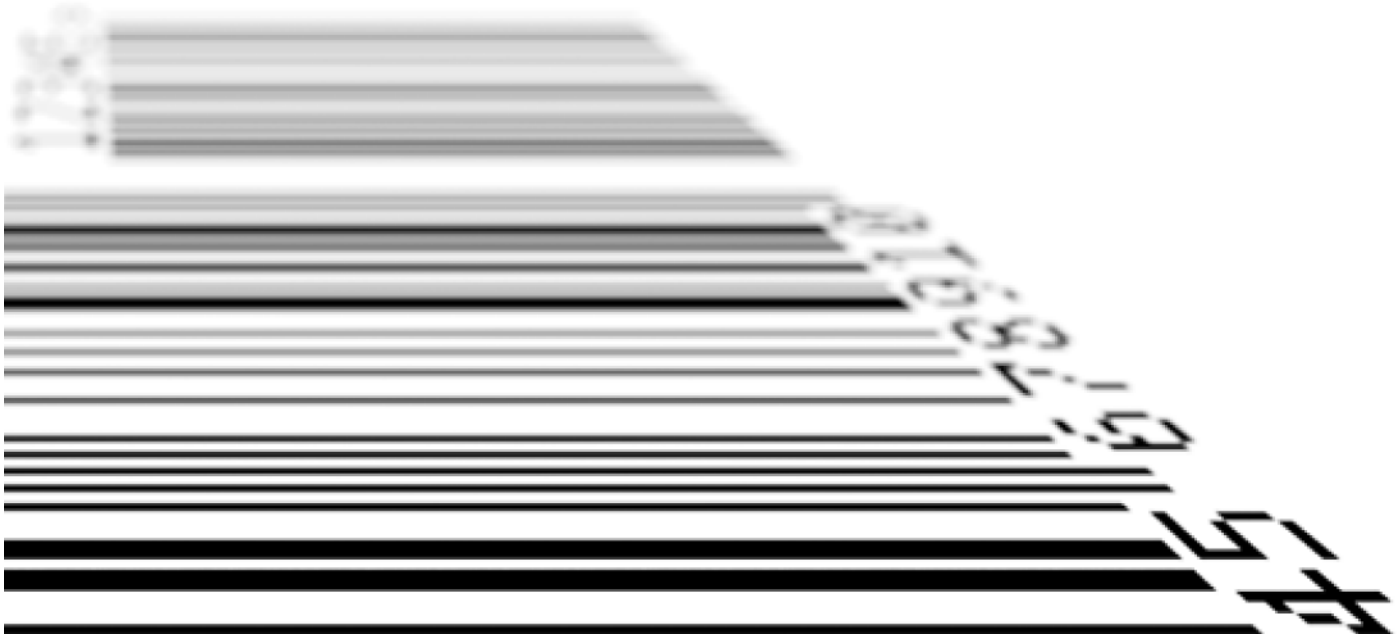
Every number is a life.™

CAP Accreditation Update

Jean Ball MBA,
MT(HHS),MLT(ASCP)
Lead Inspection Specialist



Learning Objective

1. Describe recent changes to the CAP Laboratory Accreditation Program

2. Explain recent updates to the LAP inspection checklists including the rationale for the changes

3. Describe CAP website resources to include Laboratory Improvement Programs

CAP Checklist "Freeze" 9/2007- 3/2009

As condition of an accreditation organization's deemed status under CLIA'88, CMS is required to evaluate the organization's requirements at a maximum interval of every 6 years to assure that stringency is at least equal to CLIA-88 regulations (42CFR493.553(C)).

Criteria for Adding New Checklist Requirements

- New technology/science
- Regulatory requirements
- Significant contribution to quality
- Burden on laboratory (i.e., cost-benefit)
- Medical legal implications
- Significant proportion of checklist revisions come from accredited labs/inspectors

Checklist Revisions for 2009 Highlights

- Focus on personnel qualifications, with instructions to inspectors
- Test method comparison will include qualitative and quantitative tests;
  - Requirement is to define relationship, not that different methods give same result;
  - Applies only within a single CLIA number
- New checklist requirement to verify concentration methods in addition to diluting procedures
- Manual cell count controls for blood and body fluids

Checklist Revisions for 2009 – Procedure Manual

Procedure manual contents must reflect CLIA, **as applicable** (493.1251):

1. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection
2. Microscopic examination, including the detection of inadequately prepared slides.
3. Step-by-step performance of the procedure, including test calculations and interpretation of results.

Checklist Revisions for 2009 – Procedure Manual

4. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.
5. Calibration and calibration verification procedures.
6. The reportable range for test results for the test system
7. Control procedures.
8. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability
9. Limitations in the test methodology, including interfering substances.

Checklist Revisions for 2009 – Procedure Manual

10. Reference intervals (normal values)
11. Imminently life-threatening (critical) test results
12. Pertinent literature references.
13. The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening (critical) results
14. Description of the course of action to take if a test system becomes inoperable

2009 CAP Checklists

- CMS Deemed Status Approval
- Checklists to be released (Summer 2009)
- Access behind e-*LAB* Solutions

- What's New…..?

What's NEW in Laboratory General?

- Enhanced introduction to Test Method Validation section
- Qualitative tests: Establish/verify only relevant elements—e.g., accuracy; analytic sensitivity (drug test)
- Matrices other than blood (body fluids)
- Laboratory-developed tests
- Summary of MPS approved by director

What's NEW in Laboratory General?

- Direct-to-consumer testing
- Reference laboratories – For disciplines **not** subject to CLIA (e.g., histology), must refer to CAP-accredited or CAP-accepted laboratory

What's NEW in Transfusion Medicine?

- Apheresis section divided into 3 sections: apheresis, general, therapeutic apheresis, donor apheresis
- Therapeutic phlebotomy section expanded
- Elution studies- alternative PT assessment required

What's NEW in Molecular Microbiology?

- More extensive, detailed Mol Micro section added to MIC checklist
- All molecular microbiology testing inspected with Microbiology checklist
- Molecular section of MIC checklist need not be used to inspect non-amplified FDA-approved/cleared tests run directly on cultures—can use Mycobacteriology and Mycology sections of MIC.

What's NEW in Anatomic Pathology?

- Digital imaging section
- Synoptic reporting of cancer cases

How Often is “Periodic?”

“Periodic” Defined!

- This word being replaced in all checklists by “at least annually”
- Note that there are some requirements with different time interval requirements
  - AMR validation—6 months
  - Validation of calculations by LIS—2 years
- Exception: “periodically” may still be found in LIS section in GEN

A NEW CAP Checklist in 2010!

- New Numbering Schema
- New Format

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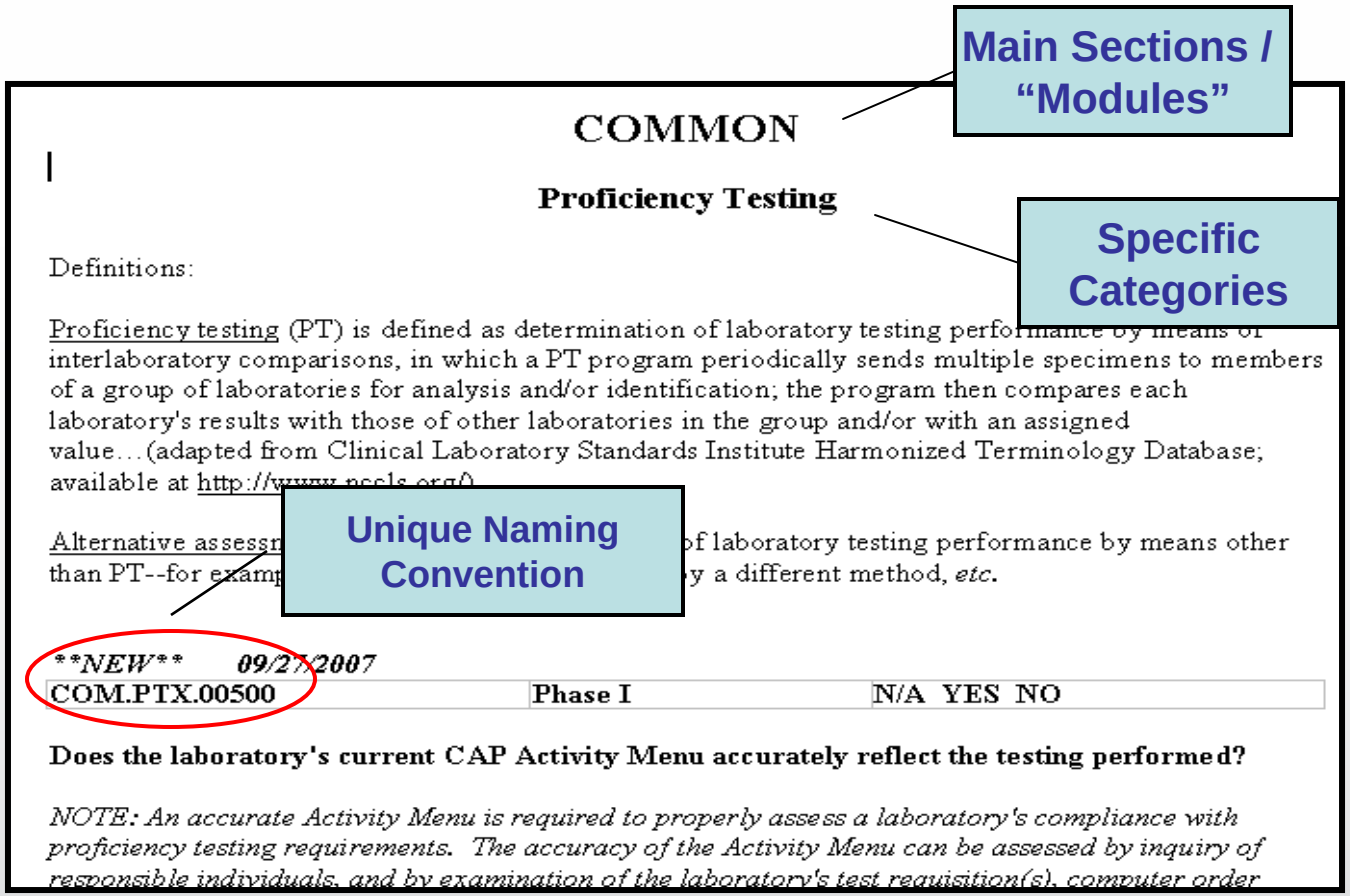
New Checklist Numbering Schema - 2010

- Checklist organized by main “modules” or sections.
- Key sections are further arranged into smaller, manageable categories that contain requirements of a related nature, i.e., proficiency testing, quality control

New Numbering Schema



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New Checklist Format – 2010

Reducing redundancy of requirements:

- Certain requirements appear in multiple checklists; includes topics such as procedure manual, quality management, quality control, reagent handling, proficiency testing, results reporting

- Requirements identified as “Common” will be provided once for each department or Section Unit and will appear in a “Common” module

New Checklist Format - 2010

- Checklist requirements listed once per Section Unit
- Less deficiencies cited
- More organized, streamlined inspection

CAP Website Resources

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e-*LAB* Solutions

e-*LAB* Solutions
- Proficiency Testing/ Quality Management
- Laboratory Accreditation
- Competency Assessment
- Administration Options

Personalized Options
- Education Transcript
- Pay Dues Online
- Admin Tools
- Change My Password
- Update My Profile

Online Submission
- Web Content

Logout

Save time with newly added LAP online features!

Join nearly 10,000 laboratories that have made e-*LAB* Solutions a part of their daily activities!

- Access Laboratory Accreditation Program Information
- Access Proficiency Testing Program Information

What is e-*LAB* Solutions?
- View frequently asked questions
- Getting started with e-*LAB* Solutions (PDF, 1,000 K)

ONLINE FEATURES

ACCREDITATION
- **NEW** Customized Checklists
- My Lab's Activity Menu
- Checklist Selection Report
- Missing PT Enrollment Report
- Test Menu Change Form

PROFICIENCY TESTING
- Enter Data
- View Results
- Access Management Reports

Electronic Data Entry Forms
- Reduce clerical errors with pre-populated forms with drop-down instrument, reagent, and method selections
- Correct clerical errors due to scanning or faxing prior to evaluation and avoid unnecessary PT failures
- E-mail notifications if the CAP has not received your data

Online Evaluations and Reports
- Receive your evaluation up to 10 days sooner online
- Access images online

Custom Management Reports
- Take a quick look at your laboratory's performance across up to six mailings

Competency Assessment Program
- Learn more about the program
- Access Program

Quality Management Tools
- Learn more about the program (PDF, 702 K)

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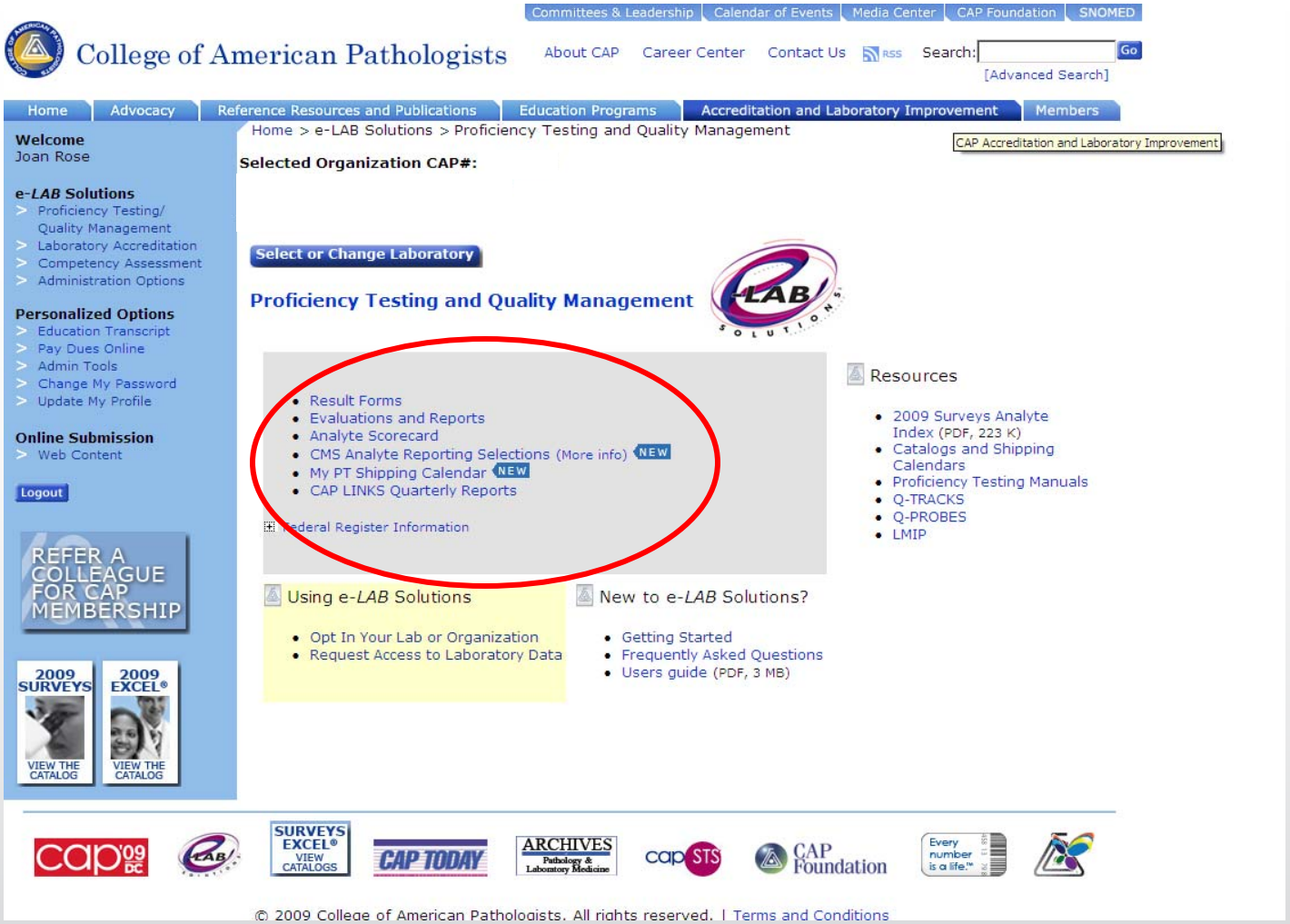
e-*LAB* Solutions Features

- Proficiency Testing and Quality Management:
  - Result forms
  - Evaluations and Reports
  - Analyte Scorecard
  - CMS Analyte Reporting Selections
  - My PT Shipping Calendar

- Laboratory Accreditation:
  - Master and Custom Checklists
  - Activity Menu with PT Options
  - Missing PT Enrollment Report

e-*LAB* Solutions – Proficiency Testing



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e-*LAB* Solutions – Laboratory Accreditation

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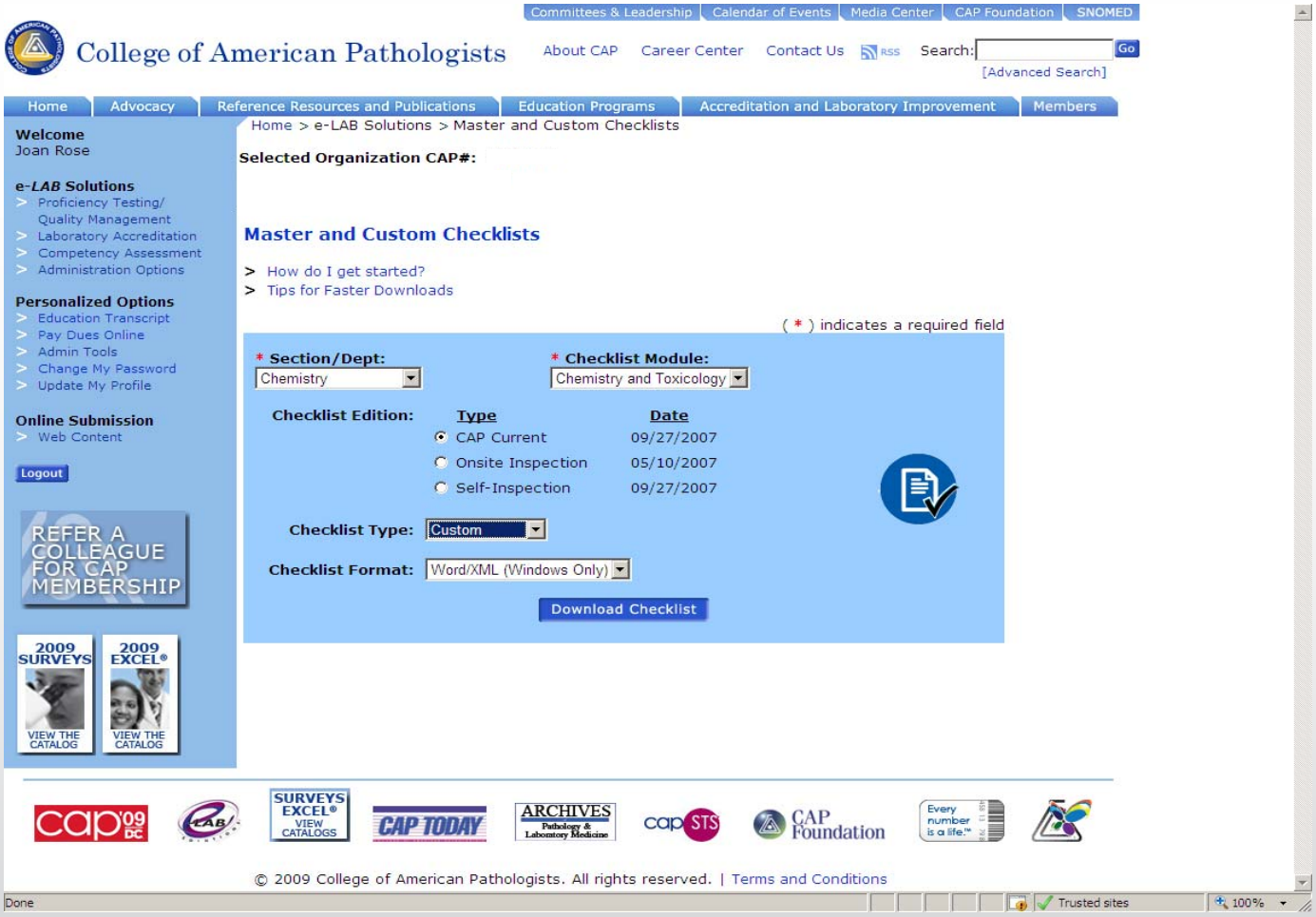
e-*LAB* Solutions Master and Custom Checklists



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CAP Checklists-Word/XML Format

CHM.11200	Phase II	N/A YES NO

Does the director (or a designee who meets CAP director qualifications) review and approve all new policies and procedures, as well as substantial changes to existing documents, before implementation?

NOTE: Current practice must match the policy and procedure documents.

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):7164 [42CFR493.1251(d)]

CHM.11300	Phase II	N/A YES NO

Does the laboratory have a system documenting that all personnel are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities?

NOTE: The form of this system is at the discretion of the laboratory director. Annual procedure sign-off by testing personnel is not specifically required.

CHM.11400	Phase II	N/A YES NO

If there is a change in directorship, does the new director ensure (over a reasonable period of time) that laboratory procedures are well-documented and undergo at least annual review?

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):7164 [42CFR493.1251(d)]

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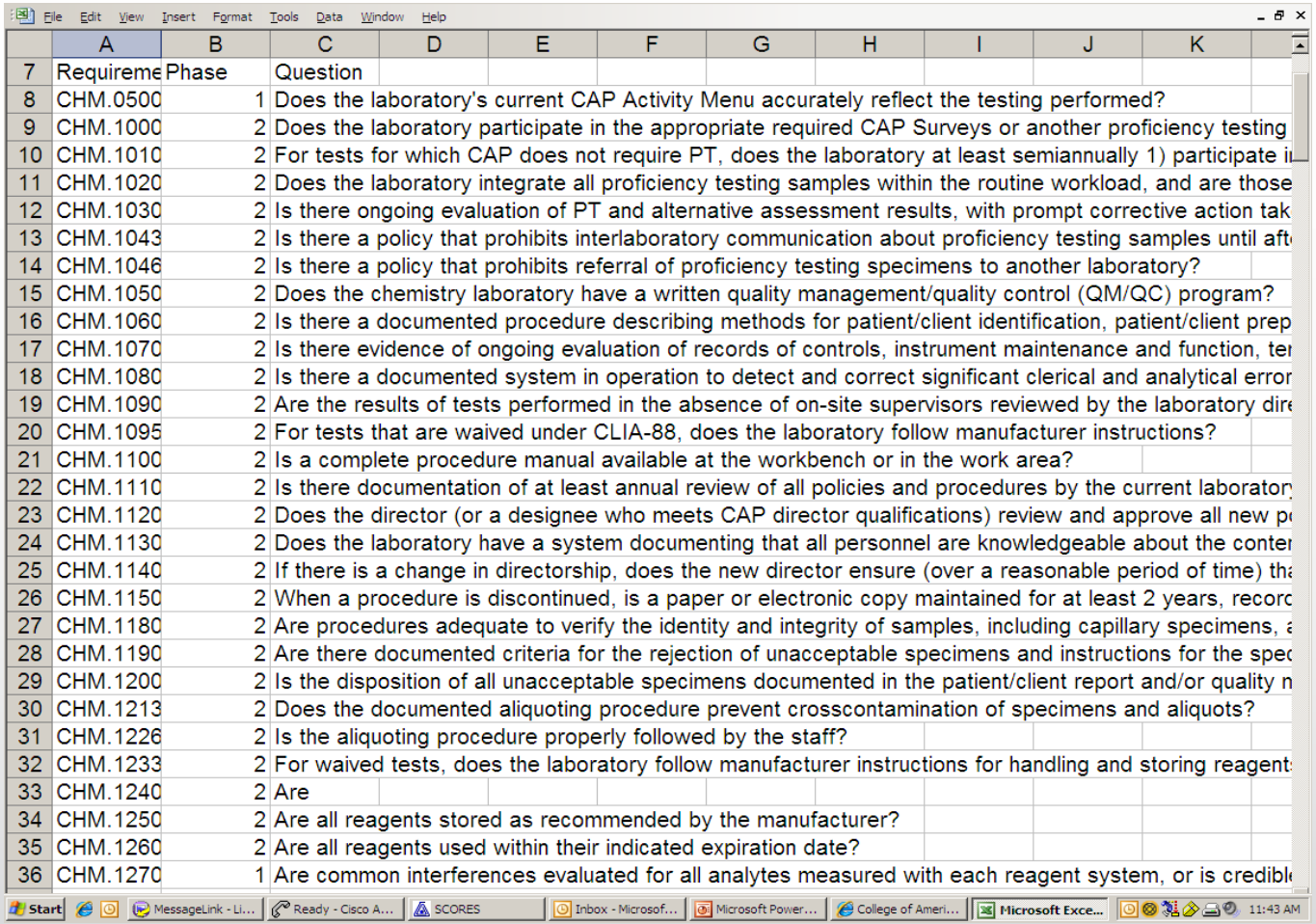
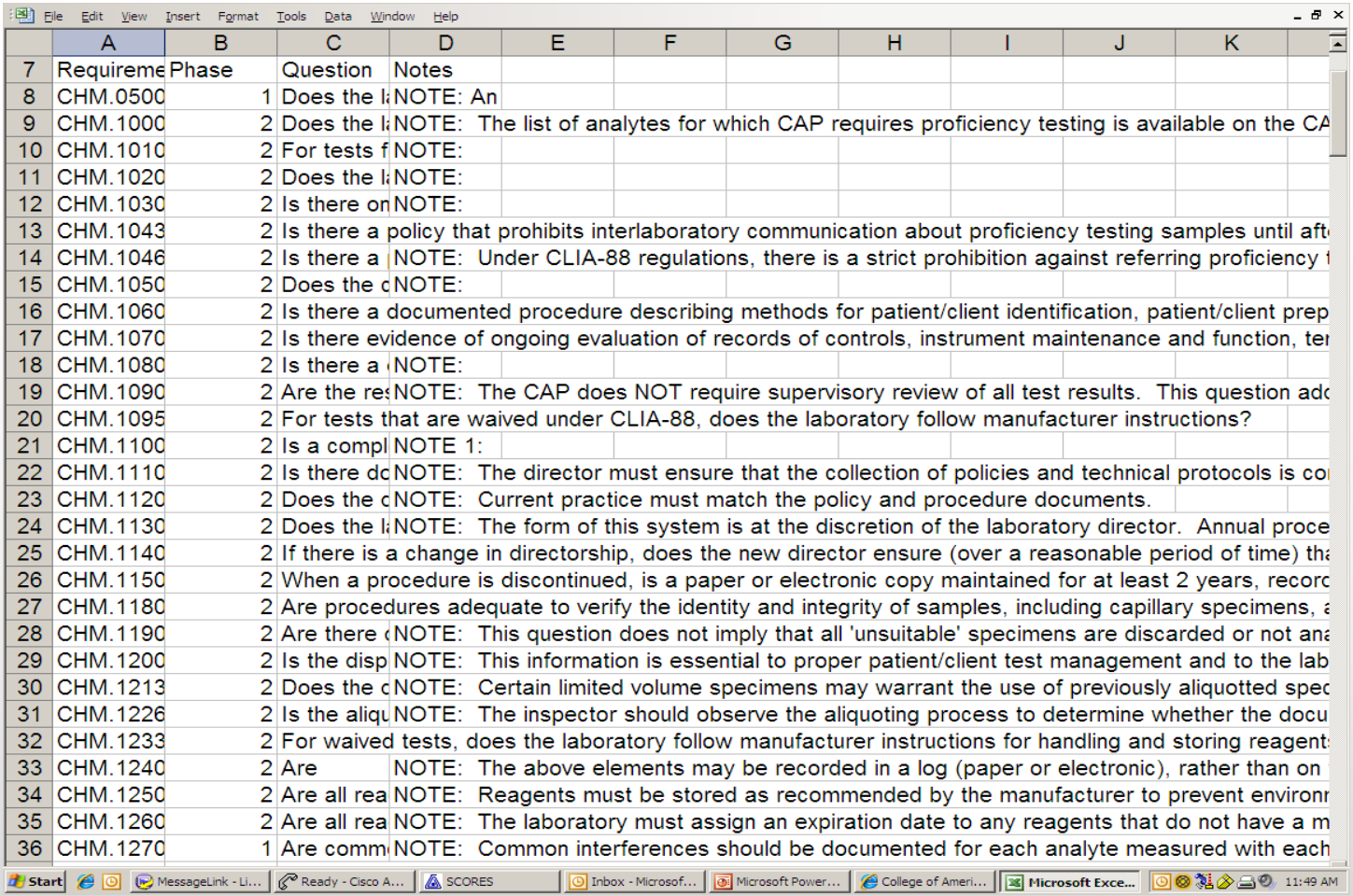
CAP Checklists-Excel/CSV Format (short)



	A	B	C
7	Requireme	Phase	Question
8	CHM.0500	1	Does the laboratory's current CAP Activity Menu accurately reflect the testing performed?
9	CHM.1000	2	Does the laboratory participate in the appropriate required CAP Surveys or another proficiency testing
10	CHM.1010	2	For tests for which CAP does not require PT, does the laboratory at least semiannually 1) participate i
11	CHM.1020	2	Does the laboratory integrate all proficiency testing samples within the routine workload, and are those
12	CHM.1030	2	Is there ongoing evaluation of PT and alternative assessment results, with prompt corrective action tak
13	CHM.1043	2	Is there a policy that prohibits interlaboratory communication about proficiency testing samples until aft
14	CHM.1046	2	Is there a policy that prohibits referral of proficiency testing specimens to another laboratory?
15	CHM.1050	2	Does the chemistry laboratory have a written quality management/quality control (QM/QC) program?
16	CHM.1060	2	Is there a documented procedure describing methods for patient/client identification, patient/client prep
17	CHM.1070	2	Is there evidence of ongoing evaluation of records of controls, instrument maintenance and function, ter
18	CHM.1080	2	Is there a documented system in operation to detect and correct significant clerical and analytical error
19	CHM.1090	2	Are the results of tests performed in the absence of on-site supervisors reviewed by the laboratory dire
20	CHM.1095	2	For tests that are waived under CLIA-88, does the laboratory follow manufacturer instructions?
21	CHM.1100	2	Is a complete procedure manual available at the workbench or in the work area?
22	CHM.1110	2	Is there documentation of at least annual review of all policies and procedures by the current laboratory
23	CHM.1120	2	Does the director (or a designee who meets CAP director qualifications) review and approve all new pr
24	CHM.1130	2	Does the laboratory have a system documenting that all personnel are knowledgeable about the conter
25	CHM.1140	2	If there is a change in directorship, does the new director ensure (over a reasonable period of time) tha
26	CHM.1150	2	When a procedure is discontinued, is a paper or electronic copy maintained for at least 2 years, recorc
27	CHM.1180	2	Are procedures adequate to verify the identity and integrity of samples, including capillary specimens, a
28	CHM.1190	2	Are there documented criteria for the rejection of unacceptable specimens and instructions for the spec
29	CHM.1200	2	Is the disposition of all unacceptable specimens documented in the patient/client report and/or quality n
30	CHM.1213	2	Does the documented aliquoting procedure prevent crosscontamination of specimens and aliquots?
31	CHM.1226	2	Is the aliquoting procedure properly followed by the staff?
32	CHM.1233	2	For waived tests, does the laboratory follow manufacturer instructions for handling and storing reagent
33	CHM.1240	2	Are
34	CHM.1250	2	Are all reagents stored as recommended by the manufacturer?
35	CHM.1260	2	Are all reagents used within their indicated expiration date?
36	CHM.1270	1	Are common interferences evaluated for all analytes measured with each reagent system, or is credibl

CAP Checklists-Excel/CSV Format (long)



	A	B	C	D
7	Requireme	Phase	Question	Notes
8	CHM.0500	1	Does the l	NOTE: An
9	CHM.1000	2	Does the l	NOTE: The list of analytes for which CAP requires proficiency testing is available on the CA
10	CHM.1010	2	For tests f	NOTE:
11	CHM.1020	2	Does the l	NOTE:
12	CHM.1030	2	Is there on	NOTE:
13	CHM.1043	2	Is there a policy that prohibits interlaboratory communication about proficiency testing samples until aft	
14	CHM.1046	2	Is there a	NOTE: Under CLIA-88 regulations, there is a strict prohibition against referring proficiency t
15	CHM.1050	2	Does the c	NOTE:
16	CHM.1060	2	Is there a documented procedure describing methods for patient/client identification, patient/client prep	
17	CHM.1070	2	Is there evidence of ongoing evaluation of records of controls, instrument maintenance and function, ter	
18	CHM.1080	2	Is there a	NOTE:
19	CHM.1090	2	Are the res	NOTE: The CAP does NOT require supervisory review of all test results. This question adc
20	CHM.1095	2	For tests that are waived under CLIA-88, does the laboratory follow manufacturer instructions?	
21	CHM.1100	2	Is a compl	NOTE 1:
22	CHM.1110	2	Is there dc	NOTE: The director must ensure that the collection of policies and technical protocols is co
23	CHM.1120	2	Does the c	NOTE: Current practice must match the policy and procedure documents.
24	CHM.1130	2	Does the l	NOTE: The form of this system is at the discretion of the laboratory director. Annual proce
25	CHM.1140	2	If there is a change in directorship, does the new director ensure (over a reasonable period of time) tha	
26	CHM.1150	2	When a procedure is discontinued, is a paper or electronic copy maintained for at least 2 years, recorc	
27	CHM.1180	2	Are procedures adequate to verify the identity and integrity of samples, including capillary specimens, a	
28	CHM.1190	2	Are there	NOTE: This question does not imply that all 'unsuitable' specimens are discarded or not ana
29	CHM.1200	2	Is the disp	NOTE: This information is essential to proper patient/client test management and to the lab
30	CHM.1213	2	Does the c	NOTE: Certain limited volume specimens may warrant the use of previously aliquotted spec
31	CHM.1226	2	Is the aliqu	NOTE: The inspector should observe the aliquoting process to determine whether the docu
32	CHM.1233	2	For waived tests, does the laboratory follow manufacturer instructions for handling and storing reagent	
33	CHM.1240	2	Are	NOTE: The above elements may be recorded in a log (paper or electronic), rather than on
34	CHM.1250	2	Are all rea	NOTE: Reagents must be stored as recommended by the manufacturer to prevent environr
35	CHM.1260	2	Are all rea	NOTE: The laboratory must assign an expiration date to any reagents that do not have a m
36	CHM.1270	1	Are comm	NOTE: Common interferences should be documented for each analyte measured with each

e-*LAB* Solutions Activity Menu with PT Options

LAMT_LAMS - Windows Internet Explorer provided by College of American Pathologists

Contents First Prev Next Last Goto Page 1 of 2 100% Excel Export PDF Export Print

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Advancing Excellence

Laboratory Accreditation Program
Laboratory Activity Menu

SU: 1482853 - Hematology

Page 1 of 2
03/13/2009 11:35 AM

CAP Number:
Laboratory:
City/State(Province):

Checklist Selection Report
Master Activity Menu
Missing PT Enrollment Report
PT Enrollment Guide
Test Menu Change Form

Department /Section: Hematology

Subdiscipline	Test/Activity	Test / Activity ID	PT Required	Alternative Assessment Required	Scope of Service/Analytic Method	2009 Missing PT Enrollment
Body Fluid Analysis	Body fluid cell count, manual	2094	Y			
Body Fluid Analysis	Body fluid differential/cell identification	2095	Y			
Coagulation	D-dimer, quantitative	2273	Y			
Coagulation	Fibrinogen	1302	Y			
Coagulation	PT, plasma	1303	Y			
Coagulation	PTT, plasma	1305	Y			
Hematology	Bone marrow collection (assist)	806			Y	
Hematology	ESR, manual, waived	2696		Y		
Hematology	Hematocrit, non-waived	2722	Y			
Hematology	Hemoglobin, non-waived	197	Y			
Hematology	nRBC count, automated	2186		Y		
Hematology	Platelet count, automated	198	Y			
Hematology	RBC count	201	Y			
Hematology	RBC indices (e.g. MCV, RDW)	219		Y		
Hematology	Reticulocyte count, automated	2895	Y			
Hematology	Reticulocyte count, manual	2896	Y			
Hematology	WBC count, automated	203	Y			
Hematology	WBC differential, automated	2898	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.

College of American Pathologists

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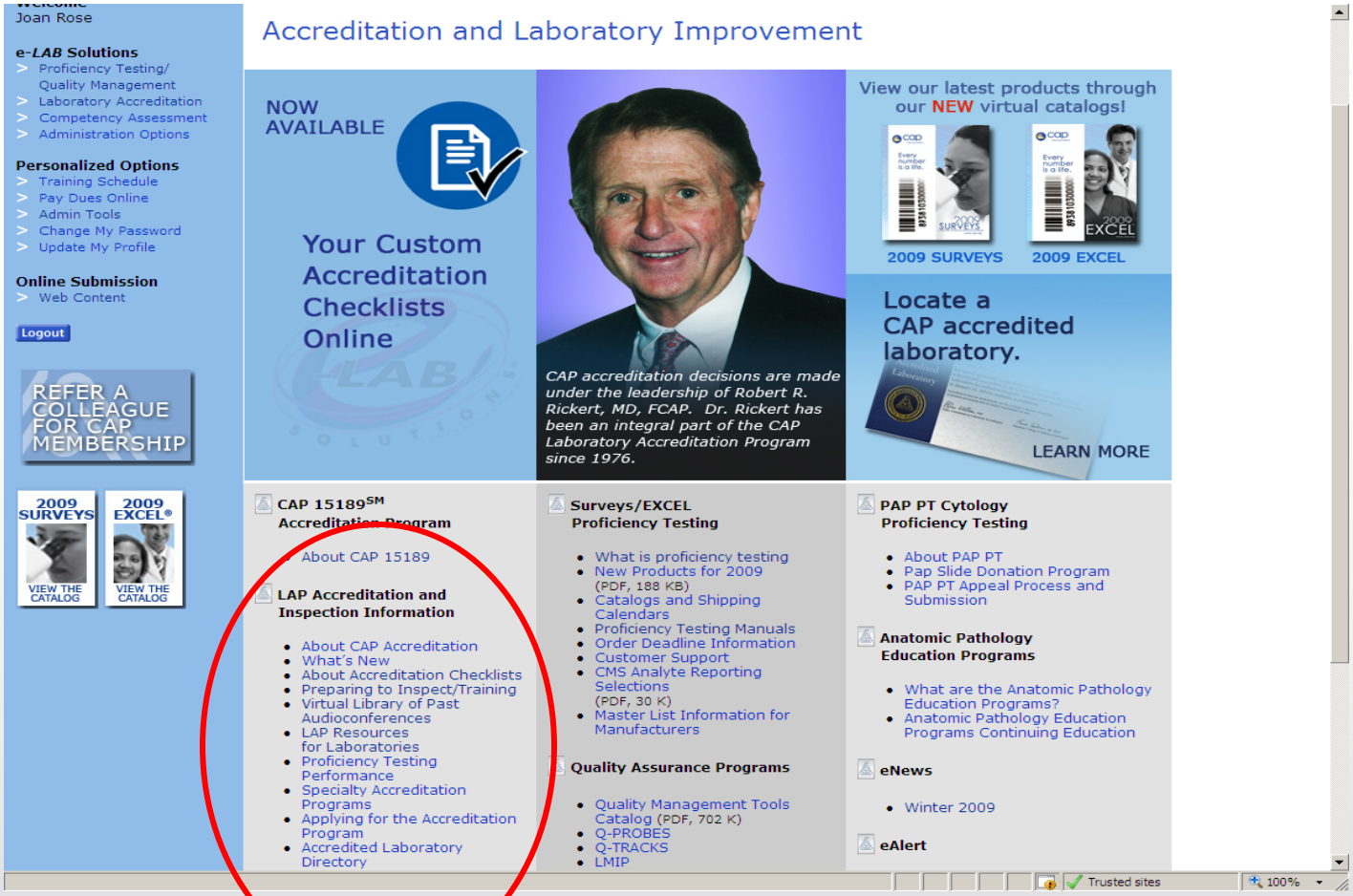
Accreditation Resources



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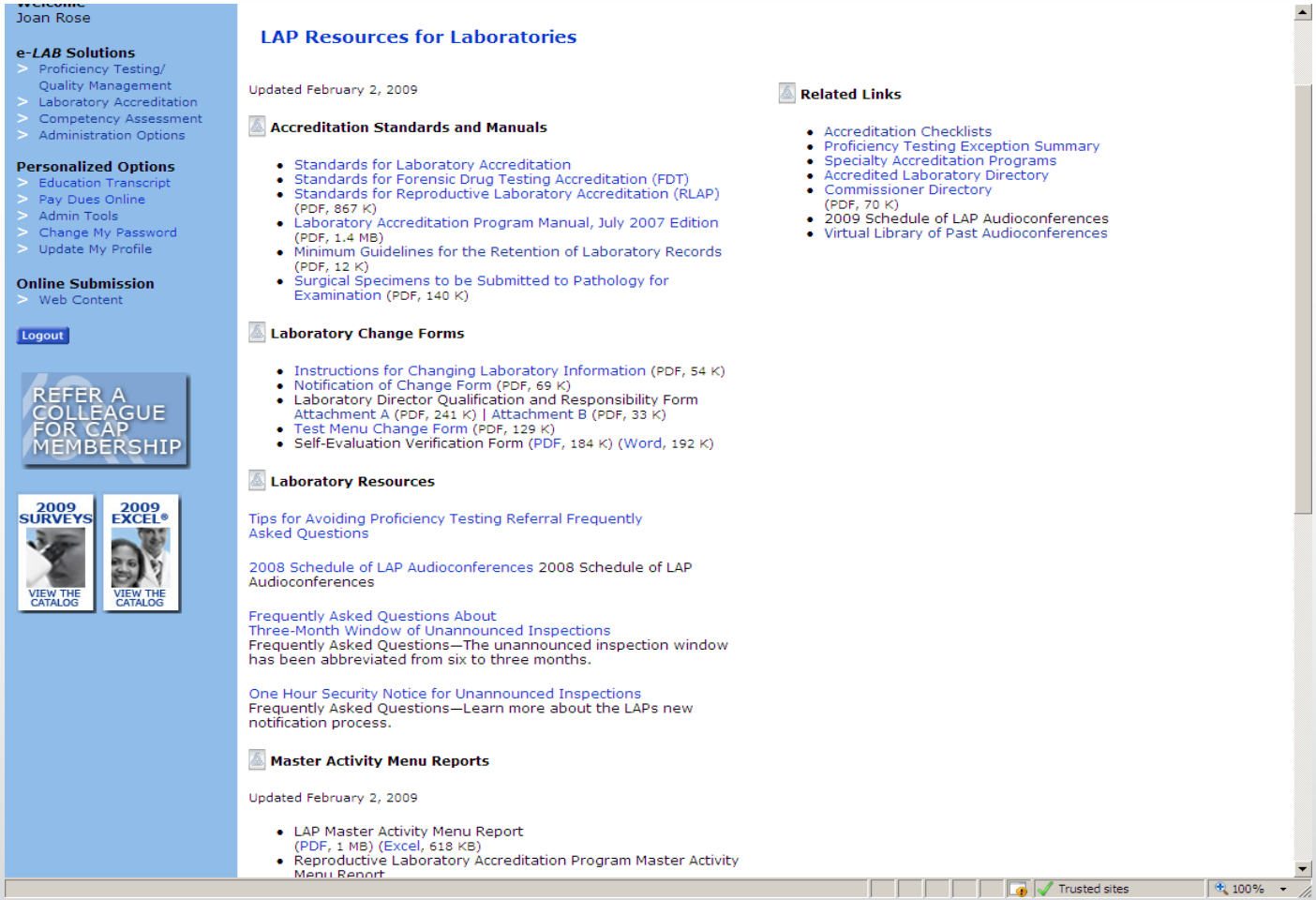
LAP Resources for Laboratories

- Accreditation Standards and Manuals
- Laboratory Change Forms
- Master Activity Menu Reports
- Deficiency Responses and Root Cause Analysis Template

Accreditation Resources – LAP Resources for Laboratories



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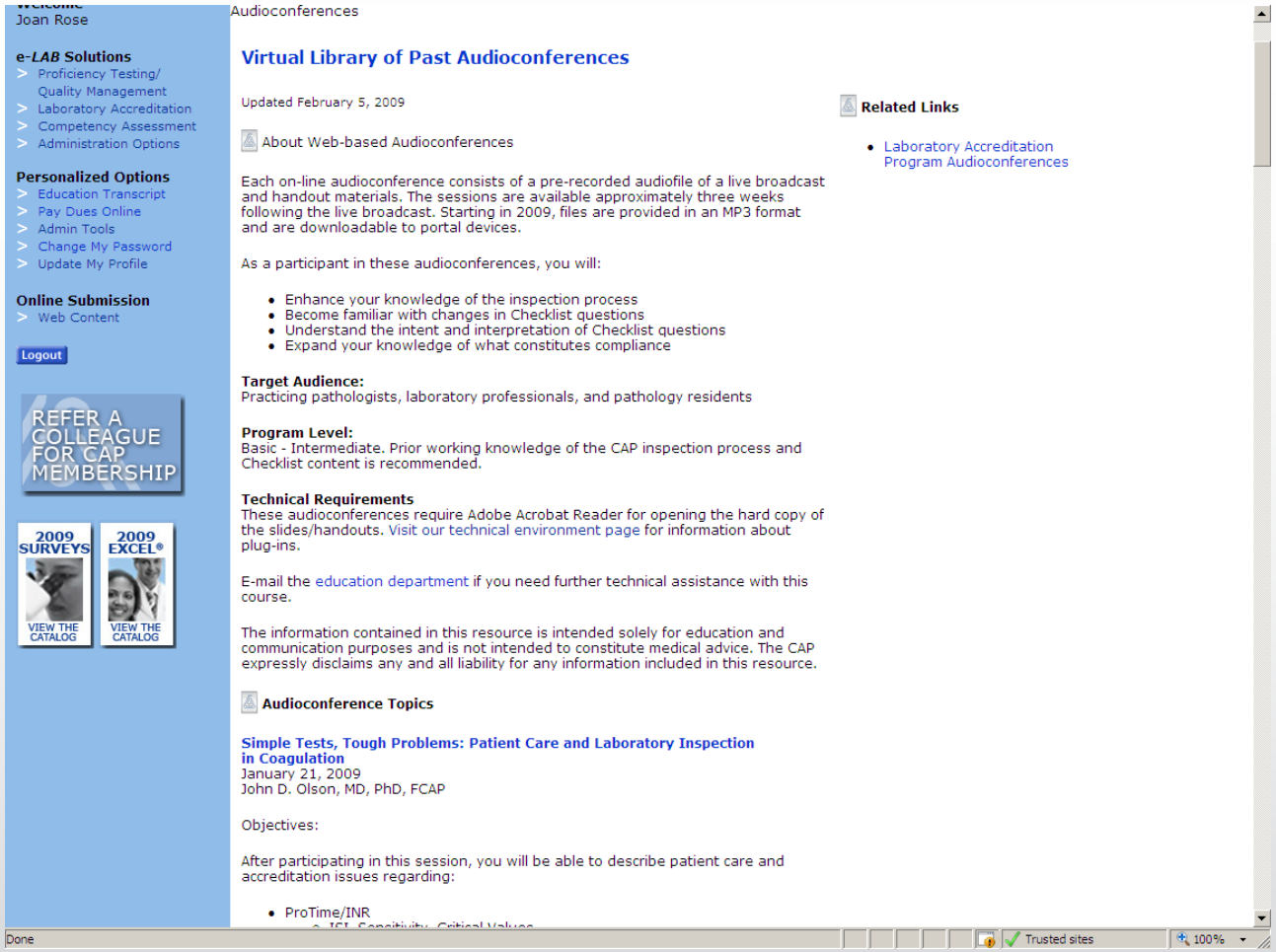
Accreditation Resources – Virtual Library of Past Audioconferences



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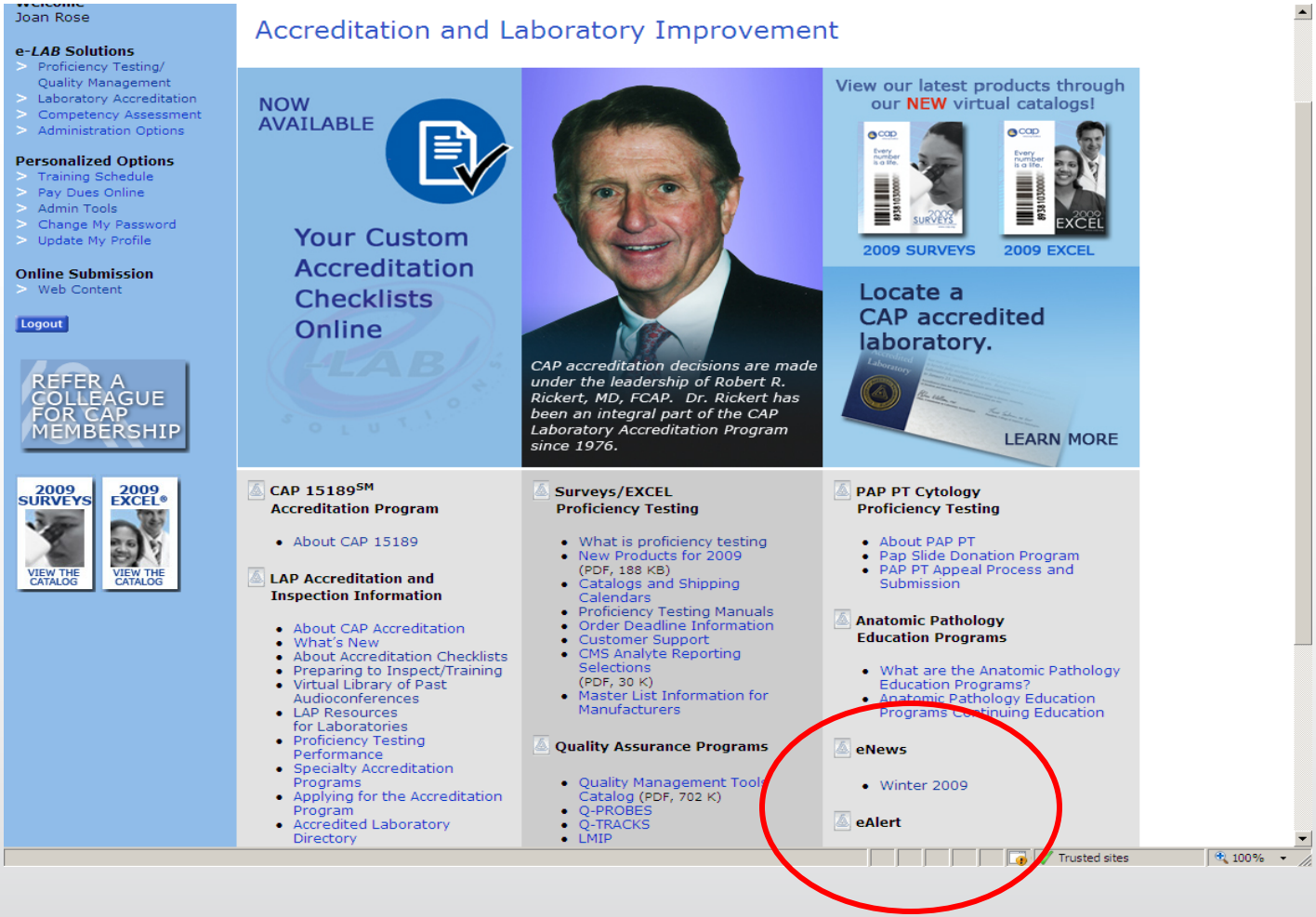
Accreditation Resources



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Accreditation Resources - eAlert

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Accreditation Resources - eNews

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CAP Education Resources

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Education Programs

Course Catalog

Search/View all courses

Access the links to view course details

- Accreditation Education Activities
- Anatomic Pathology
- Annual Meetings
- *Archives* Test Your Memory Program
- EXCEL
- Practice Management
- Q-PROBES and Q-TRACKS
- Surveys
- SNOMED Terminology Solutions

Education Resources

- **Frequently Asked Questions** (HTML | PDF | Microsoft Word)
- **Quick Guide** (PDF)
- Visual Tours COMING SOON
- Technical Requirements

Featured Education Programs

Competency Assessment Program

The most convenient and comprehensive competency assessment program that you can order for your laboratory.
Details on Competency

Maintenance of Certification

The board certification program for assessment of continuing competence of physicians...
Details on MOC

SNOMED Terminology Solutions

The world's leading and most trusted resource for SNOMED CT expertise and advice. We can help you achieve the clinical and business outcomes enabled by SNOMED CT and other clinical medical terminologies and classifications...
Details on CAP STS

What's New

2009 VBP-A Lung Lesions

CPT Coding Tutorial

Team Leader Update Training

New from CAP Press

CAP Practical Guide to Gynecologic Cytopathology

An Algorithmic Approach to Hemostasis Testing

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Learning Management System – Continuing Education CME/CE

Accreditation Education Activities

- Inspector Training
- Optional Educational Activities – Accreditation Checklist Activities; Laboratory Accreditation Manual Activity; Continuing Compliance Audioconferences; Specialty Seminars
- Surveys Education

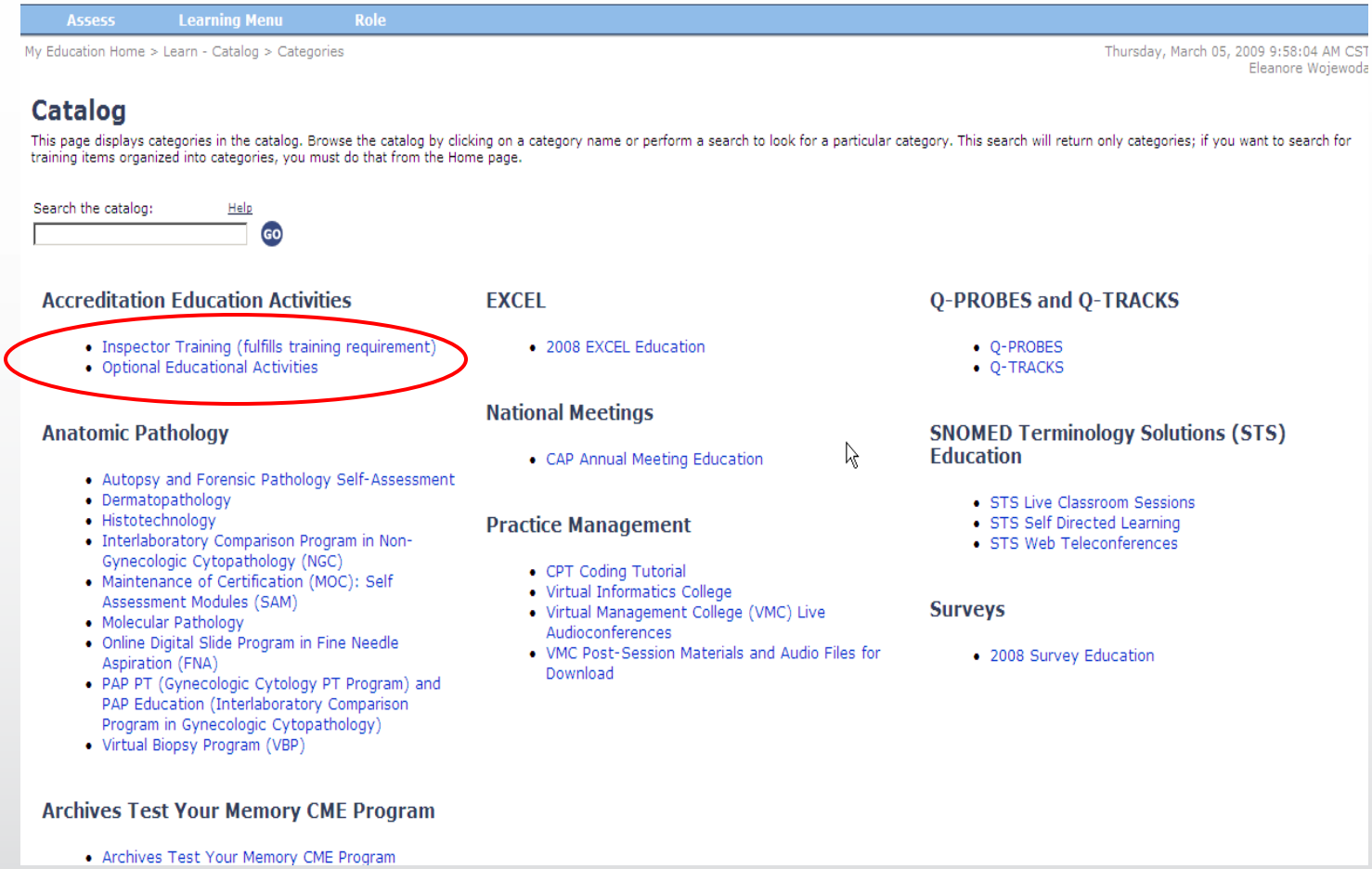
2008 Surveys Education Activities

			Name	Start Date	End Date
Register			Online Course: ABT-B 2008: The Purpose and Clinical Applications of Anti-A Titers		
			Intended Audience: Medical technologists, laboratory technicians, and practicing pathologists from a laboratory that participated in the ABT-Titer Survey product. Description: Staff from laboratories participating in the ABT-B 2008... --more--		
Register			Online Course: AL1-C 2008: The Non-Ethanol Volatiles and Ethylene Glycol		
			Intended Audience: Medical technologists, laboratory technicians, and practicing pathologists from a laboratory that participated in the AL1-C Blood Alcohol/Volatiles Survey product. Description: Staff from laboratories participating in ... --more--		
Register			Online Course: AL2-C 2008: The Non-Ethanol Volatiles and Ethylene Glycol		
			Intended Audience: Medical technologists, laboratory technicians, and practicing pathologists from a laboratory that participated in the AL2-C Alcohol/Volatiles Survey product. Description: Staff from laboratories participating in the AL... --more--		

LAP Education Activities – Preparing to Inspect

- Team Leader/Team Member On-Line Training
- Team Leader Workshops
- Specialty Seminars
- Inspection Preparation

LAP Education Activities



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Inspector Training (Meets Training Requirements)

Subcategories

Initial Team Leader Training

Initial Team Member Training

Specialty Seminars

Team Leader Update Training

Team Member Update Training

Workshops for Team Leaders

LAP Education Activities – Optional

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Accreditation Checklist Activities

		Name	Start Date	End Date
Register		Course: LAP: Anatomic Pathology Checklist Activity (Sep 2007)		
		Intended Audience: Practicing pathologists, laboratory professionals, and pathology residents preparing for a laboratory inspection. Desc Standards for Laboratory Accreditation are the fundamental principles by which the CAP accredits la... --more--		
Register		Course: LAP: Chemistry and Toxicology Checklist Activity (Sep 2007)		
		Intended Audience: Practicing pathologists, laboratory professionals, and pathology residents preparing for a laboratory inspection. Desc Standards for Laboratory Accreditation are the fundamental principles by which the CAP accredits la... --more--		
Register		Course: LAP: Cytogenetics Checklist Activity (Sep 2007)		
		Intended Audience: Practicing pathologists, laboratory professionals, and pathology residents preparing for a laboratory inspection. Desc Standards for Laboratory Accreditation are the fundamental principles by which the CAP accredits la... --more--		

2009 LAP Audioconferences

		Name	Start Date	End Date
Register		Class: 04-15-2009 LAP Audioconference - Unannounced Inspections: A Guide for Continual Readiness	Wednesday, April 15, 2009	Wednesday, April 15, 2009
		Description: You have just received the page that the laboratory inspectors are on site. During the initial moment of panic, you wonder what yo done differently to be more prepared. This session will provide you with suggestions and approach... --more--		
Register		Class: 05-20-2009 LAP Audioconference - Accreditation Requirements in Molecular Pathology	Wednesday, May 20, 2009	Wednesday, May 20, 2009
		Description: The molecular pathology laboratory performs tests using FDA approved kits as well as laboratory developed assays. Verification a of these assays in the laboratory need to be addressed from an analytical as well as a clinical pe... --more--		
Register		Class: 06-17-2009 LAP Audioconference - The Rules, Tools and Jewels of the Cytopathology Laboratory Inspection	Wednesday, June 17, 2009	Wednesday, June 17, 2009
		Objectives: As a result of participating in this activity, you will be able to: Discuss CLIA' 88 and compliance requirements unique to the Cytopat laboratory Explain the rationale behind the new/recent checklist requirement changes as they apply... --more--		

Department Contacts

Customer service: (800) 323-4040, Option 1

Proficiency Testing: (800)323-4040, Option 1

Accreditation:

Technical (800)323-4040- ext. 6065

Pre-Inspection: ext. 6055

accred@cap.org

Education: (800) 323-4040, ext. 7525

Questions?

Thank You!

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