

Competence Assessment for Testing Personnel

Purpose	This document describes the process of training, evaluation, and competence assessment of each person performing patient testing in compliance with Clinical Laboratory Improvement Act (CLIA), State and accrediting agency requirements.
Scope	This policy applies to all testing personnel who perform waived and non-waived testing.
Policy General	<ul style="list-style-type: none">• It is the responsibility of all staff to maintain competency to perform the duties to which they are assigned and which are detailed in the <i>Task Authorization Grid</i>.• Prior to starting patient testing and prior to reporting patient results, each individual must have training, and be evaluated for proper test performance.• The process of competence assessment is delegated by the Laboratory Director to the Technical Consultant (Moderate Complexity) or Technical Supervisor (High Complexity) per <i>CLIA Personnel Duties, Responsibilities, and Requirements</i>.• General Supervisor can fulfill the responsibility of evaluating and documenting the performance of testing personnel as delegated in writing by the Lab Director and/or Technical Supervisor, as long as the final overall assessment of competency is reviewed and signed by the Technical Supervisor. (Minimum requirement for General Supervisor: bachelor's degree in chemical, physical, biological, clinical laboratory science or medical technology plus 2 years training or experience in designated specialty /subspecialty).• For new or revised test methodology or instrument, training is conducted and performance is reevaluated prior to reporting patient test results. Competence assessment for this change will be incorporated within the next scheduled assessment.• If an employee fails to demonstrate satisfactory performance on the competence assessment, the laboratory shall have a plan of corrective action to retrain and reassess the employee's competency.• Retraining and reassessment of employee competency must occur when problems are identified with employee performance. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which may include, supervisory review of work, reassignment of duties, or other actions deemed appropriate by the laboratory director.• Competency should be reassessed after an extended leave of absence at the discretion of the Laboratory Director or Technical Consultant/Supervisor.

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Competence Assessment for Testing Personnel, Continued

**Policy for
Waived
Testing**

- Competence assessment must be performed at least annually (semiannual assessment is not required).
 - The laboratory may select which elements to assess for each test system.
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**Policy for
Non-Waived
Testing**

- Competency process for a new employee:
 - Testing personnel's performance is evaluated after training.
 - The first semi-annual assessment is conducted within the first six months of employment for the tests systems to which the employee has completed training.
 - The second assessment is done within the following six months and encompasses all the test systems to which the employee has completed training.
 - Assessments are performed yearly thereafter.
 - Competence assessment must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system. Elements of competence assessment include but are not limited to:
 - Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing.
 - Monitoring the recording and reporting of test results, including, as applicable, reporting critical results.
 - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
 - Direct observation of performance of instrument maintenance and function checks.
 - Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
 - Evaluation of problem-solving skills.
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Competence Assessment for Testing Personnel, Continued

Definitions

Annual	Every 12 calendar months
Corrective Action	Action taken to eliminate the cause of a detected nonconformity or other undesirable situation
Non-waived	Tests categorized as either moderately complex (including provider-performed microscopy) or highly complex by the US Food and Drug Administration (FDA), according to a scoring system used by the FDA
Semiannual	Every 6 calendar months
Testing Personnel	Individual responsible for performing laboratory assays and reporting laboratory results
Test System	The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.
Waived	A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result." Laboratories performing waived tests are subject to minimal regulatory requirements.

Non- Controlled Documents

The following non-controlled documents support this procedure.

- College of American Pathologist Laboratory General Checklist

Controlled Documents

The following controlled documents support this procedure.

Reference
CLIA Personnel Duties, Responsibilities and Requirements

Form
Task Authorization Grid

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Competence Assessment for Testing Personnel, Continued

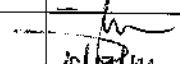
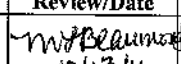
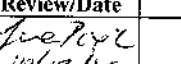
Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
Name: <u>Mary Jo Beaumont</u> Operations Director, Area Laboratory	10/13/16
Name: <u>J. P. L. S.</u> CLIA Laboratory Director	10/13/16

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Competence Assessment for Testing Personnel, Continued

HISTORY PAGE

Type of Change: New Major, Minor	Description of Change(s)	Quality Systems Leader/Date	Operations Director, Area Laboratory Review/Date	CLIA Laboratory Director Review/Date	Date Change Implemented
NEW		 10/13/16	 10/13/16	 10/13/16	10/18/16

Signature Manifest

Document Number: SCPMG-PPP-0130

Revision: 01

Title: Policy_Compentence Assessment for Testing Personnel

All dates and times are in Pacific Standard Time.

Competence Assessment for TP

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
Maureen Ahler (K083442)	Quality Systems Leader	16 Aug 2016, 05:33:31 PM	Approved
Fred Urg (K057175)	SCPMG LABORATORY QCD	17 Aug 2016, 08:18:47 AM	Approved

Final Approval

Name/Signature	Title	Date	Meaning/Reason
Darryl Palmer-Toy (T188420)	SCPMG Laboratory Sys Med Dir	09 Sep 2016, 10:05:57 PM	Approved
Gary Gochman (P091953)	SCPMG Laboratories AP Dir	19 Sep 2016, 11:25:10 AM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Aidzz Ticsay (K109967)	Regional QA Coordinator		
Helen To (K209312)	MGR AREA LAB		
Ruben Balmaceda (C342855)	Quality Systems Manager		
Maureen Ahler (K083442)	Quality Systems Leader	19 Sep 2016, 02:53:33 PM	Approved

Task Authorization Grid

Laboratory: Type Here	Department: Type Here																				
Job Assignment	Employee 1	Employee 2	Employee 3	Employee 4	Employee 5	Employee 6	Employee 7	Employee 8	Employee 9	Employee 10	Employee 11	Employee 12	Employee 13	Employee 14	Employee 15	Employee 16	Employee 17	Employee 18	Employee 19	Employee 20	
Assignment 1 (e.g., DxC, Manual Differential, Gram stain)																					
Assignment 2																					
Assignment 3																					
Assignment 4																					
Assignment 5																					
Assignment 6																					
Assignment 7																					
Assignment 8																					
Assignment 9																					
Assignment 10																					
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Assignment 14																					
Assignment 15																					
Assignment 16																					
Assignment 17																					
Assignment 18																					
Assignment 19																					
Assignment 20																					

1. Perform Sample Collection, transport, labeling, processing.
2. Performs Test setup, basic testing process; cannot make decisions regarding result release.
3. Phones test results, reference ranges; explains test information using official scores.
4. Performs all phases of testing, makes decisions regarding result release.
5. Performs tasks related to competence assessment.
6. Makes supervisory decisions; monitors results; oversees remedial actions.

The employees listed above have been trained and are competent to perform job assignments at the level indicated.

Technical Supervisor/Consultant Signature: _____ Date: _____

The employees listed above are authorized to perform the duties and assume responsibilities as indicated.

Laboratory Director Signature: _____ Date: _____

3-Initial Approval	Approved	All
<u>User</u>	<u>Title</u>	<u>Notified</u>
Fred Ung (K057175)	SCPMG LABORATORY QCD	19 Aug 2016 4:12 PM
Maureen Ahler (K083442)	Quality Systems Leader	19 Aug 2016 4:12 PM
4-Final Approval	Approved	All
<u>User</u>	<u>Title</u>	<u>Notified</u>
Gary Gochman (P091953)	SCPMG Laboratories AP Dir	23 Aug 2016 8:49 AM
Darryl Palmer-Toy (T188420)	SCPMG Laboratory Sys Med Dir	23 Aug 2016 8:49 AM
5-Set Effective Date	Approved	One
<u>User</u>	<u>Title</u>	<u>Notified</u>
Ruben Balmaceda (C342855)	Quality Systems Manager	19 Sep 2016 1:32 PM
Maureen Ahler (K083442)	Quality Systems Leader	19 Sep 2016 1:32 PM
Aidzz Ticsay (K109967)	Regional QA Coordinator	19 Sep 2016 1:32 PM
Helen To (K209312)	MGR AREA LAB	19 Sep 2016 1:32 PM
6-Notify Users	Notify	One
<u>User</u>	<u>Title</u>	<u>Notified</u>
Ruben Balmaceda (C342855)	Quality Systems Manager	19 Sep 2016 2:54 PM
Maureen Ahler (K083442)	Quality Systems Leader	19 Sep 2016 2:54 PM
Aidzz Ticsay (K109967)	Regional QA Coordinator	19 Sep 2016 2:54 PM
Helen To (K209312)	MGR AREA LAB	19 Sep 2016 2:54 PM

Complete History

Step Name	User	Status	Time	Comments
1-Change Request	Laura Perry (S533438)			Apj
2-Collaboration	Laura Perry (S533438)			Co
3-Initial Approval	Maureen Ahler (K083442)			Apj
	Fred Ung (K057175)			Apj
4-Final Approval	Darryl Palmer-Toy (T188420)			Apj
	Gary Gochman (P091953)			Apj
5-Set Effective Date	Maureen Ahler (K083442)			Apj

<u>Completed</u>	<u>Status</u>	<u>Modify Step?</u>	<u>Comments</u>
23 Aug 2016 8:49 AM	<input checked="" type="checkbox"/> Approved	None	None
21 Aug 2016 8:28 PM	<input checked="" type="checkbox"/> Approved	None	None
<u>Completed</u>	<u>Status</u>	<u>Modify Step?</u>	<u>Comments</u>
19 Sep 2016 1:32 PM	<input checked="" type="checkbox"/> Approved	None	None
12 Sep 2016 4:05 PM	<input checked="" type="checkbox"/> Approved	None	None
<u>Completed</u>	<u>Status</u>	<u>Modify Step?</u>	<u>Comments</u>
n/a	n/a	None	n/a
19 Sep 2016 2:54 PM	<input checked="" type="checkbox"/> Approved	None	None
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n/a	n/a	None	n/a
<u>Completed</u>	<u>Status</u>	<u>Modify Step?</u>	<u>Comments</u>
19 Sep 2016 2:54 PM	<input checked="" type="checkbox"/> Email Sent	None	None
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19 Sep 2016 2:54 PM	<input checked="" type="checkbox"/> Email Sent	None	None
19 Sep 2016 2:54 PM	<input checked="" type="checkbox"/> Email Sent	None	None

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19 Aug 2016 4:11 PM
19 Aug 2016 4:12 PM
21 Aug 2016 8:28 PM
23 Aug 2016 8:49 AM
12 Sep 2016 4:05 PM
19 Sep 2016 1:32 PM
19 Sep 2016 2:54 PM