tests such as allergen testing, alternative assessment may be performed in batches of analogous tests.*

*NOTE 3: Semi-annual alternative performance assessment must be performed on tests for which external PT is not available.*

*NOTE 4: This checklist requirement applies to both waived and nonwaived tests.*

*The list of analytes for which CAP requires proficiency testing is available on the CAP website [<http://www.cap.org/>] or by phoning 800-323-4040 (or 847-832-7000), option 1.*

## **Evidence of Compliance:**

- ✓ List of tests defined by the laboratory as requiring alternative assessments **AND**
- ✓ Records of those assessments

## **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):7184 [42CFR493.1236(c)(1)]
- 2) Shahangian S, et al. A system to monitor a portion of the total testing process in medical clinics and laboratories. Feasibility of a split-specimen design. *Arch Pathol Lab Med*. 1998;122:503-511
- 3) Shahangian S, Cohn RD. Variability of laboratory test results. *Am J Clin Pathol*. 2000;113:521-527
- 4) CLSI. *Assessment of Laboratory Tests When Proficiency Testing is not Available; Approved Guideline-Second Edition*. CLSI Document GP29-A2. [ISBN 1-56238-673-5]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2008
- 5) Marks V. False-positive immunoassay results: a multicenter survey of erroneous immunoassay results from assays of 74 analytes in 10 donors from 66 laboratories in seven countries. *Clin Chem*. 2002;48:2008-2016

## Scenario 2

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- You are inspecting a limited services laboratory and see on their Activity Menu that they are performing non-waived fecal occult blood and that it requires APA. When asked, the technician shows you the past 2 years worth of results (from 3 challenges twice/year) with signatures of the laboratory director. APA was done by split sample analysis with a neighbor laboratory and accuracy criteria (+/+ or -/-) are defined. Both positive and negative samples included each time.

## Scenario 2

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This laboratory is:

- Meeting the requirement
- Not meeting the requirement
- Performing Best Practice AAP

## Scenario 2

Subdiscipline	Test/Activity	Test / Activity ID	PT Required	Alternative Assessment Required	Scope of Service/Analytic Method	2014 Missing PT Enrollment
All Common	Common (CAP Office use)	4334			Y	
Bacteriology	Antimicrobial susceptibility, aerobes	343	Y			
Bacteriology	Antimicrobial susceptibility, urine	345	Y			
Bacteriology	Bacterial identification, complete/partial, other	350	Y			
Bacteriology	Bacterial identification/isolation, anaerobic	4091	Y			
Bacteriology	Bacterial identification/presumptive ID gonococcus	349	Y			
Bacteriology	Bacterial identification/presumptive ID, throat	351	Y			
Bacteriology	Bacterial identification/presumptive ID, urine	352	Y			
Bacteriology	Blood culture, complete/partial ID	4092	Y			
Bacteriology	Fecal leukocytes, lactoferrin	2464		Y		
Bacteriology	Gram stain, gonococcus	332	Y			
Bacteriology	Gram stain, other	333	Y			
Bacteriology	Occult blood, fecal, non-waived	2641		Y		
Bacteriology	Occult blood, fecal, waived	2634		Y		
Bacteriology	Salmonella and/or Shigella typing	743	Y			
Bacteriology	Shiga-like toxin, stool	2327		Y		
Bacteriology	Urine colony count	1222	Y			

For activities requiring alternative assessment, laboratories can use PT provided by the CAP or other providers.

NOTE: Activities noted as Scope of Service / Analytical Method do not require PT or alternative assessment.

## CLSI GP29-A2

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- CLSI GP29-A2 (2008). Assessment of Laboratory Tests When Proficiency Testing Is Not Available
  - Situations in which PT may not be available:
    - *Unstable material/analyte (RBC osmotic frag, some micro)*
    - *Analytes in unusual matrices (interstitial fluid, stool)*
    - *In vivo testing (bleeding time, Schilling test)*
  - APA using patient samples avoids matrix effects and assesses pre-analytic factors, best practice

## Other Methods From CLSI

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- Analysis of manufacturer's product calibrator or control material
  - Use different lot calibrator or QC, limitations
- Analysis of interlaboratory QC data
- Analysis of patient averages/medians
  - Both forms of continuous QC, could be used for AAP if nothing else exists
- Re-evaluation of reference interval or interpreted result
  - Periodic re-evaluation RI can detect changes
  - Re-interpretation relevant to interpretive testing (morphology)

# Sample Exchange Registry

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- Internet-based service
- Connects laboratories performing testing where no formal proficiency testing (PT) is available
- Participate in the registry service at any time
- When  $\geq 3$  laboratories are identified as testing for the same analyte, the CAP will facilitate the sample exchange
- Primarily used for rare molecular tests



# Sample Exchange Registry

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- CAP will distribute the samples to participating laboratories
- Laboratories will test the samples and send their results to CAP
- Data will be anonymized and each individual laboratory will receive its own results along with an anonymous summary report of all the participants



## CAP Resources

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- Contact the Compliance Group
  - LAP PT Compliance Group
  - Phone: 800-323-4040, ext. 6052
  - Fax: 847-832-8174
  - Email: [ptcn@cap.org](mailto:ptcn@cap.org)
- Or you may use the following address:
  - LAP PT Compliance Group  
College of American Pathologists  
325 Waukegan Road  
Northfield, IL 60093-2750

**Thank you!**

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**Questions?**



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