New Directions in the Laboratory Accreditation Program

What’s New in LAP

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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

*Focus group 2014
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
Monitor consistency and standardization: Personalize reporting groups
Take immediate actions & look for trends at the Accreditation and PT dashboards

- Color coded alerts to take immediate actions
- Apply filters to access only the data you need
- Look for trends and comparisons

Dashboard with options for selecting views such as Site List, Proficiency Testing, Accreditation, Analyte Scorecard, Report Links, and Party Page.

Profiency Testing Performance Overview:
- Acceptable Proficiency Testing by Year and Group

Accreditation Performance Overview:
- Deficient Accreditation Performance By Cycle and Group

Graphs showing data analysis with bars and percentages.
Perform in-depth analysis with more than 20 reports

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.
Be ready for accreditation inspections

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.
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
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

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

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

Inspection Cycle

Not Recurring  Recurring - Previous Inspection  Recurring - Previous Two Inspections  Recurring - Inspection Before Previous

Number of laboratories

0 2 4 6 8 10 12 14 16

PT Attestation  Instrument Reviews  PT Integration  Competency
Best Practices
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
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

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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!