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Blood Bank Proficiency, Competency & QC: A Practical Approach to CLIA Requirements and AABB, CAP, and TJC Expectations

Interagency Relationships

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- October 2018

- CAP, AABB, TJC have deemed status with CMS.
- CAP, AABB, TJC have deemed status with California State
- CAP & AABB have a cooperative agreement for assessment performance.
  - AABB assessor performs simultaneous assessment and inspection, if the facility has requested a joint assessment/inspection.
- CAP has deemed status with TJC.
  - In TJC accredited hospital, CAP can inspect TJC hospital laboratories.
- AABB & TJC have a joint PBM certification program.

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Competency

Anne Chenoweth, MBA, MT(ASCP)^{CM}, CQA(ASQ)
Senior Director
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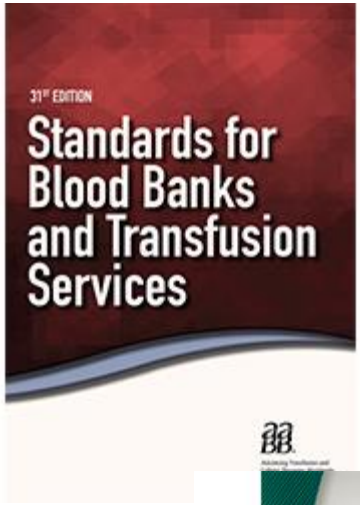
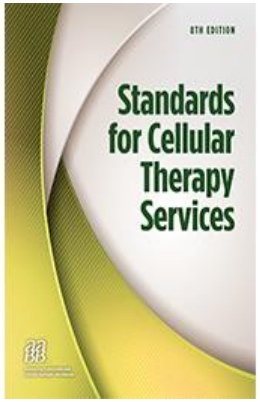
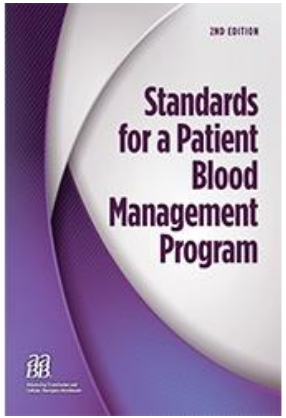
October 2018

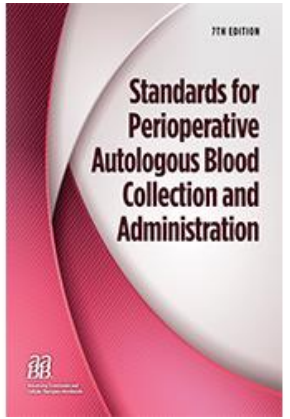
Objectives

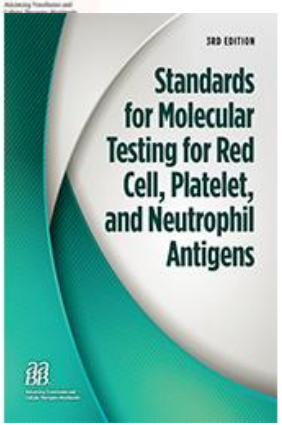
- Understand CLIA requirements
- Understand which tests / tasks require competency assessment
- Determine who requires competency assessment

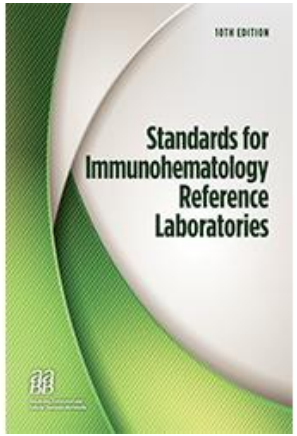


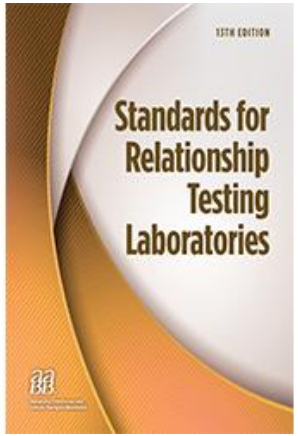












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Standard 2.1.3

- Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.*

*42 CFR 493.1235 and

42 CFR 493.1451 (b)(8)(9)

* 42 CFR 493.1235

Personnel competency assessment policies.

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

*42 CFR 493.1451(b)(8)
42 CFR 493.1413(b)(9)

- 1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
- 2. Monitoring the recording and reporting of test results;
- 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
- 4. Direct observations of performance of instrument maintenance and function checks;
- 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
- 6. Assessment of problem solving skills.

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42 CFR 493.1451(b)(9)
42 CFR 493.1413(b)(9)

Evaluating and documenting the performance of individuals responsible for **high & moderate** complexity testing at least semiannually during the first year the individual tests patient specimens.

*42 CFR 493.1451(b)(9)
42 CFR 493.1413(b)(9)

Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

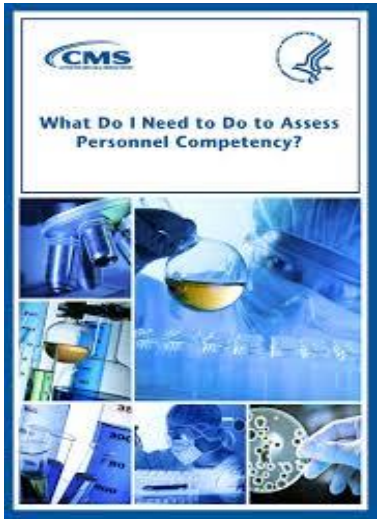
Common questions

- What tests? All tests???
- How often?
- Who needs competency?

CLIA Brochure #10

What Do I Need to Do to Assess Personnel Competency?

Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform.



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Example of Testing Performed in the facility

- ABO
- Rh
- Antibody Transfusion
- Antibody Non Transfusion (prenatal)
- Antibody Identification
- Compatibility Testing
- Infectious Disease Testing of donors

Semi-Annual? Annual?

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Semi-annual
Annual

- Clock starts at time of initial competency. *Don’t confuse training with competency*
- Per test/task
- *NOTE: Semi-annual applies to the FIRST year ONLY!*

“The laboratory may coordinate the competency assessment with its routine practices and procedures to minimize impact on workload”

Element 1

- Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

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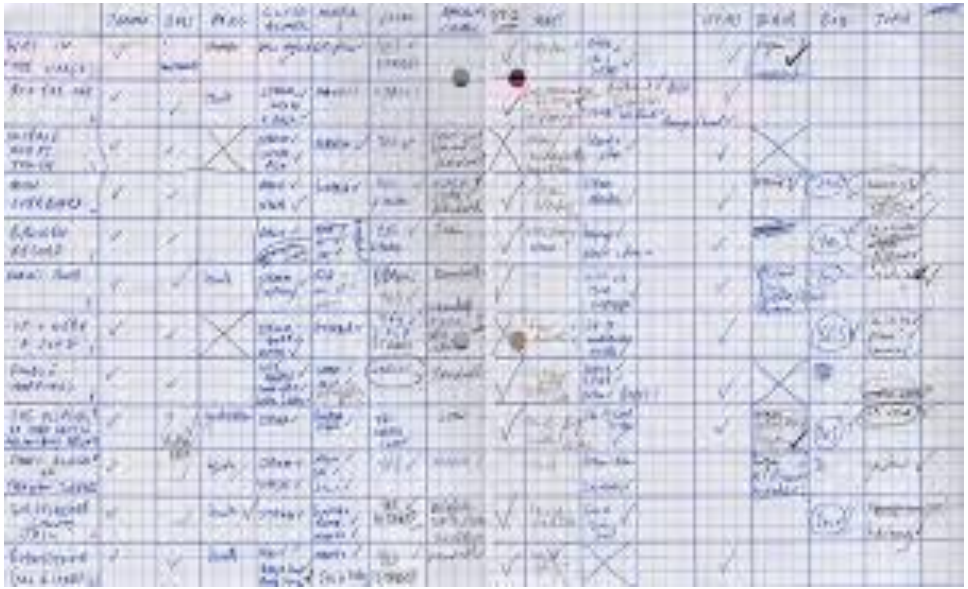
Element 2

- Monitoring the recording and reporting of test results;



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Element 3

- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

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Element 4

- Direct observations of performance of instrument maintenance and function checks;

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Element 5

- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples

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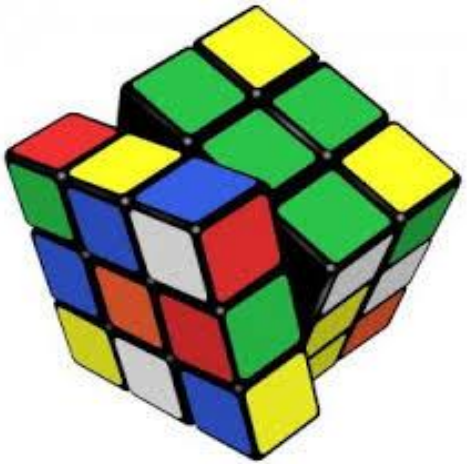
Element 6

- Assessment of problem solving skills.



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Who Can Assess Competency

- The Technical Supervisor for high complexity testing (42 CFR 493.1451(b)(8)) is responsible for performing and documenting competency assessments. This responsibility **can be delegated, in writing**, to a General Supervisor
- General supervisor requirements for high complexity
  - Doctoral / Master's / Bachelor's degree in clinical laboratory science or chemical, physical or biological science and 1 year training and experience in high-complexity
  - Associate's degree in Medical Laboratory Technology and 2 years laboratory training and/or experience in high complexity testing.

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Who Can Assess Competency

- Moderate complexity – assessments by individual meeting the qualifications of a technical consultant for moderate complexity testing
  - Doctoral / Master's degree in clinical laboratory science or chemical, physical or biological science and 1 year training and/or experience in non-waived testing in designated specialty
  - Bachelor's degree in clinical laboratory science or chemical, physical or biological science and 2 years experience in non-waived testing in designated specialty

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Assessment of Competency

- 2.1.3 Competence

Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.*

*42 CFR 493.1235 and 42 CFR 493.1451(b)(8)(9).

- ***2.1.3.1 Action shall be taken when competence has not been demonstrated.***

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Reevaluating Competency

- *If test methodology or instrumentation changes, an individual's competency must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.*

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Competency

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Checklist Technical Content Analyst, Laboratory Accreditation Program

The College of American Pathologists

Competency

- GEN.55500 The competency of each person performing patient testing to perform his/her assigned duties is assessed
- Competency assessment must include all six elements for each individual on each test system (the process that includes pre-analytic, analytic and post analytic steps used to produce a test result or set of results (e.g., manual testing, automated, etc)

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Blood Bank Competency Assessment

ANNUAL/SEMI-ANNUAL COMPETENCY ASSESSMENT

Employee Name: | Date of Hire: | Period of Evaluation:

1 Direct observation of routine patient test performance including, as applicable, patient identification and preparation, handling and processing.
2 Monitoring the recording and reporting test results, including, as applicable, reporting critical results.
3 Review of intermediate test results or worksheet, quality control records, proficiency test resulting and preventive maintenance.
4 Direct observation of performance of instrument maintenance and function checks.
5 Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
6 Evaluation of problem solving skills.

BLIND ABSC #
BLIND DAT #
BLIND FMH #
BLIND SICKLE #

		TUBE TEST							GEL TEST INDIRECT		GEL TEST DIRECT	KITS		
	Specify Instrument / Assay	ABORH	ABSC/ABID	ISXM	AHG XM	AG TYPE	DAT (IGG)	DAT(C3)	ABSC/ABID	AHG XM	DAT	FMH	SICKLE	ELUTION
1	Specimen Processing Patient ID accuracy													
1	Patient Testing													
2	Result Entry													
2	Reporting Criticals/Delays	N/A	N/A	N/A	N/A	N/A	N/A	N/A				N/A	N/A	N/A
3	Review Intermediate results/Worksheets	N/A		N/A	N/A	N/A	N/A	N/A		N/A	N/A	N/A	N/A	
3	Review QC									N/A				
3	Review Patient Results													
3	Review PM records	e)		b)		N/A	c)	c)	a)		d)	N/A	N/A	
4	Direct Observation of Maintenance	e)		b)		N/A	c)	c)	N/A	c)	d)	N/A	N/A	
5	Proficiency Testing or Blind Samples									c)				
6	Problem Solving													
	Comments													

a) daily temps; b) saline bottles; c) cell washer; d) MTS weekly, e)serofuge qc

S Satisfactory - Requires minimal supervision with no more than 10% prompting and minimal oversight in less than the time scheduled.
N Needs Improvement - Needs additional training prior to working alone.

I have read and understand the standard operation of procedures for the tests listed above, and I had an opportunity to review and ask questions about policies and procedures related to equipment and testing above.

Date: | Employee Signature: | Date: | Evaluator Signature:

Based upon successful completion of their competency assessment, the employee is deemed to be competent to perform patient testing unsupervised.

Date: | Technical Coordinator Signature: | Date: | Blood Bank Manager Signature:

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Transfusion Medicine EXAMPLE - Appropriate Test System Delineation

Competency elements:

1. *Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing*
2. *Monitoring the recording and reporting of test results, including, as applicable, reporting critical results*
3. *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records*
4. *Direct observation of performance of instrument maintenance and function checks*
5. *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency samples*
6. *Evaluation of problem-solving skills*

Method of assessment key:
DO: Direct Observation
RR: results review
WR: worksheet review

TEST SYSTEM	W=waived NW=non waived or LDT	1	2	3	4	5	6	Method: DO, RR, WR	Competent date/assessor	Retrain/corrective action date/assessor
ABO/ Rh										
Tube Method										
Automation										
Antibody Screening										
Tube Method										
Automation										
Direct Antiglobulin Testing - DAT										
Tube Method										
Automation										
IS Compatibility Testing										
Tube Method										
AHG Compatibility Testing										
Tube Method										
Automation										
Donor Retyping										
Tube Method										
Automation										
Fetalscreen										
Kleihauer-Betke										
Antibody Titer Testing										
Elutions										

Competency Assessment-Waived Testing

- GEN.55499 *NEW*- The competency of personnel performing waived testing is assessed at the required frequency
  - After individual has performed his/her duties for one year, competency must be assessed annually
  - Records of competency may be retained centrally within a healthcare system
  - Laboratory director may determine how competency will be assessed for personnel performing waived testing at multiple test sites (same CAP/CLIA number)

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Section Director (Technical Supervisor) Qualifications/Responsibilities

- GEN.53400 Section Directors/Technical Supervisors (TS) meet defined qualifications and fulfill the expected responsibilites
  - Requirements for the technical supervisor of transfusion medicine services are more stringent and are found in the Transfusion Medicine Checklist
  - Credentials for personnel trained outside the US must be recorded to ensure equivalency to CLIA requirements

Transfusion Service Medical Director/Section Director

- TRM.50050 The transfusion service medical director/section director (technical supervisor) is qualified
  - Must be a MD or DO, licensed to practice medicine in State in which the laboratory is located and either possess qualification required for board certification in clinical pathology or have at least one year training or experience in immunohematology.
  - DOD laboratories must meet Clinical Laboratory Improvement Program (CLIP) requirement at a minimum

Performance Assessment of Supervisors/Consultants

- GEN.55525 Performance of section directors/technical supervisors, general supervisors, and technical consultants is assessed and satisfactory
  - Responsibilities of individuals must be delegated in writing
  - If any individuals perform nonwaived testing, GEN.55550 applies

Who decides complexity level?

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/Search.cfm

Competency

Ron Quicho, MS
Project Director, Standards and Survey Process
Laboratory Program
The Joint Commission

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Competency

- ✓ Annual = 12 months +/- 30 days
- ✓ Semiannual = 6 months +/- 15 days
- ✓ Requirement for competency assessment of nontechnical duties once every 2 years or more frequently if required by policy or regulations
- ✓ 6 Methods of competency evaluation used per **test system**
- ✓ Can use testing personnel to document methods of evaluation

Competency Requirements

- ✓ Completed by:
  - **High complexity:** Delegated in writing to the Technical Supervisor or General Supervisor
  - **Moderate complexity:** Delegated in writing to the Technical Consultant

- ✓ Immunohematology Technical Supervisor:
  - Doctor of medicine or doctor of osteopathy; certified in clinical pathology
  - Doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine; one year training/experience in high complexity testing in the specialty of immunohematology

Proficiency

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The College of American Pathologists

October 2018

Objectives

- Understand the different terms of proficiency testing (regulated, non-regulated, etc)
- Know the CLIA requirements for PT testing
- What to do if you get a CEASE TESTING notification

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CAP Relationships

- Deemed status with CMS
- Deemed status with TJC
- Relationship with the AABB

Definition of Terms

- Regulated and Non-regulated analytes/tests
- Required analytes/tests means MUST perform proficiency testing
- CAP-accepted PT Program
- Alternative Performance Assessment

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CAP Checklists reflect best practices

- General and discipline-specific guidelines for lab policies, procedures, and processes
- Guide the inspection
- Help ensure accurate, reliable test results, and focus on patient and employee safety
- Over 2,900 checklist requirements; revised annually

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Ungraded PT Challenges

- COM.01100 Written procedure for assessing performance on PT challenges intended to be graded, but were not

- *42 CFR 493.859, 42 CFR 493.861, 42 CFR 493.863, 42 CFR 493.865, 42 CFR 493.865

* 42 CFR Standards for Return of PT Testing Results

- ABO group and D (Rho) typing (42 CFR 493.859)
- Antibody Screen (42 CFR 493.861)
- Compatibility Testing (42 CFR 493.863)
- Antibody Identification (42 CFR 493.865)
- Failure to return PT results to the PT program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

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PT Participation

- COM.01300 Participation in appropriate required PT/external quality assessment (EQA) program accepted by the CAP for the patient testing performed

- *42 CFR 493.801

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PT Participation (Cont'd)

- The list of analytes for which CAP requires PT available on the CAP website (www.cap.org)
- Must include all analytes on this list for which it performs patient testing
- Applies to both waived and non-waived tests

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How are required analytes identified?

- Current list of required analytes designated in Analyte/Procedure index of CAP Surveys Catalog with an “X” in LAP ENR column

Analyte/Procedure	LAP ENR	Program Code	Description	Pg
Alprazolam (cont.)		T	Toxicology	87
		UT	Urine Toxicology	87
Aluminum	X	R	Trace Metals	70
Amikacin	X	CZ, CZ2, CZ2X, CZX, Z	Chemistry and TDM	55-57
		LN3	TDM Cal Ver/Lin	110
Amino acids, qualitative	X	BGL	Biochemical Genetics	208
Amino acids, quantitative		BGL	Biochemical Genetics	208
Aminoclonazepam		FTC	Whole Blood Forensic Toxicology	93
		T	Toxicology	87
		UT	Urine Toxicology	87
Aminoflunitrazepam		T	Toxicology	87
		UT	Urine Toxicology	87
Amitriptyline		FTC	Whole Blood Forensic Toxicology	93

Analyte/Procedure	LAP ENR	Program Code	Description	Pg
Amylase, urine (cont.)	X	U	Urine Chemistry, General	64
Analytical balance		I	Instrumentation	118
Anaplasma phagocytophilum		TTD	Antibody Detection-Tick-Transmitted Diseases	171
Androstenedione	X	Y/YY	Ligand Assay, Special	76
Angiotensin converting enzyme		ACE	Angiotensin Converting Enzyme	66
Anti-A titer		ABT, ABT1	Antibody Titer	189
Anti-beta-2-glycoprotein		CGE/CGEX	Coagulation, Extended	143
Antibody detection	X	**J, JAT**	Transfusion Medicine	187
	X	PS	Platelet Serology	192
		TMCA	Transfusion Medicine, Competency Assessment	188

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Master Activity Menu

Customized Activity Menu

COLLEGE of AMERICAN PATHOLOGISTS
325 Waukegan Road, Northfield, Illinois 60093-2750
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Master Activity Menu
With Proficiency Testing Options
Program: LAP As of: 08/07/2018

Discipline	Subdiscipline	Test/Activity	CAP Accepted PT Required **	Scope of Service/Analytic Method	Surveys CAP PT Options
Chemistry	Chemistry	ALT, body fluid			
Chemistry	Chemistry	ALT, serum/plasma	Y		C1, C3, C3X, CZ, CZ2X, CZX
Chemistry	Chemistry	ALT, whole blood, non-waived	Y		C1, C3, C3X, CZ, CZ2X, CZX
Chemistry	Chemistry	ALT, whole blood, waived	Y		C1, C3, C3X, CZ, CZ2X, CZX
Chemistry	Chemistry	AST, body fluid			
Chemistry	Chemistry	AST, serum/plasma	Y		C1, C3, C3X, CZ, CZ2X, CZX
Chemistry	Chemistry	AST, whole blood, non-waived	Y		C1, C3, C3X, CZ, CZ2X, CZX
Chemistry	Chemistry	AST, whole blood, waived	Y		C1, C3, C3X, CZ, CZ2X, CZX
Chemistry	Chemistry	Acetoacetic acid			
Chemistry	Chemistry	Acetone			

Department /Section: Rapid Response Lab Chemistry

Subdiscipline	Test/Activity	PT Required	Alternative Assessment Required	Scope of Service/Analytic Method	2018 Missing PT Enrollment
All Common	Common (CAP Office use)			Y	
Blood Gases	Carboxyhemoglobin	Y			
Blood Gases	Chloride, whole blood, non-waived	Y			
Blood Gases	Glucose, whole blood, non-waived	Y			
Blood Gases	Hematocrit (direct measure/calc), non-waived	Y			
Blood Gases	Hemoglobin, total, non-waived	Y			
Blood Gases	Methemoglobin	Y			
Blood Gases	O2 saturation		Y		
Blood Gases	Oxyhemoglobin	Y			

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*CFR 42 493.801 Enrollment and Testing of Samples

- The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification
- Laboratory must test the samples in the same manner as patients' specimens

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Attestation Page

- COM.01400 The PT attestation signed by the laboratory director or designee and the individual performing the testing
- Physical signatures must appear on a paper version of attestation form. Listing of typed names does not meet the requirement
- Signature of the laboratory director or designee need not be obtained prior to reporting results to the PT provider.

- * 42 CFR 493.801(b)(1)

*42 CFR 493.801(b)(1) Testing of PT Samples

- The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

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PT Attestation Delegation

- COM.01400 Proficiency testing attestation signed by the laboratory director or designee and all individuals involved in the testing process
- For moderate complexity testing, director may delegate the responsibility for signing attestation statement to a technical consultant meeting the qualifications of 42 CFR 493.1411
- For high complexity testing, director may delegate responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of 42 CFR 493.1449

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*42 CFR 493.1411 Technical Consultant Qualifications

- Must be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine AND
- Have one year of laboratory training or experience, or both for area of responsibility or
- Hold doctoral or master's degree in chemical, physical, biological, or clinical laboratory science and
- One year of laboratory training or experience in area of responsibility OR

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*42 CFR 493.1411 Technical Consultant Qualifications (Cont'd)

- Bachelor's degree in chemical, physical, or biological science or medical technology from an accredited institution and
- Have at least two years of laboratory training or experience, or both in non-waived testing in area of responsibility

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*42 CFR 493.1411 Technical Consultant Qualifications (Cont'd)

- Examples of how one-year requirement for training and experience can be met:
  - Medical Technology internship
  - One year of experience performing non-waived testing in a particular specialty(ies) or
  - Performance of non-waived testing in a particular specialty(ies) on part-time basis, equivalent to 2080 hours

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*42 CFR 493.1449(q)(1)(ii) Technical Supervisor(Transfusion Service Medical Director/Section Director) Qualifications

- Be a doctor of medicine, doctor of osteopathy, or doctor of podiatry medicine licensed to practice medicine, osteopathy, or podiatry in the state in which the laboratory is located AND
- Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology

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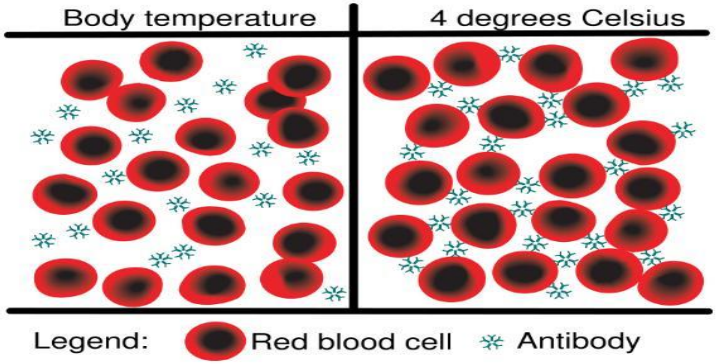
Alternative Performance Assessment

- COM.01500 For tests for which CAP does not require PT, alternate performance assessment performed at least semi-annually
- Example: Cold Agglutinin testing

- * 42 CFR 493.1236 (c)(1)



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*42 CFR 493.1236(c)(1) Evaluation of PT Performance

- For non-regulated analytes, the laboratory must verify the accuracy of the test or procedure twice annually, including the accuracy of calculated results, if applicable.

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PT Integration Routine Workload

- COM.01600 Laboratory integrates all PT samples within the routine laboratory workload
- Samples are analyzed by personnel who routinely test patient/client samples
- Testing methods must be same as for patient/client/donor samples

* 42 CFR 493.801(b)

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PT Evaluation

- COM.01700 Ongoing evaluation of PT and alternative assessment results, with prompt corrective action taken for unacceptable results:
  - Each unacceptable result must be evaluated
  - Acceptable results showing bias or trends should also be investigated

- *42 CFR 493. 1407(e)(4)(iv)

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*42 CFR 493.1407(e)(4)(iv) Laboratory Director Responsibilities

- An approved corrective action plan is followed when any PT results are found to be unacceptable or unsatisfactory.

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PT Interlaboratory Communication

- COM.01800 Interlaboratory communication about PT samples not allowed until after deadline for submission of data to the PT provider
  - PT must be performed at CLIA site for which PT was ordered
  - Written policies forbidding interlaboratory communications in place

- *42 CFR 493.80(b)(3)

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*42 CFR 493.801(b)(3)- Testing of PT Samples

- Laboratories must not engage in any interlaboratory communications pertaining to the results of PT samples until after the date by which the laboratory must report PT
- Laboratories with multiple testing sites or separate locations must not participate in any communication across sites until after due date of testing event.

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PT Referral

- COM.01900 Written policy prohibiting referral of PT specimens to another laboratory or acceptance from another laboratory

- *42 CFR 493.801(b)(4)

*43 CFR.493.801(b)(4)- Testing of PT Samples

- Do not send PT samples or portions of PT samples to another lab for any analysis for which the lab is certified to perform in its own lab. Consequences of doing so may result in revocation of certification for at least one year.
- Do notify CMS if the lab receives a PT sample from another lab for testing regardless of whether the referral was made for reflex, confirmation testing, or any other reason.

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Cease Testing for Repeat PT Failures

- COM.01950 If laboratory instructed to cease testing:
  - Must show evidence that no patient results are released during cease testing period
  - To resume patient testing, laboratories must meet conditions as outlined in cease patient testing notification

*42CFR 493.807 Reinstatement of Laboratories Performing Nonwaived Testing

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For more information

- Contact the PT Compliance Group:
  - Call: 800-323-4040 ext. 6052 or 847-832-7000
  - Email: PTCN@cap.org.
- Visit the Proficiency Testing/External Quality Assurance Toolbox (Analyte Specific Troubleshooting Guides are available in the Toolbox) on the CAP website
- Visit https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf

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Proficiency Testing

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Project Director, Standards and Survey Process
Laboratory Program
The Joint Commission

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Proficiency Testing

- ✓ Nonregulated Analytes
  - Accuracy and Precision every 6 months +/- 15 days
  - May use Proficiency Testing to meet this
- ✓ Laboratory Director or Technical Supervisor document review of PT program report
- ✓ Laboratory Director signs the attestation
  - **High Complexity:** Delegated in writing to the Technical Supervisor
  - **Moderate Complexity:** Delegated in writing to the Technical Consultant

Proficiency Testing

- ✓ CMS **and** The Joint Commission are notified of PT samples received from another lab for testing
- ✓ Top 10 noncompliance issue since 2010
  - Participation
  - Records
  - Process

Proficiency

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Senior Director
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October 2018

Proficiency Testing

- ✓ 5.1.2 Proficiency Testing Program

  AABB Standard mirrors CMS requirements

AABB also has separate standards for PT for facilities outside the US

Quality Control

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Objectives

- Outline CLIA requirements
- Understand different requirements surrounding Quality Control
- Review IQCP requirements and trends of noncompliance

QSA.02.06.01 – Quality Control Policy

- ✓ Written QC policy for each specialty/subspecialty that:
  - Defines QC number, type and frequency
  - Provides criteria for acceptability
  - Provides QC limits and reportable ranges
    - Limits are strict enough to promote precision and accuracy
    - Limits based upon lab specific data
    - Limits and ranges provide results with meaningful clinical applications
  - Is accessible to staff

42 CFR 493.1256

QSA.02.08.01 – Correlations

- ✓ Same CLIA number: Different methodologies/Different instruments/Different locations
- ✓ Once every 6 months +/- 15 days
- ✓ Defined tolerance limits
- ✓ If using QC - define the target value and range of analytic values that are acceptable for multiple instrument comparisons

42 CFR 493.1281(a), 42 CFR 493.1281(c), 42 CFR 493.1291(e)

QSA.02.09.01 – Performance of Quality Control Testing

- ✓ Staff who perform QC testing must:
  - Also perform patient testing
  - Perform QC testing in same manner as patient specimens
  - Rotate QC testing among those who perform patient testing: by shifts, by week/month, as part of the competency assessment

42 CFR 493.1256

QSA.02.10.01 – QC to Monitor Accuracy and Precision

- ✓ QC materials:
  - Are at a level and frequency consistent with manufacturers' recommendations
  - Must have a negative and a graded positive control
  - If they are not available, then the lab performs alternate QC testing
- ✓ QC results are documented
- ✓ Patient results are not reported unless QC criteria is met

42 CFR 493.1200, 42 CFR 493.1256, 42 CFR 493.1278

QSA.02.11.01 & QSA.02.12.01 – QC Surveillance and Corrective Action

- ✓ Surveillance activities include a review of QC results
- ✓ For each QC result outside of acceptable limits the lab must:
  - Conduct an investigation
  - Take corrective action before patient testing is resumed

42 CFR 493.1239(b), 42 CFR 493.1249(b), 42 CFR 493.1251(b)(8), 42 CFR 493.1282(b)(2)

§493.1271(a) Patient Testing

- ✓ (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e).
  - Reagent red cell panels used in antibody identification: follow manufacturer's instructions
  - Multiple racks of reagent typing sera and cells: QC each rack and each bottle
  - New lot of reagent when first used
  - In-date reagents are unavailable
    - Must be a documented exception
    - QC must be acceptable

QSA.05.06.01 – Immunohematology QC

The laboratory conducts reactivity testing on the potency and reliability of reagents used for ABO grouping, Rh typing, antibody detection, and compatibility determination.

- ✓ **EP 1** Written policies and procedures
- ✓ **EP 2** Each day the procedure is performed, and when a new lot of reagents is first used, **the laboratory tests at least one vial from each lot number** of antisera, reactive cells, and reagents for reactivity**.** The reactivity results are documented. Note: This testing includes positive and negative reactivity when recommended by the manufacturer.

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QSA.05.06.01 – Immunohematology QC

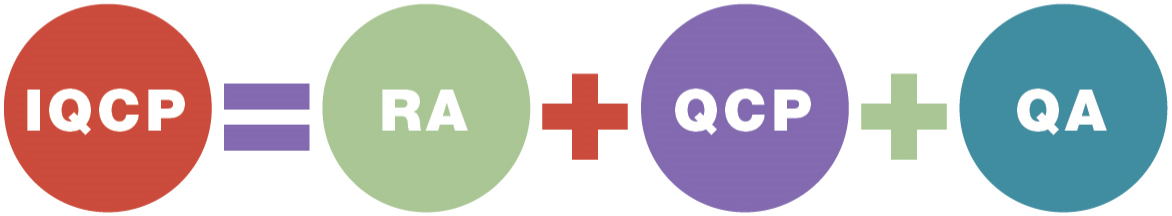
- ✓ **EP 3** Confirms and documents that each reagent reacts as expected
- ✓ **EP 4** Retains a copy of the manufacturers' reagent package inserts documenting the date place into service
- ✓ **EP 5** The laboratory reviews manufacturers' package inserts of reagent lots for changes in instructions and updates procedures
- ✓ **EP 6** Policies and procedures are followed

QSA.02.04.01 – IQCP

- ✓ All specialties/subspecialties except tests that are only listed within pathology or cytology
- ✓ If approved for use by the state, in Joint Commission accredited labs IQCP is a QC option for immunohematology
- ✓ Several labs have implemented IQCP in immunohematology to change the frequency of QC testing and/or to not require QC on every open bottle of reagent
- ✓ **Appendix C:** IQCP Eligible Requirements

Risk Assessment – How Critical?

The IQCP Equation



Step 1

Step 2

Step 3

Risk Assessment – Testing Personnel

- Training and competency
- Education and experience qualifications
- Adequate staffing

Risk Assessment – Testing Personnel

CLIA IG asks…

Do you see a potential risk of an error in test results due to:

- There is no documentation of CLIA-required competency assessment for all laboratory personnel
- The laboratory does not have adequate personnel to perform patient testing in a safe and timely manner?

Risk Assessment – Testing Personnel

TJC findings…

“Staff competency for transfusion services was completed by an individual that did not quality as a technical supervisor.”

“The lack of communication between lab staff and leadership did not allow reporting of damage to handheld instrumentation.”

Final Advice

1. Question “Risks” associated at every process
2. Think of the “Domino Effect”
3. Consider Risk Assessment “Beyond” IQCP
4. Seek “Leadership Involvement”

Quality Control

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Checklist Technical Content Analyst, Laboratory Accreditation Program

The College of American Pathologists

Comparability of Instruments/Method

- COM.04250 If laboratory uses more than one nonwaived instrument/method to test for a given analyte, instruments/methods are checked against each other at least twice a year for comparability of test results
  - Applies to tests performed by different methods
  - Intended to evaluate relationship between test results using different methodologies (e.g. tube vs. automated vs. solid phase manual)
  - Applies to enhancement techniques (e.g. tube vs PEG)
  - Human samples preferred to avoid matrix effects

  *42 CFR493.1281(a)

*42 CFR 493.1281(a)

- If the laboratory performs the same testing using different methodologies or instruments, or performs the same test at multiple sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites

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New Reagent Lot Confirmation of Acceptability

- COM.30450 New reagent lots and shipments are checked against old reagent lots or with suitable reference material before or concurrently being placed in service
  - Daily QC of ABO, Rh, Antibody Screen satisfies intent of checklist item providing acceptance criteria are defined and outcome of results are recorded
  - May not apply to panel cells (see TRM.31241) unless required by manufacturer
  - Applicable to test kits containing external controls (such as fetal maternal screen test kits)

Reagent QC

- TRM.31241 All new lots of reagents and critical materials (e.g. blood collection sets) are inspected and tested, as applicable, before use with records of acceptance.

  - If manufacturer's instructions require testing prior to use (e.g. panel cells, antisera) then lab is expected to test

  -If manufacturer's instructions recommend testing prior to use, it is up to the discretion of the laboratory to test

  -Once reagents are put into use, TRM.31400 applies

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Reagent Expiration Date

- TRM.31250 All reagents are used within their indicated expiration date
  - Rare antisera may be used beyond expiration date if appropriate positive and negative controls are run each day of use and react as expected.
  - Lab expected to have in-date reagents for routine antibody panel testing
  - Written policy for evaluating reagents beyond expiration date

*42 CFR 493.1252(d)

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*CFR 42 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality

Antisera/Reagent Red Cell QC

- TRM.31400 There are records of acceptable reactivity and specificity of typing sera and reagent cells on each day of use, including a check against known positive and negative cells or antisera, or manufacturer's directions for daily quality control are followed
  - Requirement can be satisfied by testing one vial of each reagent lot each day of testing

*42 CFR 493.1271(a)

Individualized Quality Control Plan (IQCP)
COM.50200-COM.50500

- If state does not allow IQCP as an option, lab must perform daily quality control per state regulations and CAP requirements . Refer to COM.50200, COM.50300, COM.50400, COM.50500 and COM.50600
- Eligibility for use of IQCP
  - Nonwaived tests that employ an internal (electronic/procedural/built-in) quality control system
  - Does not apply to Anatomic Pathology or Cytopathology

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Quality Control

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Senior Director
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AABB Standard 5.1.3

- A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment and methods perform as expected

Standards 5.1.3.1 and 5.1.3.2

- Address validity of test results and methods and investigation of quality control failures

IQCP

- The AABB only accepts IQCP for the specialty of bacteriology

Thank You & Questions?

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Blood Bank Proficiency, Competency and QC: A Practical Approach to CLIA Requirements and AABB, CAP, and TJC Expectations

10/15/2018

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The following faculty have no relevant financial relationships to disclose:

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The following faculty have a relevant financial relationship:

- Tricia McGann MBA, MLS(ASCP) SBB

  Immucor, Inc.: Full-time/Part-time Employee

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Learning Objectives

- Discuss the relationships between the laboratory, CLIA deemed status of accrediting organizations and bodies.
- Define requirements for IQCP
- Describe and compare the criteria for competency, proficiency and QC of three deemed status accrediting based upon CLIA requirements
- Illustrate methods used by a transfusion service for fulfilling these requirements

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