



COLLEGE of AMERICAN
PATHOLOGISTS

New Directions in the Laboratory Accreditation Program

What's New in LAP

Becky Damiani, MT(ASCP), Senior
Inspection Specialist, Laboratory
Accreditation

May 5, 2016

Objectives

- **Performance Analytics Update**
- **2016 Checklist Update**
- **Top Ten Deficiencies and Best Practices**

What's New with CAP Accreditation?

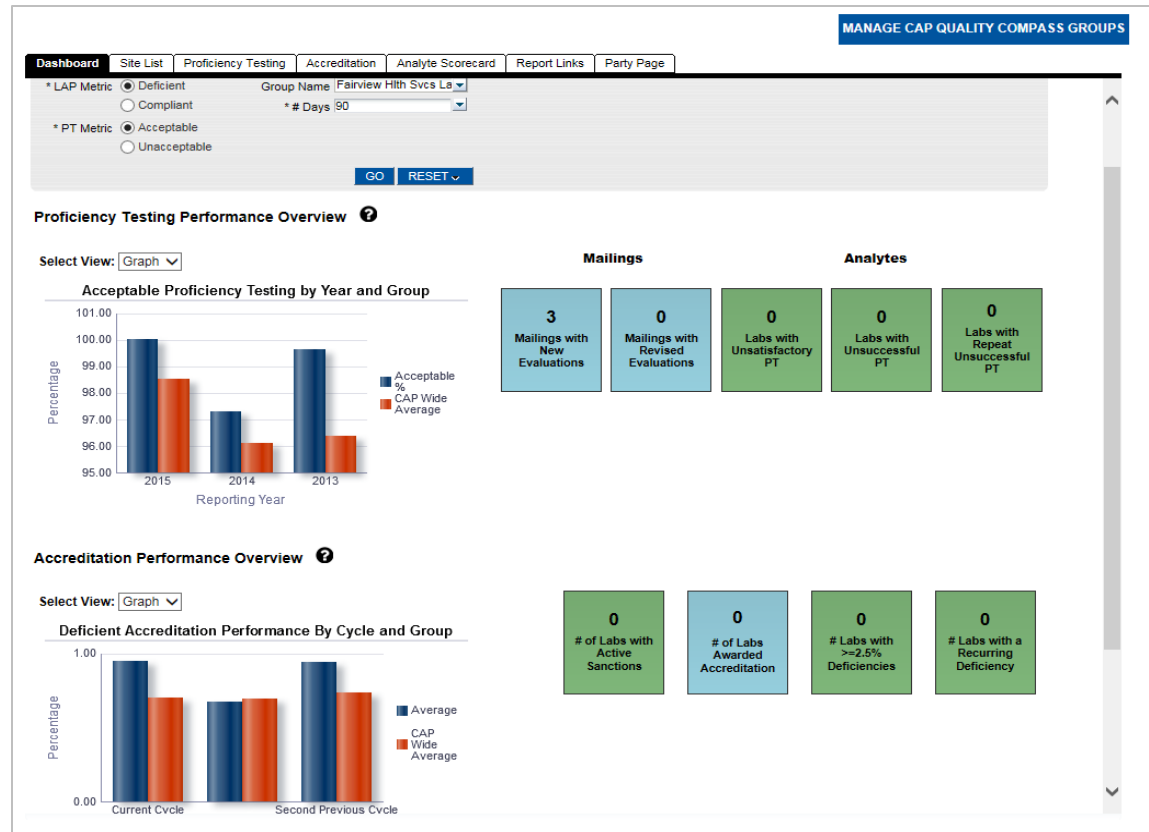
CAP Performance Analytics Dashboard at a glance



What's New with CAP Accreditation?

Performance Analytics Dashboard Update

- Real time data
- **Summer 2016**



Laboratories have key needs for monitoring quality assurance performance* to mitigate risk

Ensure standardization and consistency throughout all networked labs or for all areas in a lab

Consolidating QA data from multiple lab sites, locations, areas, etc.

Manage occurrences of laboratory errors

Analyzing patterns, bias, trends, etc. to perform root cause analysis

Monthly or quarterly

Manage data and systems

Extracting current and historical data such as PT, accreditation, QC, etc. from multiple PT providers and/or lab sites

Manage documents

Collecting, managing and tracking supporting documentation

Manual Methods

CAP Links + Manual Methods or BI tools

Manual data extraction + BI tools

Current monitoring methods are time consuming and resource intensive

Mitigate risk by managing Surveys PT and Accreditation LAP compliance and performance

The Performance Analytics Dashboard is a web based reporting solution that enables laboratory management to access and monitor consistency in PT and LAP performance and compliance in real time for a single lab or all labs in a network, all in one place.

Ensure consistency and standardization

Easy monitoring and comparison of PT and LAP performance across all networked labs, all in one place

Data updated daily

More than 20 predefined online reports and scorecards

Perform data analysis to quickly mitigate risks

Identify trends and patterns

Access PT events, evaluations or LAP documentation on inspection deficiencies

Drill down to specific sections, areas, disciplines, and tests across all laboratories

Manage access to your data more efficiently

Customize reporting groups and security levels

Use filters to access just the information you need

Complimentary



Dashboard Overview



CAP

Monitor consistency and standardization: Personalize reporting groups

MY CAP

e-LAB SOLUTIONS SUITE
CAP #: 8750501
Text System, 21502 Murfield Ct., Evanston, IL 60202

LAB SOLUTIONS SUITE | MY PROFILE | OTHER SERVICES

LAB SELECTOR

e-LAB Solutions Suite Help

Thumbnail View | List View

Organization Data / User permissions

- View My Lab Permissions
- Manage User's Online Access/Permissions

Proficiency Testing /Quality Management

- Result Form Data Entry
- Evaluation Reports
- Analyte Scorecard
- CMS Analyte Reporting Selections
- My PT Shipping Calendar

CAP Accreditation

- Accreditation Application
- Accreditation Checklists
- Activity Menu with PT Options
- Laboratory Data Report
- Inspection Summation Report
- CAP Accreditation Certification Mark
- CAP Accreditation Resources

Performance Analytics

- CAP Links Quarterly Reports
- Access Program
- Access Dashboard
- Manage Lab Reporting Groups
- CMS Analyte Reporting Selections

Competency Assessment Program

- Access Program

Quick Links

- Request Access to Laboratory Data
- Claim Credit for Faxed PT Results
- Access My Committees
- My Transcript
- My In Progress Learning
- View Lab Order History

Important Alerts

- Secondary Instrument PIDs 3

Take immediate actions & look for trends at the Accreditation and PT dashboards

Dashboard | Site List | Proficiency Testing | Accreditation | Analyte Scorecard | Report Links | Party Page

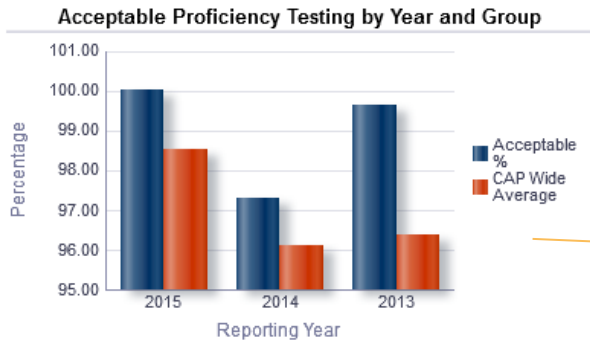
* LAP Metric: Deficient Compliant Group Name: _____
 * PT Metric: Acceptable Unacceptable * # Days: 90

GO RESET ▾

Apply filters to access only the data you need

Proficiency Testing Performance Overview ?

Select View: Graph ▾



Mailings

3
Mailings with New Evaluations

0
Mailings with Revised Evaluations

0
Labs with Unsatisfactory PT

0
Labs with Unsuccessful PT

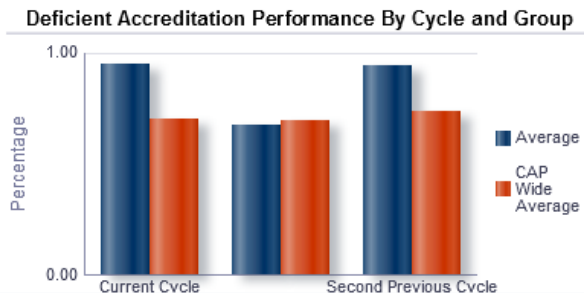
0
Labs with Repeat Unsuccessful PT

Look for trends and comparisons

Color coded alerts to take immediate actions

Accreditation Performance Overview ?

Select View: Graph ▾



0
of Labs with Active Sanctions

0
of Labs Awarded Accreditation

0
Labs with >=2.5% Deficiencies

0
Labs with a Recurring Deficiency

Perform in in-depth analysis with more than 20 reports

Dashboard Site List **Proficiency Testing** Accreditation Analyte Scorecard Report Links

Click here to collapse filter options -

* indicates required field

* PT Metric Acceptable Unacceptable

* Group Name * Year

GO RESET

Laboratory System

Yellow highlight indicates acceptable % less than 90; Red highlight indicates acceptable % less than 80.

| Group Level Hierarchy | Acceptable % | | System Average | | CAP-Wide Average | |
|---|--------------|--------|----------------|--------|------------------|--------|
| | 2015 | 2014 | 2015 | 2014 | 2015 | 2014 |
| [-] Test System (SYSTEM) | 94.67% | 96.65% | 94.67% | 96.65% | 97.56% | 96.39% |
| CAP# 7190740 Test Lab #5 Dept of Pathology and Lab Medicine 1600 Pennsylvania Ave Washington,DC 20500 | 91.14% | 97.66% | 94.67% | 96.65% | 97.56% | 96.39% |
| CAP# 7197518 Test Lab #2 Referral Laboratory 425 Easy Street Happyville,TN 11183 | 97.41% | 97.43% | 94.67% | 96.65% | 97.56% | 96.39% |
| CAP# 7223634 Test Lab #1 123 Main St. Utopia,IL 12345 | 95.63% | 95.77% | 94.67% | 96.65% | 97.56% | 96.39% |
| CAP# 8008493 Test Lab #3 Princess Haya Biotech Ctr 001 Cemetery Lane Greenbriar,NC 22110-3030 | 77.05% | 62.64% | 94.67% | 96.65% | 97.56% | 96.39% |
| CAP# 8706761 Test Lab #4 Cell Therapy & Applied Genomics Lab 1313 Mockingbird Lane Mockingbird Heights,CA 11941 | 98.41% | 98.14% | 94.67% | 96.65% | 97.56% | 96.39% |



Perform root cause analysis to mitigate risk and stay in compliance for every area, discipline or test across multiple labs, groups of labs or for a single lab.

PT Performance Overview – Laboratory Subspecialty & Analyte Summary ?

| CAP # | CLIA # | Name / Address | CAP Accredited | Demographic Group |
|---------|--------|---|----------------|-------------------|
| 8008493 | | Test Lab #3 Princess Haya Biotech Ctr Irbid, Irb 22110-3030 Jordan | N | |

Yellow highlight indicates acceptable % less than 90; Red highlight indicates acceptable % less than 80.

Select View

| Subspecialty | Acceptable % | | Demographic Group Average ? | | CAP-wide Average | |
|--------------------------------|--------------|-------|-----------------------------|------|------------------|--------|
| | 2015 | 2014 | 2015 | 2014 | 2015 | 2014 |
| Molecular Pathology & Genetics | 84.44 | 60.87 | | | 97.54% | 96.23% |
| TDM/Endocrinology | | 0.00 | | | | 95.41% |
| Virology | 56.25 | 78.95 | | | 98.63% | 96.27% |

Return



Be ready for accreditation inspections

Dashboard | Site List | Proficiency Testing | **Accreditation** | Analyte Scorecard | Report Links

Click here to collapse filter options -

* indicates required field

* LAP Metric Deficient Compliant

Group Name CAP #

Lab

Inspection Summary ?

Red highlight indicates greater than 2.5% deficiencies; ** Indicates Preliminary Data ?

| System / Group | Percent Deficient | | | System Average | | | CAP-wide Average | | |
|---|-------------------|----------------|-----------------------|----------------|----------------|-----------------------|------------------|----------------|-----------------------|
| | Current Cycle | Previous Cycle | Second Previous Cycle | Current Cycle | Previous Cycle | Second Previous Cycle | Current Cycle | Previous Cycle | Second Previous Cycle |
| <input type="checkbox"/> Test System (SYSTEM) | 0.97% | 0.74% | 0.51% | 0.97% | 0.74% | 0.51% | 0.79% | 0.65% | 0.74% |
| CAP# 7190740 Test Lab #5 Dept of Pathology and Lab Medicine 1600 Pennsylvania Ave Washington, DC 20500 | 0.70% | 0.95% | 0.40% | 0.97% | 0.74% | 0.51% | 0.79% | 0.65% | 0.74% |
| CAP# 7197518 Test Lab #2 Referral Laboratory 425 Easy Street Happyville, TN 11 | 1.68% | 0.77% | 0.69% | 0.97% | 0.74% | 0.51% | 0.79% | 0.65% | 0.74% |
| CAP# 8706761 Test Lab #4 Cell Therapy & Genomics Lab 1313 Mockingbird Lane Mockingbird Heights, CA 11941 | | | | 0.97% | 0.74% | 0.51% | 0.79% | 0.65% | 0.74% |

- [Inspection Summary by Section/Department](#)
- [Inspection Summary by Checklist Module](#)
- [Inspection Summary by Section/Department](#)



Monitor accreditation compliance and Identify areas for improvement based on inspection deficiencies for specific labs or across multiple labs – develop QM initiatives E.g. Safety, Inventory management IT, etc.

| Section Unit | Checklist Module | Cycle Type | Number Deficient | | | Number of Requirements | | | Percent Deficient | | |
|---------------------------------------|----------------------------|------------|------------------|----------------|-----------------------|------------------------|----------------|-----------------------|-------------------|----------------|-----------------------|
| | | | Current Cycle | Previous Cycle | Second Previous Cycle | Current Cycle | Previous Cycle | Second Previous Cycle | Current Cycle | Previous Cycle | Second Previous Cycle |
| Chemistry and Special Chemistry | All Common | Routine | 3 | 1 | | 59 | 30 | | 5.08% | 3.33% | |
| | Chemistry and Toxicology | Routine | 0 | 0 | 0 | 132 | 115 | 113 | 0.00% | 0.00% | 0.00% |
| | Immunology | Routine | 0 | | | 64 | | | 0.00% | | |
| Chemistry and Special Chemistry Total | | | 3 | 1 | 0 | 255 | 145 | 113 | 1.18% | 0.69% | 0.00% |
| Cytogenetics | All Common | Routine | 1 | 0 | | 59 | 30 | | 1.69% | 0.00% | |
| | Cytogenetics | Routine | 0 | 2 | | 45 | 90 | | 0.00% | 2.22% | |
| Cytogenetics Total | | | 1 | 2 | | 104 | 120 | | 0.96% | 1.67% | |
| Hematology | All Common | Routine | 1 | 1 | | 59 | 30 | | 1.69% | 3.33% | |
| | Hematology and Coagulation | Routine | 2 | 3 | 0 | 157 | 193 | 192 | 1.27% | 1.55% | 0.00% |
| | Immunology | Routine | 0 | 0 | 0 | 71 | 110 | 114 | 0.00% | 0.00% | 0.00% |
| Hematology Total | | | 3 | 4 | 0 | 287 | 333 | 306 | 1.05% | 1.20% | 0.00% |
| Histopathology & Cytology | All Common | Routine | 1 | 1 | | 59 | 30 | | 1.69% | 3.33% | |
| | Anatomic Pathology | Routine | 6 | 0 | 2 | 85 | 140 | 127 | 7.06% | 0.00% | 1.57% |
| | Cytopathology | Routine | 8 | 0 | 3 | 70 | 95 | 105 | 11.43% | 0.00% | 2.86% |
| Histopathology & Cytology Total | | | 15 | 1 | 5 | 214 | 265 | 232 | 7.01% | 0.38% | 2.16% |

2016 Checklist Edition Update



2016 Checklist Edition Update

- **Commenting period is currently open**
- **Changes will include:**
 - **New ex vivo microscopy requirements (Anatomic Pathology)**
 - **Updated personnel requirements (Laboratory General)**
 - **Updates to address new FDA guidance on bacterial contamination in platelets (Transfusion Medicine)**
 - **Updates to Personnel Roster**

2016 Checklist Edition Update Continued

- **Changes will include (continued):**
 - **Standardized set of requirements for inspection of in situ hybridization methods, including FISH, CISH, SISH and BRISH (Anatomic Pathology, Cytogenetics, and Molecular Pathology)**
 - **Expanded telepathology section to include remote data assessment (Laboratory General)**
 - **Updated/reformatted record retention requirements to be more complete and consistent (Multiple checklists)**
- **Anticipate a July 2016 release**

Accreditation

- **The Top 10 Deficiencies**
- **Recurring Deficiencies**
- **Best Practices**

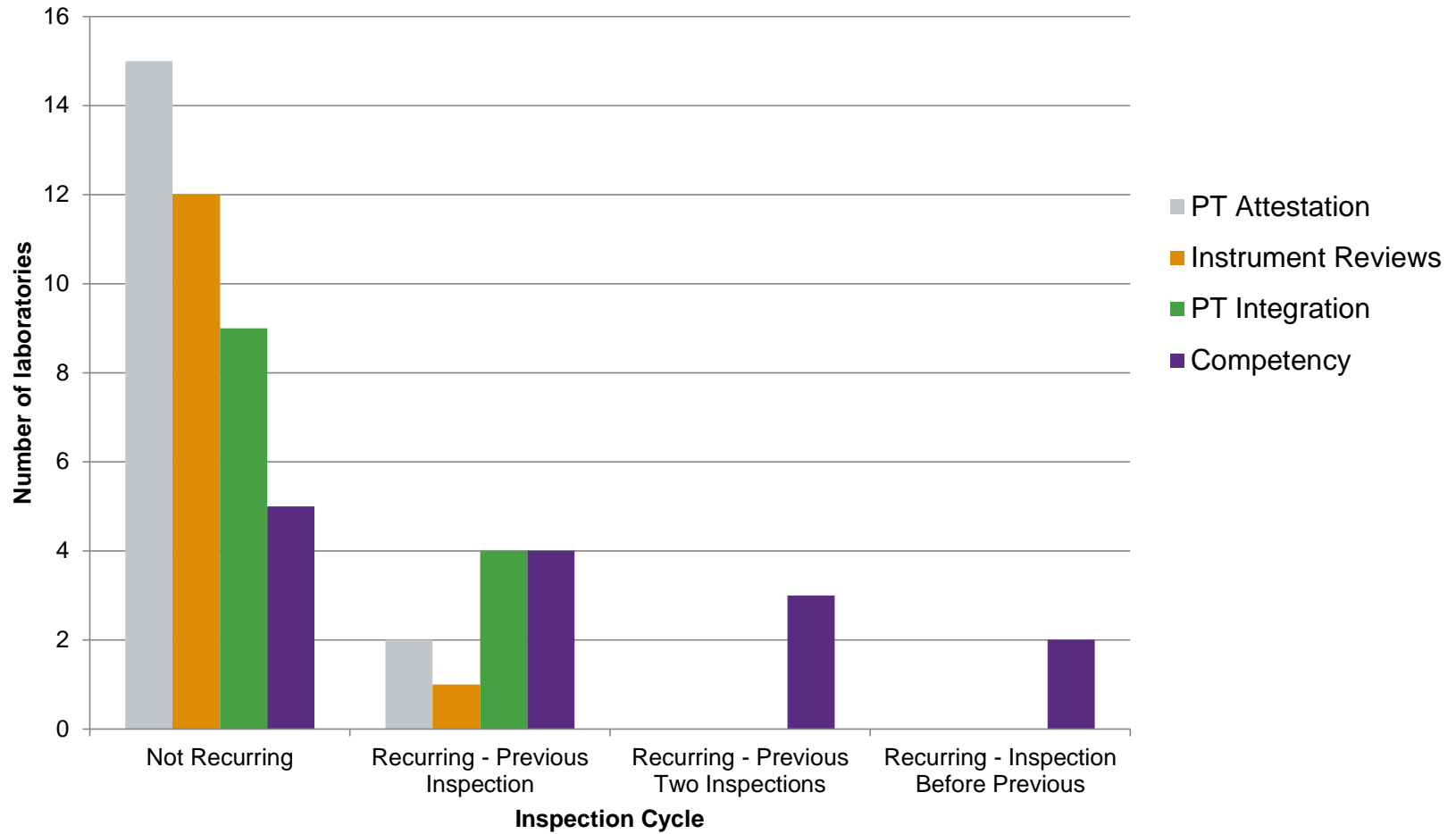


Top Ten Deficiencies

| Checklist Requirement | CAP-Wide | CAP System Inspection | Laboratory Networks |
|--|----------|-----------------------|---------------------|
| COM.01400 – PT Attestation Signature | 1 | 8 | 5 |
| GEN.55500 – Competency Assessment | 2 | 1 | 2 |
| COM.04200 – Instrument and Equipment Monthly Review | 3 | 6 | 10 |
| COM.01600 – PT Integration into Workload | 4 | N/A | N/A |
| COM.30450 – New Lot Confirmation | 5 | N/A | N/A |
| POC.06910 – Competency Assessment- Non-waived | 6 | N/A | N/A |
| COM.01200 – Activity Menu | 7 | 2 | 1 |
| COM.30300 – Reagent Labeling | 8 | 9 | 6 |
| COM.01700 – PT Evaluation | 9 | 4 | 4 |
| COM.10000 – Complete Procedures | 10 | 3 | 3 |

*Based on 2014/15 data
N/A- not in top ten

Recurring Deficiencies



Best Practices

COM.01400 Attestation Statement

The proficiency testing attestation statement is signed by the laboratory director or designee and all individuals involved in the testing process.

- **Physical signatures must be present**
- **Must be on the original attestation page**
- **High complexity- technical supervisor/section director**
- **Moderate complexity- technical consultant**

Attestation Statement Continued

Delegation

- **CLIA requires special qualifications for technical supervisor in:**

- **Transfusion Medicine**
- **Cytopathology, Cytogenetics**
- **Histopathology, Oral pathology**
- **Histocompatibility (493.1449)**

For these specialties, required qualifications include being a **physician and/or doctoral scientist**

GEN.55500 & POC.06910 Competency Assessment

Competency of each person performing patient testing to perform his/her assigned duties is assessed



Competency Assessment

For nonwaived testing, competency assessment must include all **6 elements** for each test system :

- **Direct observations test performance**
- **Monitoring recording and reporting of test results**
- **Review of intermediate test results or worksheets**
- **Direct observation of instrument maintenance & function checks**
- **Employee analysis of PT or blind sample**
- **Evaluation of problem-solving skills**

Competency Assessment Continued

For waived testing:

- **Assessed annually (semiannual assessment not required)**
- **Laboratory choice**

For nonwaived testing:

- **Assessed semiannually 1st year only for new employees**
- **All 6 elements for each test system**

Competency Assessment Continued

- **Qualifications of Assessors**
 - **Qualify via education and experience for test complexity**
 - **High Complexity - assessed by section director, or individual meeting general supervisor requirements**
 - **Moderate Complexity - Technical consultant**
 - **Waived Complexity – Laboratory Director decision**

Competency Assessment Continued

- **Test System**

- **Laboratory must identify each test system**
- **Test System includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results**
- **Test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment or instruments required to produce results**
- **Test system may encompass multiple identical analyzers or devices**
- **Different test systems may be used for the same analyte**

COM.04200 Instrument/Equipment Review

- **Assessed at least monthly**
 - Signature, initials and date required
- **Ensure all maintenance form templates include reviewed by and date**
- **Effective review with corrective actions for missing maintenance and records**
- **Includes centrifuges, microscopes, temperature logs**
 - Implement a checkoff list of equipment to review, especially those manual things that get forgotten

COM.01600 PT Integration

- **Integrated into workload**
- **Routine testers (all shifts)**
- **Use Primary method**



Duplicate analysis of any proficiency sample is acceptable only if patient/client specimens are routinely analyzed in the same manner

COM.30450 New Reagent Lot Confirmation of Acceptability

- **New reagent lots and shipments are checked against old reagent lots/shipments with suitable reference material before or concurrently with being placed in service**
 - Patient samples, reference materials
 - QC products
 - Proficiency testing materials

Best Practice

- **Ensure tracking of lots and shipments with dates verified**
- **Design system that is easy to use and review records versus lots in use periodically**

Other LAP Updates

CAP Quality Cross Check

- **Is a quality assurance program**
- **Use in fulfilling the competency assessment requirement**
- **Instrument comparability program**
 - customized reports based on peer group and instrument comparability statistics
- **Is compliant with CMS directive for multiple PT instrument reporting**
- **Three challenges/two shipments a year**
- **Several new programs added in 2016**

LAP Resource Roadmaps

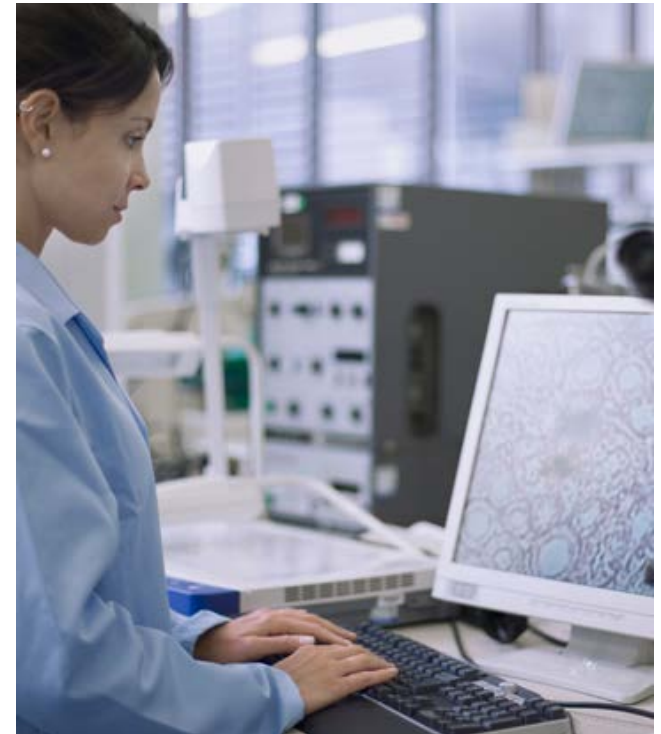
- **Overview of the lab accreditation and inspection process**
- **Describes key resources and personnel available to assist customers and inspectors at each stage**
- **Located in e-LAB solutions Suite (ELSS)**

LAP Resource Roadmaps

- **List of LAP Resource Roadmaps Available**
 - **CAP Accreditation Resources for Laboratories Seeking First-time Accreditation**
 - **CAP Accreditation Resources for Accredited Laboratory and Laboratory Reapplying for Accreditation**
 - **CAP Accreditation Resources for the Inspector**

Questions?

- **Contact CAP at 1-800-323-4040, ext. 6065**
- **Send email inquiries to accred@cap.org**
- **Contact Becky Damiani at rdamian@cap.org**



Thank you!



COLLEGE of AMERICAN
PATHOLOGISTS