

Competency Assessment Program

Responsibilities, Management and
Implementation

January 2015

Training Module Objectives

- You will understand who is responsible for what parts of the competency program
- You will understand how to set up and maintain a competency program for your lab(s)
- You will be able to select associates meeting CLIA standards for personnel approved to evaluate testing personnel competency
- You will be able to use the competency templates provided and complete them appropriately

Competency program responsibilities

- **Managers are responsible for their lab's competency program. This includes:**
 - Filling in templates with each required test system for that lab and using these forms to document competencies
 - Requesting guidance in test system definitions as needed
 - Performing competencies yourself or assigning qualified personnel to do so, and reviewing competencies completed by others
 - Ensuring timely completion of competencies, both annual and competencies required during first year of employment (initial, 6-month and 12-month)
 - Ensuring associates asked to contribute quiz questions have time to do so
- **QA provides program coordination. This involves:**
 - Guidance and oversight on test system definitions
 - Coordination of quiz question assignments to technical personnel/Best Practice Team and assembly and distribution of these quizzes by test system or technical discipline
 - Management and maintenance of competency program documentation templates
 - Oversight of program compliance

Who is qualified to do what?

- Individuals qualified to perform MACL-defined test systems' competency assessments must meet one of these education and experience requirements:
 - Have a PhD with 1 year experience in discipline
 - Have a MS with 2 years experience in discipline
 - Have a Bachelors degree with 4 years experience in discipline
 - The degree used to qualify someone needs to be in the sciences (eg, chemistry, life sciences, clinical lab sciences)
- These individuals must have written delegation to perform competencies on file. This is usually QA.GEN.2.3 *Technical Supervisor Delegation Form*. Delegation form QA.GEN.2.7 also provides delegation if the person also meets above qualifications.

What is a Test System?

- Test System is a CLIA term used to group tests performed by the same process and/or instrument
- Labs may define their own test systems, but may only group tests that have the same testing process (procedure is identical)
 - For example, sample pretreatment is required for transplant drug testing on the Architect. This means these tests must be defined as a separate test system from the Architect's routine chemistries.
- Competency assessments are required on all test systems

How to set up your lab's program

- Use the Test System List and your test menu to determine which test systems apply to your lab
- Use the Templates in SharePoint to document competency assessment
 - QA.DEVELOP.2.3 for CLIA Non-Waived Tests
 - QA.DEVELOP.2.11 for CLIA Waived tests
- Each test system is to be listed on a separate line of the appropriate template
- Non-waived tests need all 6 components evaluated; waived tests need the 2 listed components evaluated
- At least 1 more form will be released to cover competencies not directly related to testing (eg, QLS, Sunquest, DI, Blood Bank product handling and release processes, Regional Chemistry's track operation)

How to use the competency program templates

1. Complete the associate information

2. Circle which type of competency is being performed



QA.DEVELOP.2.3---COMPETENCY ASSESSMENT FOR NON-WAIVED TESTING
 Name: _____ Date of Hire: _____ Period of Evaluation: _____ Initial/6-month/12-month/Annual

Six Components of Competency:

1. → Direct observation of routine patient test performance, including, as applicable, specimen acceptability (handling) and processing
2. → Monitoring the recording and reporting of test results, including, as applicable, critical results
3. → Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative 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 samples or external proficiency testing samples
6. → Evaluation of problem-solving skills

Record date of review or observation, evaluator's initials and whether Satisfactory (S) or Needs Improvement (NI) in appropriate block. NA = Test or action not performed by this associate

| Component | 1 | | | 2 | | 3 | | 4 | 3/5 | 6 | Comments |
|----------------------------------|------------------------|----------------|----------------|---------------------------|-------------------|----------------|-------------------|---------------|--------------------------------------|-----------------|----------|
| Procedure/Test | Specimen Acceptability | Processing | Testing | Reporting Critical/Normal | Review Worksheets | Review QC | Review-PM Records | Maintenance | Proficiency Testing or Blind Samples | Problem-Solving | |
| Kit Testing - Non-Waived | | | | | | | | | | | |
| Example: Architect c4000 | S- 1/25/15-KCH | S- 1/25/15-KCH | S- 1/25/15-KCH | S-104569 KC-1/24/15 | S- 1/25/15-AWH | S- 1/28/15-GGH | S- 2/1/15-RBH | S- 2/8/15-GGH | 2014 C-B-C08 S- 3/2/15-GGH | S- 3/25/15-GGH | |
| RSV BD-EZ | | | | | | | | | | | |
| FLUAB BD-EZ | | | | | | | | | | | |
| HCGB Stanbio True-20 | | | | | | | | | | | |
| MONSC Surevue | | | | | | | | | | | |
| Rapid-HIV-Ag/Ab-Combo | | | | | | | | | | | |
| C-diff Quik Check-Complete Alert | | | | | | | | | | | |
| Serum Ketone (ATONE) | | | | | | | | | | | |

3. Each component of competency assessment is defined here (1-6) and each column in the template corresponds to a competency component

I have had an opportunity to review and ask questions about policies and procedures related to equipment and testing above. Employee Signature: _____ Date: _____
 Following successful completion of this competency assessment, the employee is deemed competent to perform patient testing unsupervised. Manager's signature: _____ Date: _____

How to use the competency program templates



QA.DEVELOP.2.3---COMPETENCY-ASSESSMENT-FOR-NON-WAIVED-TESTING

Name: _____ Date-of-Hire: _____ Period-of-Evaluation: _____ Initial/6-month/12-month/Annual

Components of Competency:

1. → Direct observation of routine patient test performance, including, as applicable, specimen acceptability (handling) and processing
2. → Monitoring the recording and reporting of test results, including,
3. → Review of intermediate test results or worksheets, quality control
4. → Direct observation of performance of instrument maintenance and
5. → Assessment of test performance through testing previously analyzed
6. → Evaluation of problem-solving skills

Component #1: Direct observation

- Has associate demonstrated understanding of specimen requirements for this test system?
- Has the associate demonstrated the ability to properly process specimens for this test system?
- Has the associate demonstrated the ability to competently perform the test procedure?

Record whether or not these items were performed satisfactorily or not (“S” or “NI”), the date observation was made and your initials (see example row)

NOTE: If assessment was “NI”, see corrective action section of form

| Record date of review or observation, evaluator's initials and whether | | | | associated |
|--|------------------------|------------------|------------------|------------|
| Component | 1 | | | |
| Procedure/Test | Specimen Acceptability | Processing | Testing | Comments |
| Kit Testing - Non-Waived | | | | |
| <i>Example:</i> Architect c4000 | S 1/25/15-KCH | S 1/25/15-KCH | S 1/25/15-KCH | |
| RSV | | | | |
| BD-EZ | | | | |
| FLUAB | | | | |
| BD-EZ | | | | |
| HCGB | | | | |
| Stanbio True-20 | | | | |
| MONSC Surevue | | | | |
| Rapid HIV Ag/Ab Combo | | | | |
| C-diff Quik Check-Complete | | | | |
| Alert | | | | |
| Serum Ketone (ATONE) | | | | |

I have had an opportunity to review and ask questions about policies and procedures related to equipment and testing above. Employee Signature: _____ Date: _____

Following successful completion of this competency assessment, the employee is deemed competent to perform patient testing unsupervised. Manager's signature: _____ Date: _____

How to use the competency program templates



QA.DEVELOP.2.3---COMPETENCY-ASSESSMENT-FOR-NON-WAIVED-TESTING

Name: _____ Date of Hire: _____ Period of Evaluation: _____ Initial/6-month/12-month/Annual

Components of Competency:

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

Component #2: Reporting Critical/Normals

- Over the evaluation period, has the associate demonstrated the ability to correctly evaluate, document, and report normal, abnormal, and critical results?

Record whether or not these items were performed satisfactorily or not (“S” or “NI”), the date assessment was made, including an example report (document MR or JI number) and your initials (see example row)

NOTE: If assessment was “NI”, see corrective action section of form

| Record date of review or observation, evaluator's initials and whether Satisfactory (S) or Need | | | | | |
|---|------------------------|-------------------|-------------------|----------------------------|------------|
| Component | 1 | | | 2 | |
| Procedure/Test | Specimen Acceptability | Processing | Testing | Reporting Critical/Normals | Review |
| Kit Testing - Non-Waived | | | | | |
| <i>Example:</i> Architect c4000 | S- 1/25/15-KCH | S- 1/25/15-KCH | S- 1/25/15-KCH | S-104569 KC-1/24/15 | S 1/25/ |
| RSV | | | | | |
| BD-EZ | | | | | |
| FLUAB | | | | | |
| BD-EZ | | | | | |
| HCGB | | | | | |
| Stanbio True-20+ | | | | | |
| MONSC | | | | | |
| Surevue | | | | | |
| Rapid-HIV-Ag/Ab-Combo | | | | | |
| C-diff Quik | | | | | |
| Check-Complete | | | | | |
| Alert | | | | | |
| Serum Ketone (ATONE) | | | | | |

I have had an opportunity to review and ask questions about policies and procedures related to equipment and testing above. Employee Signature: _____ Date: _____

Following successful completion of this competency assessment, the employee is deemed competent to perform patient testing unsupervised. Manager's signature: _____ Date: _____

How to use the competency program templates



QA.DEVELOP.2.3---COMPETENCY-ASSESSMENT-FOR-NON-WAIVED-TESTING-¶

Name: _____ --Date-of-Hire: _____ --Period-of-Evaluation: _____ ----Initial/6-month/12-month/Annual¶

Components of Competency:¶

1. → Direct observation of routine patient test performance, including, as applicable, specimen acceptability (handling) and processing¶
2. → Monitoring the recording and reporting of test results, including, as applicable, critical results¶
3. → Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records¶

Internal blind samples or external proficiency testing samples¶

or Needs Improvement (NI) in appropriate block. NA= Test or action not performed by this associate¶

| 3¶ | | | 4¶ | 3/5¶ | 6¶ | ¶ Comments¶ |
|------------------------|--------------------|------------------------|-------------------|---|----------------------|----------------|
| Review¶ Worksheets¶ | Review¶ QC¶ | Review-PM¶ Records¶ | Maintenance¶ | Proficiency¶ Testing or¶ Blind Samples¶ | Problem- Solving¶ | |
| S-¶ 1/25/15-AW¶ | S-¶ 1/28/15-GG¶ | S-¶ 2/1/15-RB¶ | S-¶ 2/8/15-GG¶ | 2014-C-B-C08¶ S-3/2/15-GG¶ | S-¶ 3/25/15-GG¶ | ¶ |
| ¶ | ¶ | ¶ | ¶ | ¶ | ¶ | ¶ |
| ¶ | ¶ | ¶ | ¶ | ¶ | ¶ | ¶ |
| ¶ | ¶ | ¶ | ¶ | ¶ | ¶ | ¶ |
| ¶ | ¶ | ¶ | ¶ | ¶ | ¶ | ¶ |
| ¶ | ¶ | ¶ | ¶ | ¶ | ¶ | ¶ |
| ¶ | ¶ | ¶ | ¶ | ¶ | ¶ | ¶ |
| ¶ | ¶ | ¶ | ¶ | ¶ | ¶ | ¶ |

Component #3: Review of intermediate test records, QC records, PT results, and PM records

- Over the evaluation period, has the associate demonstrated the ability to and compliance with correctly documenting and evaluating these required actions?

Record whether or not these items were performed satisfactorily or not (“S” or “NI”), the date assessment was made, including an example report (document MR or JI number) and your initials (see example row). If an item does not apply to this test system, or associate does not have these responsibilities use NA

NOTE: If assessment was “NI”, see corrective action section of form

equipment and testing above. Employee Signature: _____ Date: _____¶

ent to perform patient testing unsupervised. Manager's signature: _____ Date: _____¶

How to use the competency program templates



QA.DEVELOP.2.3---COMPETENCY-ASSESSMENT-FOR-NON-WAIVED-TESTING

Name: _____ Date of Hire: _____ Period of Evaluation: _____ Initial/6-month/12-month/Annual

Components of Competency:

1. → Direct observation of routine patient test performance, including, as applicable, specimen acceptability (handling) and processing
2. → Monitoring the recording and reporting of test results, including, as applicable, critical results
3. → Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records
4. → Direct observation of performance of instrument maintenance and function checks

...national proficiency testing samples

| NI) in appropriate block: NA = Test or action not performed by this associate | | | | | |
|---|--------------|--------------------------------------|-----------------------------|---------------|----------|
| | 4 | 3/5 | 6 | | |
| Review-PM Records | Maintenance | Proficiency Testing or Blind-Samples | Problem-Solving | | Comments |
| 15-GG | S- 2/1/15-RB | S- 2/8/15-GG | 2014-C-B-C08 S-3/2/15-GG | S- 3/25/15-GG | |
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Component #4: Direct observation of performance of instrument maintenance and function checks

- Over the evaluation period, has the associate demonstrated the ability to complete maintenance and function checks under their responsibility?


Record whether or not these items were performed satisfactorily or not (“S” or “NI”), the date observation was made and your initials (see example row). If an item does not apply to this test system, or associate does not have these responsibilities use NA

NOTE: If assessment was “NI”, see corrective action section of form

I have had an opportunity to review and ask questions about policies and procedures related to equipment and testing above. Employee Signature: _____ Date: _____

Following successful completion of this competency assessment, the employee is deemed competent to perform patient testing unsupervised. Manager's signature: _____ Date: _____

How to use the competency program templates

 QA.DEVELOP.2.3---COMPETENCY-ASSESSMENT-FOR-NON-WAIVED-TESTING-¶

Name: _____ --Date-of-Hire: _____ --Period-of-Evaluation: _____ ----Initial/6-month/12-month/Annual¶

ix-Components-of-Competency:¶

1. → Direct-observation-of-routine-patient-test-performance, including, as applicable, specimen-acceptability (handling)-and-processing¶
2. → Monitoring-the-recording-and-reporting-of-test-results, including, as applicable-critical-results¶
3. → Review-of-intermediate-test-results-or-worksheets, quality-control-records, proficiency-testing-results, and-preventative-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-samples-or-external-proficiency-testing-samples¶

Component #3/5: Assessment of test performance through blind samples or external proficiency testing samples

- Has the associate successfully performed testing on a blind sample?

Record whether or not testing was performed satisfactorily or not (“S” or “NI”), sample identification, the date testing was performed, and your initials (see example row).

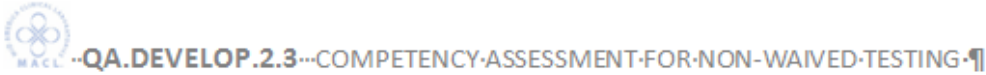
NOTE: If assessment was “NI”, see corrective action section of form

| ate-block-NA=Test-or-action-not-performed-by-this-associate | | | | |
|---|-------------------|--|----------------------|---------------|
| | 4¶ | 3/5¶ | 6¶ | ¶ |
| ew-PM¶ ords¶ | Maintenance | Proficiency¶ Testing-or¶ Blind-Samples | Problem- Solving¶ | ¶ Comments |
| S-¶ /15-RB¶ | S-¶ 2/8/15-GG¶ | 2014-C-B-C08¶ S-3/2/15-GG¶ | S-¶ 3/25/15-GG¶ | ¶ |
| | ¶ | ¶ | ¶ | ¶ |
| | ¶ | ¶ | ¶ | ¶ |
| | ¶ | ¶ | ¶ | ¶ |
| | ¶ | ¶ | ¶ | ¶ |
| | ¶ | ¶ | ¶ | ¶ |
| | ¶ | ¶ | ¶ | ¶ |
| | ¶ | ¶ | ¶ | ¶ |
| Alere¶ | | | | |
| Serum-Ketone- (ATONE)¶ | ¶ | ¶ | ¶ | ¶ |

I have had an opportunity to review and ask questions about policies and procedures related to equipment and testing above. --Employee Signature: _____ --Date: _____

Following successful completion of this competency assessment, the employee is deemed competent to perform patient testing unsupervised. --Manager's signature: _____ --Date: _____

How to use the competency program templates



Name: _____ Date of Hire: _____ Period of Evaluation: _____ Initial/6-month/12-month/Annual

Components of Competency:

1. → Direct observation of routine patient test performance, including, as applicable, specimen acceptability (handling) and processing
2. → Monitoring the recording and reporting of test results, including, as applicable, critical results
3. → Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative 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 samples or external proficiency testing samples
6. → Evaluation of problem-solving skills

Component #6: Evaluation of problem solving skills

- Has the associate successfully demonstrated problem solving skills?

Quiz questions are now required to assess problem solving skills. The Best Practice Teams and QA will coordinate quizzes. Record whether quiz section applicable to test system was completed satisfactorily or not (“S” or “NI”), the date skills were assessed, and your initials (see example row).

NOTE: If assessment was “NI”, see corrective action section of form

| | 4 | 3/5 | 6 | |
|---------------|-----------------|--|---------------------|----------|
| ew-PM ords | Maintenance | Proficiency Testing or Blind Samples | Problem- Solving | Comments |
| S- /15-RB | S- 2/8/15-GG | 2014-C-B-C08 S-3/2/15-GG | S- 3/25/15-GG | |
| | | | | |
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| | | | | |
| | | | | |

I have had an opportunity to review and ask questions about policies and procedures related to equipment and testing above. Employee Signature: _____ Date: _____
 Following successful completion of this competency assessment, the employee is deemed competent to perform patient testing unsupervised. Manager's signature: _____ Date: _____

Competency Failures—Retraining Requirements

If any item on a competency is Needs Improvement, or any quiz question is missed, retraining and reassessment of competency is to be performed and completion/results documented on the table on bottom of template. Record:

1. Date failure in assessment noted
2. Description of failure and corrective action taken
3. Date successful competency demonstrated
4. Initials of associate assessing competency
5. Associate and Manager's signature

If more space needed for documentation, attach additional pages or use back side of competency form

| Date of Failure | Failure | Date of Demonstrated Competency | Evaluator's Initials |
|--|---|---------------------------------|----------------------|
| 1/15/2015 | Missed quiz Rapid HIV question relating to troubleshooting (selected "b"). Reviewed possible causes of false positive results and reflex testing protocol with associate. | 2/2/2015 | AW |
| | | | |
| | | | |
| | | | |
| | | | |
| After follow-up on issues related above, I feel confident in my ability to perform patient testing unsupervised. | | | |
| Associate Signature 2/2/15 | | Manager's Signature 2/2/15 | |
| Employee Signature/Date | | Manager's Signature/Date | |

The Quizzes—Problem Solving Skill Assessment

- The Best Practice Teams, in conjunction with QA, will assign and coordinate quizzes.
- Quizzes will combine similar test systems when possible to minimize burden.
- Quiz questions are to be multiple choice to make grading simpler and less subjective, and to ease the transition to an automated delivery/assessment system
- Regardless of performance on any single quiz, each incorrect answer is to be reviewed with the associate, and the review documented in the corrective action section

Tips for managing your program

- **Records**
 - Separate initial training and competency documents from annual competency documents in your records. Training-related files are to be kept for at least 2 years after an associate leaves (5 years for transfusion medicine-related documentation). This includes all competency documentation for an associate's first year of employment.
 - Competency documents for all areas but transfusion medicine are to be kept for 2 full years, plus the current year in progress (eg, 2013 and 2014 should now be on file, plus whatever documents have been completed for the 2015 program)
- **Getting it done**
 - Direct observations and records review are actually part of your daily presence in the lab. You review logs, proficiency testing documentation, abnormal results reports, and frequently fill in at the bench. Use these opportunities to alleviate the stress and burden of managing your program.
 - A schedule will be provided. Use this calendar to keep your lab on time. Set a final deadline before the holidays to minimize the risk of PTO interfering with getting these done on time.

Initial, 6-Month, & 12-Month Competencies

- The same template used for MACL's annual competency assessments is to be used for competency assessments for new associates during their first year of employment. These include:
 - Assessment during initial training
 - Assessment performed before associate's 6-month anniversary
 - Assessment performed before associate's 12-month anniversary
- The competency template is to be used in conjunction with training checklists as documentation of competency assessment
- Standard quizzes are under development for each of these 3 competency assessments for each test system