Blood Bank Proficiency, Competency and QC: A practical approach to CLIA requirements and AABB, CAP and Joint Commission expectations

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Executive Director
Laboratory Accreditation
The Joint Commission

Heather McGann MS, MT(ASCP) SBB
Manager
Transfusion Services
University of Maryland Medical Center
Dear Dickie,

This is a reminder that you are registered to attend: “Blood Bank Proficiency, Competency and QC: A practical approach to CLIA requirements and AABB, CAP and Joint Commission expectations” which will begin in 1 Hour on:

Thurs., April 28, 2016

Add to Calendar: Outlook® Calendar | Google Calendar™ | iCal®

Please send your questions, comments and feedback to: dnichols@immucor.com

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DEADLINE TO REGISTER FOR CE IS March 31, 2016. Certificates of attendance will be sent out by April 15, 2016. NO REGISTRATION WILL BE ACCEPTED AFTER April 1, 2016.
Continuing Education

• PACE, California DHS
  – 437-304-16

• Florida BPR
  – 20-551464

• 1.5 Contact Hours

• Each attendee registers at:
  https://www.surveymonkey.com/r/WebinarQC
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DEADLINE TO REGISTER FOR CE IS May 13, 2016.

Certificates of attendance will be sent out by May 27, 2016.
Continuing Education

• Each attendee must register for CE
• Registration deadline is May 13, 2016
• No other form of CE registration will be accepted
• Certificates will be sent via email by May 27, 2016
• Session is being recorded and will be posted on LEARN in about 2 weeks
  – *All registrants will be notified when recording is available*
  – *No CE will be issued for participating in recorded session*

• You are all muted

• Q&A following session
Disclaimer

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• The opinions contained in these presentations are those of the presenters and do not necessarily reflect those of Immucor.

• “The Joint Commission Disclaimer: This presentation is current as of April 28, 2016. The Joint Commission reserves the right to change the content of the information as appropriate.”
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College of American Pathologists

Heather McGann MS, MT(ASCP)
SBB
Manager
Transfusion Services
University of Maryland Medical Center
Objectives

• Discuss the relationships between the laboratory, CLIA and deemed status Accrediting Organizations and Bodies
• Clarify requirements for IQCP
• Describe and compare the criteria for Competency, Proficiency and QC of three of the deemed status Accrediting Organizations based upon CLIA requirements
• Illustrate methods used by a transfusion service for fulfilling these requirements
CLIA Requirements: Who do you ask?

- Who inspects your lab for CLIA?
  - Deemed status Accrediting Organizations
    - CAP
    - AABB
    - The Joint Commission
    - ABHI
    - A2LA
    - AOA
    - COLA
What are “Deemed Status Accrediting Organizations”?

- Organizations who determine a lab meets CLIA requirements
- The Organization’s criteria for determining that a lab meets CLIA requirements are approved by CMS
- The Organization’s criteria must meet, but may actually exceed CLIA requirements
# Agenda

## COMPETENCY TESTING REQUIREMENTS:
- **CLIA and additional requirements by AABB**: Anne Chenoweth, AABB  
- **Additional requirements by CAP**: Denise Driscoll and Lilly Petkovic, CAP  
- **Additional requirements by Joint Commission**: Stacy Olea, The Joint Commission

## PROFICIENCY TESTING REQUIREMENTS:
- **CLIA and additional requirements by CAP**: Denise Driscoll and Lilly Petkovic, CAP  
- **Additional requirements by Joint Commission**: Stacy Olea, The Joint Commission  
- **Additional requirements by AABB**: Anne Chenoweth, AABB

## QC REQUIREMENTS:
- **CLIA and additional requirements by Joint Commission**: Stacy Olea, The Joint Commission  
- **Additional requirements by AABB**: Anne Chenoweth, AABB  
- **Additional requirements by CAP**: Denise Driscoll and Lilly Petkovic, CAP

## PRACTICAL APPROACHES FOR FULFILLING QUALITY REQUIREMENTS
- **Heather McGann, University of Maryland Medical Center**

## Q&A
- **All**
Competency
Competency

Anne Chenoweth, MBA, MT(ASCP), CQA(ASQ)
Director
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)
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.
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.
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.
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?
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.
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?
Semi-annual Annual

• Clock starts at time of initial 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;
Element 2

- Monitoring the recording and reporting of test results;
Element 3

- Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
Element 4

- Direct observations of performance of instrument maintenance and function checks;
Element 5

• Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
Element 6

- Assessment of problem solving skills.
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.
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
Assessment of Competency

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


• 2.1.3.1 Action shall be taken when competence has not been demonstrated.
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.*
Laboratory Accreditation Program

COMPETENCY
Denise Driscoll, MS, MT(ASCP)SBB
Senior Director, Accreditation and Regulatory Affairs
Competency Assessment of Testing Personnel

- 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)
  - The next two slides show examples of ways to assess competency in the Blood Bank
## 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 results and preventive maintenance.  
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.  

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<th>Specimen Processing</th>
<th>Patient ID accuracy</th>
<th>ABORH</th>
<th>ABSC/ABID</th>
<th>ISXM</th>
<th>AHG XM</th>
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### TUBE TEST

- **Patient Testing**
- **Result Entry**
- **Reporting**
- **Review Intermediate results/Worksheets**
- **Review QC**
- **Review Patient Results**
- **Review PM records**
- **Direct Observation of Maintenance**
- **Proficiency Testing or Blind Samples**
- **Problem Solving**

### GEL TEST INDIRECT

- **GEL TEST DIRECT**
- **KITS**

### Comments

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

5. 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 understood 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:**
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

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<th>TEST SYSTEM</th>
<th>W=waived NW=non waivered or LDT</th>
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Section Director (Technical Supervisor) Qualifications/Responsibilities

• GEN.53400 Section Directors/Technical Supervisors (TS) meet defined qualifications and fulfill the expected responsibilities
  – The section director/(TS) responsible for clinical pathology must be MD or DO certified in clinical pathology or possess qualifications equivalent to those required for certification
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.
Competency Corrective Action

- GEN.57000 If an employee fails to demonstrate satisfactory performance on the competency assessment, the laboratory has a plan of corrective action to retrain and reassess the employee’s competency.
Who decides complexity level?

Competency

Stacy Olea, MBA, MT(ASCP), FACHE
Executive Director
Laboratory Accreditation
Competency

- Human Resources Chapter (HR)
- 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

The assessment is 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 eligible; 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

Top 10 noncompliance issue since 2010
Proficiency
Laboratory Accreditation Program

PROFICIENCY TESTING (PT)
Denise Driscoll, MS, MT(ASCP)SBB
Senior Director, Accreditation and Regulatory Affairs
Ungraded PT Challenges

• COM.01100  The laboratory has a procedure for assessing its performance on PT challenges that were intended to be graded, but were not.

* 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.
PT Participation

• COM.01300 The laboratory participates in the appropriate required PT/external quality assessment (EQA) program accepted by CAP for the patient testing performed.

• *42 CFR 493.801
PT Participation (Cont’d)

• The list of analytes for which CAP requires PT is available on the CAP website (www.cap.org).

• Laboratory’s participation in proficiency testing must include all analytes on this list for which it performs patient testing.

• Checklist requirement applies to both waived and non-waived tests.
*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. The laboratory must test the samples in the same manner as patients’ specimens.
• COM.01400 The PT attestation is 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.
PT Attestation Delegation

• 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.
*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
*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
• Examples of how one-year requirement for training and experience can be met:
  o Medical Technology internship
  o One year of experience performing non-waived testing in a particular specialty(ies) or
  o Performance of non-waived testing in a particular specialty(ies) on part-time basis, equivalent to 2080 hours
**42 CFR 493.1449(q)(1)(ii) Technical Specialist (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
Alternative Performance Assessment

• COM.01500 For tests for which CAP does not require PT, the laboratory at least semi-annually exercises an alternative performance assessment system for determining the reliability of analytic testing.

• Example: Cold Agglutinin testing

• * 42 CFR 493.1236 (c)(1)
**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.
PT Integration Routine Workload

- COM.01600  The laboratory integrates all PT samples within the routine laboratory workload, and those samples are analyzed by personnel who routinely test patient/client samples using the same primary method systems as for patient/client/donor samples.
- * 42 CFR 493.801(b) – Same as slide 6
PT Evaluation

• There is ongoing evaluation of PT and alternative assessment results, with prompt corrective action taken for unacceptable results.

• *42 CFR 493. 1407(e)(4)(iv)
*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.
PT Interlaboratory Communication

• COM.01800  There is a policy that prohibits interlaboratory communication about PT samples until after the deadline for submission of data to the PT provider.

• *42 CFR 493.80(b)(3)
42 CFR 493.801(b)(3) - Testing of PT Samples

• Laboratories performing tests on PT samples 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 results to the program for the testing event in which the samples were sent.

• Laboratories with multiple testing sites or separate locations must not participate in any communication across sites until after due date of testing event.
PT Referral

• There is a policy that prohibits referral of PT specimens to another laboratory or acceptance from another laboratory.

• *42 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.
Proficiency Testing

Stacy Olea, MBA, MT(ASCP), FACHE
Executive Director
Laboratory Accreditation
Proficiency Testing

- Quality System Assessment for Nonwaived Testing (QSA)

- Nonregulated Analytes
  - Accuracy and Precision every 6 months +/- 15 days
  - May use Proficiency Testing to meet this; required to meet all PT standards

- 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

Anne Chenoweth, MBA, MT(ASCP)\textsuperscript{CM}, CQA(ASQ)
Director
Accreditation
AABB
5.1.2

Proficiency Testing Program

- The BB/TS shall participate in a proficiency testing program, if available, for testing regulated by the Clinical Laboratory Improvement Amendments and performed by the facility.* When a CMS-approved program is not available, there shall be a system for determining the accuracy and reliability of test results. Results shall be reviewed and corrective action taken, where appropriate, when expected results are not achieved.

*42 CFR 493.1236.
Quality Control

Stacy Olea, MBA, MT(ASCP), FACHE
Executive Director
Laboratory Accreditation
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 date
  - Limits and ranges provide results with meaningful clinical applications
- Is accessible to staff

42 CFR 493.1256
QSA.02.08.01 Correlations

- 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

42 CFR 493.1256
QSA.02.10.01 Quality Control 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

QSA.02.11.01 & QSA.02.12.01
Quality Control 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
- Multiple racks of reagent typing sera and cells
- New lot of reagent when first used
- In-date reagents are unavailable
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 each opened vial 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.
QSA.05.06.01 EP 1 – 6
Immunohematology Quality Control

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
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
- To date we have surveyed one lab that is using IQCP in immunohematology

QSA.02.04.01 EPs 1 – 8

Appendix C: IQCP Eligible Requirements
Quality Control

Anne Chenoweth, MBA, MT(ASCP)CM, CQA(ASQ)
Director
Accreditation
AABB
IQCP

AABB does not accept IQCP

You must follow the manufacturer’s written instructions or the quality control requirements found in the CFR
Laboratory Accreditation Program

QUALITY CONTROL
Denise Driscoll, MS, MT(ASCP)SBB
Senior Director, Accreditation and Regulatory Affairs
Comparability of Instruments/Method

• COM.04250 If the laboratory uses more than one nonwaived instrument/method to test for a given analyte, the 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.
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 satisfy the intent of the checklist item provided acceptance criteria are defined and outcome of results are recorded
  - May not apply to panel cells (see TRM.31241)
  - Does apply to kits (such as fetal maternal screen test kits)
• 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 (see slide 8)
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)
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)

- If state does not allow IQCP as an option, lab must perform daily quality control per state regulations and CAP requirement

- 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
### ABO/Rh Discrepancies

<table>
<thead>
<tr>
<th>Activity</th>
<th>Explanation</th>
<th>Code</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recognizes and resolves ABO/Rh discrepancy between primary testing and recheck</td>
<td>Discuss &amp; document in training domain X 2</td>
<td>mC-1</td>
<td>Perform</td>
</tr>
<tr>
<td>Recites expected results from various combinations of patient types without-of-group/type HSCTs/transfusions</td>
<td>Check trainee’s knowledge</td>
<td>mC-1</td>
<td>Perform</td>
</tr>
<tr>
<td>Correctly completes HSCT Evaluation form to notify BB physician of changes in ABO/Rh reactivity for HSCT patients</td>
<td>Perform X 2</td>
<td>mB9</td>
<td>Perform</td>
</tr>
<tr>
<td>Correctly interprets ABO/Rh of patients who received out-of-group/type HSCTs or transfusions</td>
<td>Perform X 3</td>
<td>mC-1</td>
<td>Perform</td>
</tr>
<tr>
<td>Recognizes and records mixed field results appropriately</td>
<td>Perform X 3</td>
<td>rB-20</td>
<td>Perform</td>
</tr>
<tr>
<td>Completes the “evaluation of mixed field agglutination” form correctly</td>
<td>Perform X 3</td>
<td>mC-1</td>
<td>Perform</td>
</tr>
<tr>
<td>Enters appropriate mixed field result notes using templates</td>
<td>Perform X 3</td>
<td>rB-20</td>
<td>Perform</td>
</tr>
<tr>
<td>Recognizes and resolves missing reactivity with patient plasma</td>
<td>Perform X 2 (in training domain if necessary)</td>
<td>mC-1</td>
<td>Perform</td>
</tr>
<tr>
<td>Performs ABO/Rh testing with auto control for babies with no initial backtype results</td>
<td>Perform X 2 (in training domain if necessary)</td>
<td>mC-1</td>
<td>Perform</td>
</tr>
</tbody>
</table>

### Use of Irradiated Blood Products

<table>
<thead>
<tr>
<th>Activity</th>
<th>Explanation</th>
<th>Code</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>States which patients usually require irradiated blood products</td>
<td>A – 5 Discuss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>States which components require irradiation</td>
<td>A – 5 Discuss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explains the rationale for the requirement for children &lt; 1 year old requiring washed red cell when irradiated greater than 3 days previous</td>
<td>A – 5 Discuss</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Rad-Sure® Labels

<table>
<thead>
<tr>
<th>Activity</th>
<th>Explanation</th>
<th>Code</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uses Rad-Sure labels temperature history indicator to determine their viability</td>
<td>E – 17 Perform X 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>States what the different colors of the Rad-Sure color indicator signify.</td>
<td>E – 17 Discuss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Records new lot numbers and the color of the temperature history indicator on the irradiation log sheet</td>
<td>E – 17 Discuss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completes and apply an “Opened/Expires” sticker to the new Rad-Sure box</td>
<td>E – 17 Discuss</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Irradiation of Blood Products

<table>
<thead>
<tr>
<th>Activity</th>
<th>Explanation</th>
<th>Code</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>States when product labels should be completed during irradiation</td>
<td>E – 17 Discuss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>States the maximum unit capacity of irradiator for different blood products; a) RBCs b) Pheresis platelets</td>
<td>E – 17 Discuss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Writes your initials and the date of irradiation in the appropriate spaces of the Rad-Sure label and apply to product</td>
<td>E – 17 Perform X 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completes the first six columns of the irradiation log sheet for each unit to be irradiated</td>
<td>E – 17 Perform X 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verifies that instrument is powered up</td>
<td>E – 17 Perform X 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Logs into irradiator computer by scanning badge</td>
<td>E – 17 Perform X 10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### IRRADIATION OF BLOOD PRODUCT

<table>
<thead>
<tr>
<th>Task</th>
<th>Pass</th>
<th>RemEDIATE</th>
<th>Evaluator:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Properly selects components to irradiate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verifies that instrument is powered up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Logs into system by scanning badge</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Addition of Rad-Sure label and obliteration of license number completed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Properly enters unit data in irradiator computer</td>
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<td></td>
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<tr>
<td>Places the correct number of units in the Gamma irradiator</td>
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</tr>
<tr>
<td>Properly operates the Gamma irradiator</td>
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</tr>
<tr>
<td>Promptly removes the units from the irradiator and checks Rad-Sure label for proper exposure</td>
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<tr>
<td>Reviews/updates expiration of product after irradiiation</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Reviews computer record of irradiation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selects and applies correct component label</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Computer entry accurate</td>
<td></td>
<td></td>
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<tr>
<td>Unit verified in the BBIS</td>
<td></td>
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</tr>
</tbody>
</table>

### SAMPLE ACCESSIONING

<table>
<thead>
<tr>
<th>Task</th>
<th>Pass</th>
<th>RemEDIATE</th>
<th>Evaluator:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube and order document checked for completeness (including date/time stamped) and agreement of patient identification</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Computer history reviewed and documented</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Request entry performed correctly</td>
<td></td>
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<tr>
<td>Special transfusion requirements, if any, documented on slip and entered into the computer</td>
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<tr>
<td>Blood bank comment entered into computer as required</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Sample centrifuged and checked for hemolysis</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

PRODUCT NUMBER: __________

ACCESSION NUMBER: __________
### Competency Matrix Example: completed for staff after 1 year of employment

<table>
<thead>
<tr>
<th>Test System</th>
<th>Task</th>
<th>1 Direct Observation</th>
<th>2 Monitoring recording results</th>
<th>3 Review work sheets and/or QC</th>
<th>4 Observe Instrument Maintenance</th>
<th>5 Blind samples</th>
<th>6 Problem Solving</th>
<th>7 Computer Skills</th>
<th>Accession # / Reference/ or Assessor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type &amp; Screen</strong></td>
<td>Observe manual antibody screen</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Manual ABO recheck</td>
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<tr>
<td></td>
<td>Reagent QC record review</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Weekly data archiving</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>PT/Self-Check or blind A/S</td>
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</tr>
<tr>
<td></td>
<td>Problem Solving Scenario/ Quiz #</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Donor Conformations</strong></td>
<td>Verification of ECHO donor confirmation results</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Load donor confirmation samples on ECHO</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>ECHO daily QC review</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Observe checking probe alignment</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Blind ABO on donor sample</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Problem Solving Scenario/ Quiz #</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
## Competency Matrix Example:
completed for staff after 1 year of employment

<table>
<thead>
<tr>
<th>Antigen Typing</th>
<th>Task</th>
<th>1 Direct Observation</th>
<th>2 Monitoring recording results</th>
<th>3 Review work sheets and/or QC</th>
<th>4 Observe Instrument Maintenance</th>
<th>5 Blind samples</th>
<th>6 Problem Solving</th>
<th>7 Computer Skills</th>
<th>Accession # / Reference/ or Assessor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observe phenotype testing</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Review test result on daily report</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Antigen QC review on daily report</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blind sample for antigen phenotyping</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quiz #</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Cross-matching</td>
<td>D.O. of tagging units with correct chart copy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Record review of Coombs XM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Observe heat block temp. recording</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Observe cell washer volume check</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>PT, Self-check, or blind sample XM</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quiz #</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Direct Observation

2015 DIRECT OBSERVATION CHECKLIST - ANTIBODY SCREEN

MANUAL LISS ANTIBODY SCREEN

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Pass</th>
<th>Remediate</th>
<th>Evaluator:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptable station QC verified</td>
<td></td>
<td></td>
<td></td>
<td>9/2/15</td>
</tr>
<tr>
<td>Correct amount of patient plasma added</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct amount of reagent rbc added</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct amount of LISS added: adequately mixed</td>
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</tr>
<tr>
<td>Cells, plasma and LISS added in the correct order</td>
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<tr>
<td>Tubes incubated at 37°C for the appropriate time</td>
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<tr>
<td>Cells washed according to procedure</td>
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<tr>
<td>Correct amount of IgG added</td>
<td></td>
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<tr>
<td>Tubes spun within 1 minute of adding IgG</td>
<td></td>
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<tr>
<td>Reactions read macroscopically</td>
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<tr>
<td>Button completely dislodged before recording result</td>
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<tr>
<td>Results recorded tubes in hand</td>
<td></td>
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<tr>
<td>Results interpreted correctly</td>
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<tr>
<td>IgG sensitized cells added to negative test</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Computer entry accurate</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

WEEKLY DATA ARCHIVING

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Pass</th>
<th>Remediate</th>
<th>Evaluator:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checks that instrument is not processing samples before loading a new disc into D: drive.</td>
<td></td>
<td></td>
<td></td>
<td>10/7/15</td>
</tr>
<tr>
<td>In File Management, verifies that all batches are V'd in the Results, Event logs and Configuration files tabs.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Verifies the Archive location is the D: drive and returns to the Results screen.</td>
<td></td>
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</tr>
<tr>
<td>Selects the Archive radio button and YES to start archiving.</td>
<td></td>
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</tr>
<tr>
<td>Monitors progress of operation and waits for disc to eject.</td>
<td></td>
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</tr>
<tr>
<td>Reloads the disc into the D: drive.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Uses the Results tab in the General Options window to change the location of the results to the D: drive.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Checks in the Results panel that all files have been copied onto the disc.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Uses the Results tab in the General Options window to return the location of results field to the normal location.</td>
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</tr>
<tr>
<td>Labels and stores the disc correctly.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Uses the Results tab of File Management to verify only Results file is selected</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Selects Delete files and monitors progress</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Record on QC sheet</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Problems Identified By Evaluator & Remediation Plan.
Note: Document date remediation completed.

Additional Comments:

Reviewed by: Date: 10/7/15

*p Procedure element Performed according to SOP; 0 = improvement required
"Pass" = ALL procedure elements performed according to SOP
Competency Assessment

• CAP Proficiency Samples, Self-Check, known samples are used as blind samples for:
  – ABO/Rh
  – Antibody ID
  – Antibody Screen
  – Antigen Typing
  – Cross-matching

• Problem Solving
  – Built into direct observation for each test system as verbal questions.
    • What would you do if or What would you do next ?
    • What policy would you look to for guidance ?
  – Quizzes / Problem Solving written activities.
The "Individualized Quality Control Plan" (IQCP) is the Clinical Laboratory Improvement Amendments (CLIA) Quality Control (QC) policy currently under development as an alternate QC option allowed by 42CFR493.1250. IQCP permits the laboratory to customize its QC plan according to test method and use, environment, and personnel competency while providing for equivalent quality testing.

“When the manufacturers’ instructions do not address quality control or those instructions are less stringent than the regulatory control procedures for Analytic Systems…

the laboratory needs to follow the regulatory requirements or develop an IQCP.

Laboratories have the flexibility to follow all regulatory requirements as written or customize their control procedures using the IQCP procedure.

Whichever option is selected laboratories are not permitted to establish quality control procedures that are less stringent than those specified by the manufacturer of the test system.”

The purpose of IQCP is to develop a QC system when CLIA QC requirements are not being fulfilled. IQCP is not required if the manufacturer’s instructions are being followed and CLIA requirements are fulfilled. Laboratories may have the flexibility to follow all regulatory requirements as written or customize their control procedures using the IQCP procedure. This statement is true for laboratories that receive a CLIA Certificate of Compliance and are surveyed by their state agency. However, not all accreditation organizations allow IQCP for blood banking. Accredited laboratories must follow the standards of their accreditation organization, which may be more stringent than CLIA. A laboratory’s QC requirements can never be less than the manufacturer’s QC requirements, regardless of whether the laboratory is following the CLIA QC regulations or has developed an IQCP.
• AABB / CAP accredited
• No Individualized Quality Control Plan Created
• No Risk Assessment’s performed.
• Thorough review of all manufactures package inserts for specific wording for use.
  – Created a spreadsheet linking all critical material / reagents to a corresponding policy.
  – Choose to follow manufacturers written instructions.
  – Identified revisions to SOP’s needed.
### Package Insert / Reagent Review

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Reagent</th>
<th>Quality Control - Package Insert Wording</th>
<th>UMMC Current Practice</th>
<th>UMMC Policy #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immucor</td>
<td>Anti-A</td>
<td>tested each day of use</td>
<td>daily testing showing positive reaction / need negative</td>
<td>mG1: Daily Manual Reagent Quality Control</td>
</tr>
<tr>
<td>Immucor</td>
<td>Anti- B</td>
<td>tested each day of use</td>
<td>daily testing showing positive reaction / need negative</td>
<td>mG1: Daily Manual Reagent Quality Control</td>
</tr>
<tr>
<td>Immucor</td>
<td>Anti-A,B (Murine Monoclonal / Gamma Clone)</td>
<td>tested each day of use</td>
<td>daily testing showing positive reaction / need negative</td>
<td>mG1: Daily Manual Reagent Quality Control</td>
</tr>
<tr>
<td>Immucor</td>
<td>Anti-D (Series 4)</td>
<td>tested each day of use</td>
<td>daily testing showing both pos/neg</td>
<td>mG1: Daily Manual Reagent Quality Control</td>
</tr>
<tr>
<td>Immucor</td>
<td>Anti-A1 lectin</td>
<td>tested each day of use</td>
<td>with pos / neg control</td>
<td>rB15: Phenotyping Patient or Donor Red Cells</td>
</tr>
<tr>
<td>HemoBioscience</td>
<td>Anti-Cw</td>
<td>tested each batch</td>
<td>Add Statement for Batch</td>
<td>rB15: Phenotyping Patient or Donor Red Cells</td>
</tr>
</tbody>
</table>

- Identified need for negative controls for each Anti-A, Anti-B, and Anti-A,B not as part of a test system.
- Identified anti-sera requiring controls for each batch. Current policies was to follow specific manufacturer instructions for anti-sera which was currently followed, but the spreadsheet allowed us to thoroughly review and identify.
## Reagent Quality Control Sheets

### Daily Reagent Quality Control Station A

<table>
<thead>
<tr>
<th>Day</th>
<th>Date</th>
<th>A1 Cells</th>
<th>B Cells</th>
<th>A1 Cells</th>
<th>SCI Cells</th>
<th>B Cells</th>
<th>CC</th>
<th>SCI</th>
<th>SCII</th>
<th>SCIII</th>
<th>Heat Block</th>
<th>Last Well #</th>
<th>Temp</th>
<th>Tube Fill OK?</th>
<th>Lot #</th>
<th>Y/N</th>
<th>Results Accept?</th>
<th>Y/N</th>
<th>Tech Init</th>
<th>SC Init</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday</td>
<td></td>
<td>4+</td>
<td>0</td>
<td>4+</td>
<td>0</td>
<td>≥2</td>
<td>Neg</td>
<td>√</td>
<td>1+ - 2+</td>
<td>at IgG</td>
<td>Neg</td>
<td>Saline</td>
<td>36 - 38 C</td>
<td>X or NIU</td>
<td>Not in use</td>
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<tr>
<td>Tuesday</td>
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</tbody>
</table>

### Daily Reagent Quality Control Station B

<table>
<thead>
<tr>
<th>Day</th>
<th>Date</th>
<th>Anti-A</th>
<th>Anti-B</th>
<th>Anti-D</th>
<th>Poly AHG</th>
<th>Dilute Anti-D</th>
<th>Dilute Anti-D</th>
<th>Heat Block</th>
<th>Last Well #</th>
<th>Temp</th>
<th>Tube Fill OK?</th>
<th>Lot #</th>
<th>Y/N</th>
<th>Results Accept?</th>
<th>Y/N</th>
<th>Tech Init</th>
<th>SC Init</th>
</tr>
</thead>
<tbody>
<tr>
<td>MON</td>
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<tr>
<td>TUES</td>
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</tbody>
</table>
Questions
Q&A
Q&A

• What do I do when my lab has been found to not conform with the Accrediting Organization’s criteria

• What do I do when I disagree with a finding rendered by an Accrediting Organization?
Questions
Thank you....
Happy Lab Week!