CLIA Personnel & Competency Requirements

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Chief Medical Officer, COLA

DESCRIPTION:
In addition to the laboratory director, the CLIA regulations specify personnel positions for moderate and high complexity laboratories that must be filled by qualified individuals that meet their defined responsibilities. Personnel must be properly trained and their competency must be regularly evaluated using defined methods. This session will discuss the personnel requirements and steps for compliance.

OBJECTIVES:
At the end of the session, participants will be able to:
- Identify and summarize CLIA personnel requirements for each position
- Illustrate instances of non-compliance
- Implement appropriate corrective actions to achieve compliance
- Discuss rational for competency
- Outline six CMS requirements for Competency Assessment
OBJECTIVES

- Identify and summarize CLIA personnel requirements and responsibilities for each position other than Laboratory Director
- Illustrate instances of non-compliance
- Discuss appropriate corrective actions to achieve compliance
- Discuss rational for competency
- Outline six CMS requirements of Competency Assessment
PERSONNEL

PERSONNEL FOR NON–WAIVED TESTING

› Clinical Laboratory Improvement Amendment 1988 (CLIA)
  ▪ Specifies “CLIA” Laboratory Personnel Positions
  ▪ Indicates qualifications for each position
  ▪ Defines responsibilities for each position

› Some states have additional requirements
  ▪ Most notable is licensure
REQUIRED LABORATORY POSITIONS

<table>
<thead>
<tr>
<th>Moderate Complexity</th>
<th>High Complexity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Director</td>
<td>Laboratory Director</td>
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<tr>
<td>Clinical Consultant</td>
<td>Clinical Consultant</td>
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<tr>
<td>Technical Consultant</td>
<td>Technical Supervisor</td>
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<tr>
<td></td>
<td>General Supervisor</td>
</tr>
<tr>
<td>Testing Personnel</td>
<td>Testing Personnel</td>
</tr>
</tbody>
</table>

REQUIRED POSITIONS CONTINUED

- There must be a qualified individual designated for each of the positions specified in CLIA, based on the complexity of the laboratory
  - If qualified, the laboratory director (and others) may fill multiple positions.
- All the individuals filling positions must be qualified by education and experience
STEPS FOR PERSONNEL COMPLIANCE

- Determine complexity of testing laboratory is performing
  - Should be identifiable in package insert, instrument operator's manual or FDA data base
- Even with one high complexity test, testing personnel performing the high complexity test must meet CLIA high complexity personnel requirements and all other required positions must be filled by personnel qualified according to CLIA regulations

CLINICAL CONSULTANT Responsibilities

- Provides consultations on appropriate test ordering and test interpretation for laboratory clients
- In collaboration with the Laboratory Director, consults on matters related to the quality of reported test results
- Ensures test reports contain all pertinent information required for interpretation
  - Annual documentation of review of test report templates easy way to document
CLINICAL CONSULTANT
Non–compliant Scenario

- The major issue we see cited for Clinical Consultant is lack of annual competency assessment.

TECHNICAL CONSULTANT

- Required position in moderate complexity laboratory
- If position filled by LD, must have one year laboratory training or experience
- Often overlooked and underestimated
- Multiple LD oversight responsibilities are fulfilled by Technical Consultant
- Position in high complexity laboratory: technical supervisor
TECHNICAL CONSULTANT/SUPERVISOR Responsibilities

- Responsible for technical and scientific oversight
  - Selects appropriate test methodology
  - Establishes performance criteria
- Enrolls laboratory in appropriate proficiency testing
- Establishes quality control program and ensure adherence through periodic review
- Resolves technical problems and documents corrective action

TECHNICAL CONSULTANT/SUPERVISOR Responsibilities Continued

- Ensures results not reported when performance specifications are not met (e.g. QC, maintenance)
- Ensures performance of training and competency for all personnel
- Ensures implementation of Quality Assessment Program
- Provides regular continuing education
TECHNICAL CONSULTANT CAVEAT
Moderate Complexity Laboratory

- For MD/DO/DPM one year lab training or experience in non-waived testing required
- If lacking the experience, this course does not allow functioning as TC until completion of one year experience under a qualified TC
- Doctoral or Masters degree in laboratory science also requires one year laboratory experience in non-waived specialty/subspecialty of service
- Bachelor’s degree requires two years experience

TECHNICAL CONSULTANT
Non-Compliant Scenario

- Current Proficiency Testing lacks enrollment of recently introduced chemistry analytes.
- No documentation of review of graded results for any PT for past year
- Quality Control results for both chemistry and hematology testing not regularly reviewed and review documented
- All testing staff not adequately trained on the new chemistry analyzer
- Competency evaluations of staff last performed 18 months ago
**TECHNICAL CONSULTANT**

**Corrective Action**

- If you are TC obtain services of outside TC
- Interval between visits dependent upon
  - Volume of testing
  - Complexity of testing
  - Condition of laboratory i.e. total initiation or revamping vs. oversight
- If you are not TC, consider obtaining services of a different TC

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**TECHNICAL CONSULTANT**

**Non-Compliant Scenario**

- The laboratory director designated the de facto “lab manager” as the technical consultant
- She is an MLT with an Associates degree, and over ten years of experience running the laboratory
The title of “Lab Manager” is internal and valid for use within the testing facility; however, to qualify as the technical consultant, CLIA standards must be met:

- Bachelor of Science Degree in lab science is required + two years experience
- However, LD can be TC with oversight of the “Lab Manager”

Technical supervisor for Microbiology graduated the prior June from a school of Medical Technology, has a Bachelor of Science degree, and has been trained in this specialty.
TECHNICAL SUPERVISOR
Corrective Action

- Microbiology Technical Supervisors (High Complexity lab) must have a B.S. degree and four years of training or experience in high complexity microbiology
- (Remember: TC with B.S. degree in moderate complexity laboratory requires two years experience)

TESTING PERSONNEL
Responsibilities

- Responsible for specimen handling and processing, test performance, test reporting, and recording maintenance and all corrective actions
- May only perform those tests authorized and documented with training and competency records
Each position in the laboratory must have a written, up to date job description and it must describe individual duties and responsibilities.

This includes ALL positions:
- Laboratory Director
- Clinical Consultant
- Technical Consultant/Supervisor
- General Supervisor
- Testing personnel

Job descriptions for employees working in the laboratory and also performing other office functions do not include specific tasks and responsibilities associated with laboratory work or

Job description has not been updated and refers to testing no longer performed or instruments and kits no longer utilized.
Employee files should contain documentation defining the laboratory tasks assigned to the employee, and their level of responsibility as it pertains to all phases of testing.

There should be documentation that employee has been advised of duties and responsibilities and best documented by signature or initials of employee and date signed. This can be incorporated as part of training record.

File should contain copy of job description

File must contain documentation of the person’s education and experience that qualifies them for the position they hold in the laboratory

File must contain evidence of training and competency

Evidence of continuing education should be on file
PERSONNEL FILE
Clarification 1

- Appropriate documentation of education includes a copy of a diploma, or a transcript indicating the date of graduation from an appropriately accredited institution.
- Documentation should verify the highest level of education qualifying the person for the position they hold in the laboratory.
- Non-traditional school, copy of transcript can be evaluated.

PERSONNEL FILE
Clarification 2

- Foreign credentials must be evaluated by an acceptable credentialing agency for U.S. equivalency. Language translation of documents is not sufficient to meet this requirement.
- “Appropriate Documentation” does NOT include:
  - Non–laboratory professional licenses, such as CMA, LPN, or RT licenses
  - Certification by professional organizations such as ASCP, AMT
  - Vocational–Technical Training Certificates
PERSONNEL FILE
Primary Source Verification (PSV)

- Verification may be done by a third party in larger organizations
- Any organization that confirms an individual's credentials by verifying that a degree, certificate, or diploma was received; that licenses were granted; AND, by confirming reported work history, such as company names and locations, dates, and positions held is a considered PSV organization.
- CMS is not issuing standards to be applied to PSV organization

EDUCATION DOCUMENTATION
Non-Compliant Scenario

- High school diploma on file for a medical assistant performing moderate complexity laboratory testing is from an internet based correspondence school that is not accredited and no transcript is available
EDUCATION DOCUMENTATION
Corrective Action

- If the medical assistant did not graduate from an accredited high school or have a state issued GED, they may not meet the requirements of high school graduation and are not readily considered qualified to perform moderate complexity laboratory testing.

- Home schooling and internet based high schools must be evaluated individually. If a transcript is provided probably will be adequate. Check with AO or CMS for help with these.

EDUCATION DOCUMENTATION
Non–Compliant Scenario

- Lack of a H.S. diploma in the personnel records of a staff technologist performing moderate complex tests. Certificate of Medical Assistant training by a local vocational–technical institute is present which indicates H.S graduate.

- Laboratory technologist received education in another country, and the diploma in the file is in a language other than English and has been translated into English. No record of this diploma having been sent for review by an agency that can certify equivalency to a US diploma.
EDUCATION DOCUMENTATION
Corrective Action

- Notify your human resources department that the appropriate qualifying documents need to be obtained prior to hire and then maintained in employee files.
- If the staff has been trained in a foreign country, their degree must be verified for equivalency with an accredited certifying agency. Translation alone not adequate.
- Be aware of the specific personnel requirements for high complexity testing, including education, training, and experience.

EDUCATION DOCUMENTATION
Non-Compliant Scenario

- Testing staff for a high complexity laboratory include medical assistants with documented high school degrees.
Testing personnel in laboratories performing high complexity testing must have as a minimum an Associates degree and graduated from a laboratory training program or meet other semester hour requirements as spelled out in the regulations.
TRAINING

- Training is process to provide and develop knowledge and skills to meet requirements of a position
  - At time of hire
  - With introduction of new or changed process or procedure
  - When new technology changes the work processes
  - When training needs are identified
- The training should occur BEFORE inauguration of job performance

CLIA COMPETENCY ASSESSMENT

- Required of all supervisory and testing personnel including technical and clinical consultants but not the Laboratory Director
- Training and Competency are separate activities
- Competency assessment verifies that the knowledge and skills gained from training are used
- Competency is NOT the same as a performance evaluation
RATIONALE FOR COMPETENCY ASSESSMENT

- Qualifications for testing personnel for moderate complexity testing are minimal
- Greater education and training produces higher quality results
- CLIA survey experience indicates many problems secondary to inadequate training
- Routine competency evaluations can reduce testing errors

PERFORMANCE APPRAISAL vs. COMPETENCY ASSESSMENT

- Performance appraisals are valuable and necessary, but do not typically address technical competency in all phases of testing
- Incorporating these two important assessments into one process is difficult, as they each have a different focus
COMPETENCY vs. PERFORMANCE

<table>
<thead>
<tr>
<th>Competency</th>
<th>Performance Appraisal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to perform assigned tasks according to defined processes and procedures to assure reliable laboratory results</td>
<td>Initiative</td>
</tr>
<tr>
<td></td>
<td>Work ethic</td>
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<tr>
<td></td>
<td>Attendance</td>
</tr>
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<td></td>
<td>Behavior</td>
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<td></td>
<td>Team Player</td>
</tr>
</tbody>
</table>

TRAINING vs. COMPETENCY

- Important to document all aspects of training covered
- Competency assessment then serves as a confirmation that training was effective
Even among larger laboratories with formal structure, historically has been little uniformity as to what constituted a valid assessment of competency.

In recent years, there has been a regulatory emphasis on competency assessment, as a quality tool to reduce laboratory errors.

This emphasis will continue, as competency is a component of Individualized Quality Control Plans (IQCP).

**ASSESSING COMPETENCY**
CLIA Brochures

The following brochures help to explain the Clinical Laboratory Improvement Amendments (CLIA) regulation requirements and they are listed below as downloads:

- **Brochure #1** - How do they affect my laboratory? - Summary of the updated requirements from the CLIA regulations published January 24, 2003
- **Brochure #2** - Verification of Performance Specifications
- **Brochure #3** - Calibration and Calibration Verification
- **Brochure #4** - Discontinued 12/31/2015
- **Brochure #5** - How to Obtain a CLIA Certificate
- **Brochure #6** - How to Obtain a CLIA Certificate of Waiver
- **Brochure #7** - Laboratory Director Responsibilities
- **Brochure #8** - Proficiency Testing
- **Brochure #9** - Complaints, Do You Have a Concern About a Laboratory’s Operation?
- **Brochure #10** - What Do I Need To Do to Assess Personnel Competency?
- **Brochure #11** - CLIA Individualized Quality Control Plan Introduction (IQCP)
- **Brochure #12** - CLIA IQCP: Considerations When Deciding to Develop an IQCP
- **Brochure #13** - CLIA IQCP: What is an IQCP?

Downloads

- CLIA Brochure #1 [PDF: 523KB](#)
- CLIA Brochure #2 [PDF: 15KB](#)
- CLIA Brochure #3 [PDF: 15KB](#)
- CLIA Brochure #4 [PDF: 15KB](#)
- CLIA Brochure #5 [PDF: 15KB](#)
- CLIA Brochure #6 [PDF: 15KB](#)
- CLIA Brochure #7 [PDF: 35KB](#)
- CLIA Brochure #8 [PDF: 15KB](#)
ASSESSING COMPETENCY

- WHO is required to undergo competency assessment?
  - Clinical Consultant
  - Technical Consultant/Technical Supervisor
  - General Supervisor
  - Testing Personnel

- Essentially everyone except the Laboratory Director

ASSESSING COMPETENCY

- The Laboratory Director is not required to have competency assessment

- However
  - LD competency really assessed at time of survey
  - The Laboratory Director is responsible for oversight of all CLIA defined responsibilities
  - Actual responsibility for accessing competency falls to the technical consultant/supervisor
  - LD responsible for oversight of TC/TS fulfilling regulatory functions
CLIA POSITIONS

- Clinical Consultants, TC/TS/GS need to have the six required components used in competency assessment, just as any other testing personnel only if they perform testing.
- If these personnel do not perform testing, they only need to be assessed for their regulatory responsibilities.

DOCUMENTING COMPETENCY OF CC/TS/TC/GS

- Acceptable:
  - Review of contract by LD if testing not performed
  - Review of findings of laboratory inspections
  - Review of fulfillment of regulatory responsibilities
    - Technical and scientific oversight
    - PT, QC and QA functions
    - Continuing education of testing personnel
    - Competency evaluation of testing personnel
    - Evidence of CC reviewing reporting formats annually
CLINICAL CONSULTANT COMPETENCY EVALUATION

Name: _________________________________ Date: _____________________

The Clinical Consultant renders opinions concerning patient diagnosis and treatment, and management of patient care. In addition, the Clinical Consultant:
<table>
<thead>
<tr>
<th>Task</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is available to provide consultation to the laboratory’s clients.</td>
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<tr>
<td>Is available to assist the laboratory’s clients in ensuring that the ordered tests are appropriate to meet the clinical expectations.</td>
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<tr>
<td>Is available for consultation and communication with the laboratory’s clients on matters related to the quality of reported test results and their interpretation concerning specific patient conditions.</td>
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<tr>
<td>Ensures that reports of test results include pertinent information required for specific patient interpretation.</td>
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</tbody>
</table>

Competency has been satisfactorily demonstrated: ___YES   ___NO

Comments: ________________________________________________________________

Lab Director Review:________________________________   Date:__________________
Technical Consultant/Supervisor Competency Evaluation

Name: _________________________________   Date: _________________________

Title: _________________________________

The Technical Consultant or Technical Supervisor is responsible for technical and scientific oversight. This person is not required to be on-site at all times, but must be available to provide needed consultation either on-site, by telephone, or electronically. In addition, the Technical Consultant / Technical Supervisor:

☐ Selects test methodology appropriate for the clinical use of the test menu.

☐ Verifies procedures for testing performed and establish the laboratory’s performance criteria, including accuracy and precision of each test and test system.

☐ Enrolls the laboratory in an approved PT program commensurate with services offered.

☐ Establishes a quality control program appropriate for the testing performed, establishes the acceptable levels of analytic performance, and ensures these levels are maintained throughout the testing process.

☐ Resolves technical problems and ensures corrective actions are taken whenever test systems deviate from the laboratory’s established performance specifications.
☐ Ensures patient test results are not reported until all corrective action has been taken and the test system is functioning properly.

☐ Identifies training needs and ensures testing personnel receive regular in-service training.

☐ Evaluates the competency of all testing personnel on an ongoing basis.

☐ Evaluates and documents Testing Personnel's performance at six months and twelve months during the first year of employment and yearly thereafter. Performance is reevaluated (prior to reporting patient test results) if test methodology or instrumentation changes. The evaluation must include the use of the new test methodology or instrumentation.

Competency has been satisfactorily demonstrated: ___YES ___NO

Note: If the Technical Consultant or Technical Supervisor performs testing they are also required to undergo competency assessment as testing personnel.

Comments: __________________________________________________________

____________________________________________________________________

Lab Director Review: _______________________________ Date: ______________________
STAFF INVOLVED IN PRE-ANALYTIC ACTIVITIES

- Accreditation Organization criteria include specimen collection staff in competency assessment requirement
- This is more stringent than CLIA
  - With pre-analytic errors being more closely scrutinized an area that deserves attention

CLIA REQUIREMENTS
6 Components of Competency Assessment

1. Direct observation of routine patient test performance
2. Monitoring the recording and reporting of test results
3. Review of intermediate test results, QC 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 testing samples
6. Assessment of problem-solving skills
COMPETENCY REITERATED

- Not simply a review of individual’s initiative, relationships or work ethic
- Focus must be on individual’s ability to perform assigned tasks according to defined processes and procedures to assure reliable laboratory results. The six competency assessment requirements must be followed evaluating Pre–Analytic, Analytic and Post Analytic processes

WHEN IS COMPETENCY EVALUATED?

- Competency evaluations are preformed
  - Semi–annually during the first year of employment
  - Annually thereafter
COMPETENCY EVALUATIONS

- Two of the six required assessment activities involve Direct Observation
  1. Direct observation of routine patient test performance
  4. Direct observation of instrument maintenance and function checks

- This is best documented with a detailed process oriented check list, per test or instrument

COMPETENCY EVALUATIONS

- Two of the six required assessment activities involve Review of Records
  2. Monitoring the recording of test results
  3. Review of intermediate test results, QC, Proficiency Testing results and Preventative Maintenance

- Indication of records reviewed should be included with the competency documentation
COMPETENCY EVALUATIONS

- One of the six required assessment activities can readily be accomplished in conjunction with record review e.g. QC
  
  6. Assessment of problem solving skills

COMPETENCY EVALUATIONS

- One of the six required assessment activities involves “duplicate” test performance
  
  5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency samples

- Can be assessed by results of PT actually submitted by employee being evaluated or use of pre-evaluated PT samples

- If pre-evaluated PT samples are used, beware of second testing before the cut-off date for specimen result submission
WHO SHOULD EVALUATE COMPETENCY?

- Competent individuals must assess the competency of the personnel under review
- Should not be the Office Manager, the Nursing Supervisor, or other non-trained Laboratorians
- CLIA gives this responsibility to the TC (moderate complexity) or TS (high complexity)
- Ultimately the Laboratory Director is responsible to determine that this has been properly performed

DELEGATION OF COMPETENCY

- Components of the overall competency assessment may be delegated by the TC/TS/GS/LD to competent personnel
- BUT the TC/TS/GS/LD MUST evaluate the overall results of the competency assessment and sign off on the final document
Based on evaluation
- Is the person competent?
- Is any remedial action indicated?
  - If so, there must be evidence of follow up
- Review and sign off by TC/TS/LD

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<table>
<thead>
<tr>
<th>Direct observation of test performance</th>
<th>Specific tests / records reviewed</th>
<th>Competencies Met? Y/N</th>
<th>Date</th>
<th>Reviewer’s Initials</th>
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<tbody>
<tr>
<td>- Pre-analytic sample handling</td>
<td>CBC</td>
<td>YES</td>
<td>3/9/17</td>
<td>AR</td>
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<tr>
<td>- Reagent handling</td>
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<tr>
<td>- Step by step procedure</td>
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<tr>
<td>- Result interpretation</td>
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<td>3/9/17</td>
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<td>Monitor test result recording &amp; reporting</td>
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<tr>
<td>- Transcription</td>
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<td></td>
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<td>3/12/17</td>
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<tr>
<td>Review of worksheets, QC, PT &amp; maintenance records</td>
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<td></td>
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<tr>
<td>- Completes records as required at appropriate frequency intervals</td>
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<tr>
<td>- Dates &amp; initials records</td>
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<tr>
<td>- If needed, takes corrective action &amp; documents appropriately</td>
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<tr>
<td>- Records are legible with appropriate corrections</td>
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<tr>
<td>Direct observation of instrument maintenance</td>
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<tr>
<td>- Performs, as required</td>
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<td>Assessment of test performance (PT / blind samples)</td>
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<td>- Achieves accuracy</td>
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<tr>
<td>- Identifies problems</td>
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<td>- Reports / documents problems &amp; problem resolution</td>
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<td></td>
<td><strong>AMCSS # 1234</strong></td>
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<tr>
<td>Competency has been satisfactorily demonstrated</td>
<td></td>
<td></td>
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<td></td>
</tr>
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</table>

Reviewer's Comments: None
Corrective Actions: N/A
Reviewer's Name: AR
Reviewer's Signature: AR
Date: 3/19/17
**Competency Assessment for:**  
**Hire Date:**  
**Performed By**

***Attach supporting documentation when possible.***

<table>
<thead>
<tr>
<th>List of tests and/or instruments</th>
<th>Direct observation of test performance (Reviewer date &amp; initial when completed)</th>
<th>Monitor test result recording &amp; reporting (Specific test(s) / records reviewed - Reviewer date &amp; initial when completed)</th>
<th>Review of worksheets, QC, PT &amp; maintenance records (Specific test(s) / records reviewed - Reviewer date &amp; initial when completed)</th>
<th>Direct observation of instrument maintenance (Reviewed date &amp; initial when completed)</th>
<th>Assessment of test performance (PT / blind samples) records (Specific text(s) / records reviewed - Reviewer date &amp; initial when completed)</th>
<th>Assessment of problem-solving skills records (Specific text(s) / records reviewed - Reviewer date &amp; initial when completed)</th>
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</thead>
<tbody>
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<td>See attached form Completed 4/4/16 JD</td>
<td>Chart 234ABC Chart 145DCG 3/23/16 CK</td>
<td>Records reviewed for the month of June 2016 4/18/2016/JD/CK</td>
<td>See attached form Completed 7/1/16 JD</td>
<td>API 1st event 2014 100% 5/13/16 CK</td>
<td>Copy of problem log attached 7/13/16 JD</td>
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<td>Clinical 500 Urine analytes</td>
<td>See attached form Completed 4/12/16 JD</td>
<td>Chart 234ABC Chart 145DCG 3/23/16 CK</td>
<td>Records reviewed for the month of June 2016 4/18/2016/JD/CK</td>
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</tbody>
</table>

- **Competency has been satisfactorily demonstrated**  
  Yes  
  No

<table>
<thead>
<tr>
<th>Reviewer’s Comments</th>
</tr>
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<tr>
<td>Reviewer’s Name</td>
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<td>Reviewer’s Signature</td>
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<td>Date (when all competencies have been completed):</td>
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</tbody>
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**TC Review**  
**Date of final evaluation**  
**Next review due by 69**

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**WAIVED TESTING COMPETENCY**

- Waived Testing competency not required under CLIA
- Accreditation organizations do require it
- Many tests categorized as waived can have significant patient impact if not performed correctly
WAIVED TESTING COMPETENCY

- Waived testing competency does not require all six elements
- BUT… competency assessment for waived testing should be defined and documented
- Evaluate each waived test and perform competency on the most meaningful aspects of a given test

QUESTIONS?