Document Review: Centers for Medicare and Medical Service (CMS) What Do I Need to Do to Assess Personnel Competency?

Assessment of lab personnel performing CLIA approved tests

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Introduction:

Clinical Laboratory Improvement Amendments (CLIA)
The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 225,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Office of Clinical Standards and Quality (OCSQ) has the responsibility for implementing the CLIA Program. The objective of the CLIA program is to ensure quality laboratory testing. REFERENCE: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/

The authors reviewed the CMS document http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf. Their presentation covers the requirements for laboratory tests covered under CLIA. This presentation is focused on the CMS document, please note your accrediting agency (Joint Commission or CAP for CLIA) may have additional / more stringent requirements

For the CLIA licensed Quality Control (QC) lab for cell processing (represented by these speakers) – Sterility, CD34 and cell counts are required on their CLIA certificate. CD34 is done as Peripheral Blood CD34 to determine if a donor should or should not be apheresed. The latter part of the presentation describes how the lab has incorporated / implemented the regulations into their training and assessment program
CLIA Definition of Covered Tests

• Under CLIA, if one tests or examines human specimens and reports patient-specific results for the diagnosis, prevention or treatment of any disease or impairment, or the assessment of the health of individual patients/human beings; then the tests do fall under CLIA.

• Test system means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

• Given this, performing Quality Control (QC) laboratory tests for the quality assessment of Cell Therapy (CT) Products are not covered. (May be different if your CT products (e.g., cord blood) are licensed. The exception is sterility cultures, since the reporting of a positive find may lead to the treatment of a Donor/patient).
Cell Processing Quality Control Lab
(Dana Farber Cancer Institute)

• Our CLIA certificate is for:
  – **Immunology** (Peripheral blood CD34 to assess qualification for apheresis)
  – **Microbiology** (sterility cultures on products)
    • Results of product sterility cultures are reported to the physicians and positive findings may lead to the treatment of a Donor/patient
  – **Hematology** (TNC used for percentage method of CD34 tests)
Competency vs. Proficiency

• Competency assessment
  – Confirms Lab Personnel can adequately perform laboratory duties

• Proficiency Testing
  – Assesses the laboratory’s ability to perform accurate and reliable testing of unknown samples
Competency Assessment

• Training and personnel evaluation is not the same as competency assessment

• Competency is application of knowledge, skills and behaviors of performance after staff has been trained
  – Six methods must be used
  – Assess testing personnel for all CLIA required lab tests performed
  – Frequency
    • Semi-annually in the first year
    • Annually thereafter
    • Any time a method or instrument changes prior to reporting results
6 Methods for Assessment of CLIA Competency

• Direct observation
• Monitoring recording and reporting of results
• Review of intermediate test results
• Direct observation of instrument maintenance and function checks
• Assessment of test performance
• Assessment of problem solving skills
Which Personnel?

- Clinical Consultant (CC)*
- Technical Consultant (TC)*
- Technical Supervisor (TS)*
- General Supervisor (GS)*
- Testing personnel
- Lab Director

*In addition to the six required assessments for testing performed, must also assess for competency based on their federal regulatory responsibilities.
Who is required to have a competency assessment?

Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC), technical supervisor (TS), general supervisor (GS) and testing personnel (TP). Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities.

Note: If the laboratory director (LD) is the only individual testing and reporting test results, (s)he must establish and document a minimal level of proficiency in order to ensure that (s)he maintain the required competency for accurate and reliable testing and reporting.
Responsible Party for Performing the Assessment

• Moderate Complexity
  – Technical Consultant

• High Complexity
  – Technical Supervisor
    • Delegate in writing to a General supervisor

• Peer Testing Personnel (TP) cannot be designated to perform competency assessment if they do not qualify as General Supervisor (GS), Technical Consultant (TC), Technical Supervisor (TS)

• Lab Director ultimately responsible
Who is responsible for performing the competency assessment?

The Technical Consultant for moderate complexity testing (42 CFR §493.1413(b)(8)) is responsible for performing and documenting competency assessments. The competency assessments may also be performed by other personnel who meet the regulatory qualification requirements for TC for moderate complexity testing.

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 as long as the GS meets the regulatory qualifications as a GS for high complexity testing.

Peer testing personnel who do not meet the regulatory qualifications of a TC, TS, or GS cannot be designated to perform competency assessments.

Ultimately, the Laboratory Director is responsible for ensuring that all testing personnel are competent and maintain their competency in order to perform and report accurate and reliable test results.
Combining Assessments

- Tests performed on the same platform
  - Okay if no unique aspects, problems or procedures in the tests
  - Tests with unique aspects, problems or procedures within the same testing platform must be assessed separately to ensure that staff maintain their competency to report test results promptly, accurately and proficiently
Suggested Items to Assess for Testing Personnel

- Collect sufficient patient sample and correctly process the specimen used for the testing?
- Complete the test report correctly, using the appropriate test units of measurement?
- Perform the test correctly by adding the proper order and amount of patient specimen and reagent(s)?
- Add the testing solutions in the proper amount and order?
- Collect sufficient patient sample and add it to the testing system correctly?
- Use test solutions and reagents from the same test kit and lot number?
- Maintain records of the patient testing results?
- Treat proficiency testing samples in the same manner as patient specimens and maintain records indicating such?
- Adhere to the laboratory’s Quality Control (QC) policies and document QC activities?
- Adhere to the laboratory’s policies for instrument calibrations and maintenance activities?
- Follow the laboratory’s corrective action policies and procedures when a test system fails to meet the laboratory’s acceptable level of performance?
- Identify problems that may affect test performance or reporting test results and either correct the problem or notify the Technical Consultant or Director?
- Document all corrective action taken when there is a test system failure?
Suggested Competency Assessment for the 
TC (moderate complexity) and TS (high complexity testing)?

• Assures that performance specifications are established or verified for necessary tests

• Enrollment in an approved HHS approved proficiency testing program for each test requiring proficiency testing (PT)?
  – How well does the laboratory perform PT? Are the
  – Review of PT results

• Ensure that a Quality Control (QC) program is in effect and is adequate for the laboratory

• Resolves technical problems and insures remedial actions are taken

• Ensures patient test results are not reported until all corrective actions have been taken and the test system is functioning properly

• Identifies training needs and assures that each individual performing tests receives regular in-service training and education appropriate for the tests they are perform

• Evaluates the competency of the testing personnel and assure that all staff members maintain their competency to perform tests accurately, report results promptly, accurately and proficiently.
Dana Farber Cancer Institute-Cell Manipulation Core Facility performs high complexity testing:

<table>
<thead>
<tr>
<th>CLIA Licensed</th>
<th>Other Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO &amp; Rh</td>
<td>CD3+ Counts</td>
</tr>
<tr>
<td>CD34+ Counts *</td>
<td>CD25+ Counts</td>
</tr>
<tr>
<td>Cell Counts</td>
<td>CFU Assay</td>
</tr>
<tr>
<td>Sterility</td>
<td>Endotoxin</td>
</tr>
</tbody>
</table>

* billable testing
CURRENT PROCESS

- Six assessment methods are used annually for each person performing lab tests
- Competency assessment on key tests
- All staff assessed at six months and annually thereafter
- Assessments performed by Supervisor or qualified designee from Quality Assurance or Technical Staff
How We Track Competency

• Each assessment has its own form, which gets stored in staff members training binder.

• States clear objectives and passing criteria.

• May cover more than one assessment method.

• Staff are rated from
  • A (can train others) to
  • D (needs more training)

Competency Assessment For Flow Cytometry

Objective and acceptable criteria: This competency will be completed to assess competence of performing flow cytometry. To determine proficiency the technologist will be observed performing the procedure in accordance with appropriate SOP. A minimum passing criteria for this competency completing being documented as proficient on all observations. In the event the technologist does not meet competency requirements than the technologist will be re-trained as deemed appropriate per SOP 007.

Direct Observation

<table>
<thead>
<tr>
<th>Processing/Technique Observations:</th>
<th>Competency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample ID: W1231 13 456788</td>
<td>NA</td>
</tr>
<tr>
<td>SOP Used: 7.10.6</td>
<td>NA</td>
</tr>
<tr>
<td>1. Ensures instrument QC checks have been run and instrument is within all acceptable ranges as defined by SOP.</td>
<td>√</td>
</tr>
<tr>
<td>2. Prepares sample as described in SOP.</td>
<td>√</td>
</tr>
<tr>
<td>3. Processes sample as described in SOP.</td>
<td>√</td>
</tr>
<tr>
<td>4. Saves test results to computer database per SOP.</td>
<td>√</td>
</tr>
<tr>
<td>5. Supervisor reviews results, signs off on results and attaches a copy to this record.</td>
<td>√</td>
</tr>
<tr>
<td>6. Reports results as required in a timely manner.</td>
<td>√</td>
</tr>
</tbody>
</table>

Comments: CD34 enumeration single platform

Indicate Level of Competency (A-D): A

A. Competent is able to train and assess the competency of others
B. Competent and can perform independently
C. Some experience - may require additional training
D. Little or no experience - requires additional training

Technologist Review: ___________________________ Date __________
Assessor Review: ___________________________ Date __________
Supervisor Review: ___________________________ Date __________
Quality Assurance Review: ___________________________ Date __________
How We Track Competency

- Competency Assessment Tracking Documents created each year.
- Lists all required competency assessments
- Maintained by QA
- Provides a quick reference to track assessment throughout the year

### 2013 Competency Assessment Tracking

<table>
<thead>
<tr>
<th>Date</th>
<th>Competency Assessed</th>
<th>Description of Assessment</th>
<th>Methods Used (see key above)</th>
<th>Level of Competence</th>
<th>Assessed By</th>
<th>Documented in Training Binder</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/20/13</td>
<td>ABO &amp; Rh</td>
<td>Observation</td>
<td>1, 2, 3, 4</td>
<td>B</td>
<td>AWP</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>1/20/13</td>
<td>ABO &amp; Rh</td>
<td>Unknown Sample</td>
<td>5</td>
<td>B</td>
<td>AWP</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>1/2/13</td>
<td>ABO &amp; Rh</td>
<td>Quiz</td>
<td>6</td>
<td>B</td>
<td>AWP</td>
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<td>✓</td>
</tr>
<tr>
<td></td>
<td>Cell Counts</td>
<td>Observation</td>
<td>1, 2, 3, 4</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cell Counts</td>
<td>Unknown Sample</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Cell Counts</td>
<td>Quiz</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2/5/13</td>
<td>CD34+ Enumeration</td>
<td>Observation</td>
<td>1, 2, 3, 4</td>
<td>A</td>
<td>AWP</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>CD34+ Enumeration</td>
<td>Unknown Sample</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2/5/13</td>
<td>CD34+ Enumeration</td>
<td>Quiz</td>
<td>6</td>
<td>A</td>
<td>AWP</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>Trypan Viability</td>
<td>Observation</td>
<td>1, 2, 3, 4</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Trypan Viability</td>
<td>Unknown Sample</td>
<td>5</td>
<td></td>
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<tr>
<td></td>
<td>Sterility</td>
<td>Observation</td>
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<tr>
<td></td>
<td>Sterility</td>
<td>Unknown Samples</td>
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<td>Sterility</td>
<td>Quiz</td>
<td>6</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Note: For additional details see SOP 007 and staff training binder.

Levels of Competency:
A. Competent and able to train others
B. Competent and can perform independently
C. Some experience, requires additional training
D. Little or no experience

Final Supervisor Review: ___________________________ Date: ____________
Final QA Review: ___________________________ Date: ____________
On-going Evaluation & Areas for Improvement

- Ensure that all tests on CLIA license are included on annual competency.
  - Use all six assessment methods for each test and methods were applicable (CD34 single vs. dual platform).

- Delegation Responsibility
  - Document the delegation of responsibility from the Laboratory Director to Technical Supervisor to General Supervisors
  - All current QC Staff meet the requirement of a GS

- Timetable –
  - Clarify the timing for semi-annual competency assessment during first year of employment. (Within 3-6 months and before end of first year)
References

- **What Do I Need to Do to Assess Personnel Competency?** CMS, November 2012
- **Current CLIA Regulations**
- **FDA Searchable web site for test complexity**