POINT-OF-CARE TESTING GUIDELINES

Washington State Clinical Laboratory Advisory Council

Originally published: October 2000

Reviewed/Revised: March 2005/March 2009/Sept 2013/July 2017

INTRODUCTION

For many years, all or the majority of laboratory testing was performed in a central laboratory. This was necessary due to the complexity of the testing. With advances in technology, testing has emerged from the laboratory to the patient's bedside, the pharmacy, the physician's office, the patient's home and other non-laboratory sites. This testing is called *point-of-care testing (POCT)* and is defined as testing at the point where patient care is given, wherever that is located. With this move outside the laboratory walls some problems occur that were not problems within the laboratory. Point-of-Care testing often starts without knowing if the testing is appropriate for the setting. There may be limited understanding of requirements for licensure, training, documentation, and procedures. Soon there may be several types of instrumentation performing the same testing in various areas of a facility. There may be no evaluation or comparison of the values obtained from these different methodologies and they may not correlate well with each other. Cost-savings that may be available through quantity purchasing may be lost. It is important that a Point-of-Care Testing Program at any of the above sites is carefully planned.

REGULATIONS

All sites performing laboratory testing are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and must be licensed in order to perform *any* testing. CLIA has granted deemed status to approved accreditation organizations and exempt states, and allows these entities to accredit or license testing sites. All Point-of-Care testing must be covered by a Washington State Medical Test Site (MTS) license. Washington State recognizes those accreditation organizations listed in Table 2.

Many of the point-of-care testing procedures are identified by CLIA as *waived* while others are *moderately* complex. A site performing only waived tests must have a "Certificate of Waiver" license but will not be routinely inspected. They must however adhere to manufacturer's instructions for performing the test. "Good Laboratory Practice" dictates appropriate quality testing practices as outlined in the CLIA *moderate and high complexity* test requirements. These include training of testing personnel, competency evaluation and performance of quality control. Accreditation organizations such as Veteran's Administration and the College of American Pathologists (CAP) have stricter guidelines for waived and other point-of-care testing than the CLIA regulations. As of 2009, The Joint Commission (TJC) now has a chapter on POCT.

FOR EDUCATIONAL PURPOSES ONLY

This document is intended as a guide for facilities to use in setting up a Point-Of-Care testing program.

POINT-CARE TESTING GUIDELINES

The following guideline is a step-by-step outline that can be used in the development of a point-of-care program. Although the outline is directed to a hospital or large institution point-of-care program, it may also be adjusted to smaller sites, such as a physician's office laboratory (POL). Recommendations will be included in the text covering problems unique to physician's office point-of-care testing.

OBTAIN AUTHORITY TO COORDINATE POINT-OF-CARE TESTING PROGRAM.

Hospital, institution or medical clinic point-of-care testing

Authority to form a defined point-of-care program in this type of setting is usually needed since several departments and budgets are impacted. Regulatory agencies often mandate coordinated programs that includes an oversight committee.

A Physician Office Lab (POL)

A physician may decide to perform laboratory testing in the office. As the physician is ultimately responsible for his/her practice, the authority is implied.

SELECT MEMBERS OF POINT-OF-CARE COMMITTEE (POCC)

Nothing is more important than having the right people on this committee no matter the size of the operation.

Hospital, institution or medical clinic point-of-care testing:

It is important to involve those who have the responsibility and *authority to implement* the program. Members may include: a clinical pathologist as director or technical director/consultant, a physician as a medical director, nursing managers, a laboratory manager, educational coordinators, laboratory managers, quality assurance managers, pharmacy managers, and others who are needed to train end users, implement the testing. A specific Point-of-Care Supervisor/Coordinator is recommended for larger institutions to monitor test results. Purchasing and information technology representatives should serve as consultants to the committee.

POL

In a physician's office not only the physician, but also the testing personnel should be involved in selecting the method or equipment that they will be using. The physician usually serves as the director; however, others who should be involved include the nurse, physician's assistant, and medical assistant. If there is a laboratory in the clinic, the laboratory manager or a staff member should be involved.

COMMITTEE DEVELOPS A POINT-OF-CARE-PROGRAM

Hospital, institution or medical clinic point-of-care testing:

A *written* Point-of-Care Program/Policy is important since point-of-care testing tends to expand rapidly unless guidelines or policies are in place.

The "Program/Policy" should clearly define:

1. Who is ***responsible*** for each part of the program naming key people? For example:
   - Laboratory Point-of-Care Coordinator: keep database of testing personnel, coordinate training of new personnel, choose testing methods, monitor quality control and proficiency programs, provide ongoing coaching to testing personnel in response to daily monitoring, consult on technical issues, and analyzer meter/troubleshooting.
   - Nurse Manager: enforce policies, schedule new employee training, take disciplinary action, if necessary, and schedule annual point-of-care competency evaluation of staff.
   - Education dept. (if it exists): new employee training and annual certification of testing personnel, support committee with agenda and minutes of meetings. Preferably training is done by those reviewing daily results and quality monitoring.
   - Laboratory staff: new employee training, aid in annual certification of testing personnel, download and/or review quality control data, verify equipment function and maintenance.
2. Where the testing will be performed and by whom it will be performed.
3. For what purpose each type of point-of-care testing will be used, i.e., screening, diagnosis, treatment.
4. Who will chose the methodologies used, i.e., lab, POCC?
5. What method validation procedures will be performed prior to implementation and who will perform the validation.
6. Reporting procedures.
7. Staff training, continued competency programs, and feedback/communication with the end users.
8. Quality assurance monitoring protocols including quality control protocols.
9. Proficiency testing program.
10. Obtain and maintain appropriate licensure and compliance with regulations.
11. Protocol for requesting new/additional services.
12. Operational budget.

POL:

In the physician's office the program should define:

1. Responsibilities for each part of the program naming key people.
2. For what purpose it will be used, i.e., screening, diagnostic, treatment.
3. Who will chose the methodologies used.
4. Validation of the point-of-care methods by comparing the results with a reference or hospital laboratory where testing is also performed on their patients. This is for test result verification to assure they are comparable methods. (This practice should take place prior to implementing the test and should be in a written policy so it is not overlooked.)

5. Staff training procedure
6. Reporting of results procedures
7. Quality assurance monitoring protocols including quality control protocols
8. Proficiency testing program, if performing moderate or high complex testing.*
9. Obtain and maintain appropriate licensure and compliance with regulations.

COMMITTEE REVIEWS ALL SITES FOR POINT-OF-CARE TESTING

Hospital, institution or medical clinic point-of-care testing:

Point-of-care testing in patient care areas may be unknown to the Point-of-Care Committee members. Various methods throughout the institution may not give comparable values or the method may not be appropriate for how the results are used. All patient care areas should be reviewed for POCT testing such as urine dipsticks, occult blood, urine pregnancy test, glucose testing etc. Areas should include emergency units, admission units, intensive care units, operating rooms, outpatient clinics, specialty clinics and all wards, and interventional units. Helpful tools are reports from material supplies and also monitoring orderable tests available. Any additions or deletions in POCT methodology must be communicated to the WA Department of Health Laboratory Quality Assurance (LQA) office to update the MTS license.

POL:

This is not usually a problem due to the size and communication between those involved.

EVALUATION OF PROPOSED TESTING

Wherever the location of point-of-care testing, the following should be evaluated:

- Purpose: Why is point-of-care testing performed instead of routine laboratory testing i.e.: turn-around time, reduction of length of stay, patient convenience, improved patient care management.
- Volume: Although the test may appear to be beneficial, a low volume may results in concerns about the proficiency of the testing personnel and cause reagents and controls to outdate before reasonable usage thus escalating costs.
- Methodology:
  - What methodology is used for each analyte
  - Is the method appropriate for the purpose
    a) Sensitivity
    b) Specificity
    c) Precision
    d) Batch vs. discrete technology
    e) Reagent and control stability
    f) Reagent and control storage requirements
    g) Quality control requirements
- Cost of the method:
  Cost of a point-of-care program must look at the whole process of patient care, rather than the cost of an individual point of care test method vs. the cost in the laboratory test method. An appropriate point-of-care test in an emergency room may prevent the admission of a patient into the hospital. Items that should be assessed include:
  - Cost of training the testing personnel and maintenance of competency
  - Labor associated with processing and analyzing the specimen

- Labor associated with maintaining the equipment
- Annual reagent, control, maintenance and depreciation costs
- Costs of state licensing according to volume and test complexity
- Costs of proficiency programs for testing performed

- Reporting: How will results be recorded? Elements that should be included with each result include:
  - Date/time of collection
  - Who performed the test
  - Testing site
  - Reference range
- Other elements to consider:
  - When/how will confirmation testing be performed?
  - Will internal controls be documented along with the patient results (currently a Joint Commission requirement)?
  - How will lot numbers be tracked?
  - Who will create order code and/or billing code?
  - Who will perform external quality control; how often; who will review?
  - Who will work with purchasing?
    a) Contracts and/or service agreements
    b) Adding to purchasing system
    c) Adding to stocking system
    d) Ordering/stocking process once implemented

IMPLEMENTATION

All new point-of-care testing *regardless of the site* should follow the procedure established by the Point-of-Care Committee. The Point-of-Care Committee meetings should be kept to a minimum number and cover only topics that need to be addressed by the whole committee. Otherwise members may feel their time is wasted and be less inclined to support the program. Subcommittees should meet and address their specific responsibilities, as needed. They should report to the Point-of-Care Committee on a regular basis.

At a minimum, "waived tests' must follow the manufacturers' instructions. There are additional regulatory requirements for sites that have their waived tests accredited by TJC. TJC interprets the manufacturers "recommended" as a "must do".

Implementation of a POCT program should include:

- Method evaluation
- Planning with unit/department managers and physician directors
- New employee initial training, 6-month review, and annual staff certification
- Color vision assessment for testing personnel as needed (http://colorvisiontesting.com/ishihara.htm)
- Staff competency evaluation
- Result reporting protocol
- Quality Assurance Program
  - Proficiency testing available from manufacturers and private proficiency programs. These consist of unknown samples sent to the site for testing. The results are then compared to all other participants. Evaluations are returned to the site. Corrective

actions must be taken when values do not fall within acceptable ranges. (Test validations as described on page 4 may take the place of a proficiency program for waived tests.)
    - Quality Improvement monitors should be performed continuously to analyze and evaluate the program with actions taken when results do not meet expectations. These could include: turn-around times of results from a reference lab, or comparison of the point-of-care testing method results with those of the main or reference lab or hospital.
    - Quality control performance, documentation and evaluation
    - Supply ordering
- Feedback to the participants in the program
- Follow-up at department meetings or nursing, management, and medical oversight levels

For "moderate complex" POCT testing, in addition to the requirements listed above for "waived tests", instrument validation is required for each new instrument.

Initial implementation of this program could take over a year and then is an ongoing process that evolves with experience, new technology and changing customer needs.

EVALUATION OF POINT-OF-CARE TESTING PROGRAM

A Point-of-Care Testing Program should be monitored and evaluated periodically in order to assure that the program is meeting the needs of its customers, i.e., providers, testing personnel and patients. The POCT Committee or provider may accomplish this by using quality assurance monitors, patient surveys, and/or review of quality control and proficiency testing results, utilization reports, and development of an Individualized Quality Control Plan (IQCP).

Reference and Resources:

- To Test or Not to Test? Considerations for Waived Testing, CDC, July 2015.
- CDC Waived Testing Resources: https://wwwn.cdc.gov/clia/Resources/WaivedTests/

FORM A

Quality Assurance Monitor Report

Site: _____ **Date:** _____

Title of Report: _____

Type of Monitor: (Check all that apply)	□ Accuracy □Appropriateness	□ Efficiency □ Safety	□ Timeliness □ Effectiveness
Aspect of Care:	□ Hi Volume	□ Hi Risk to patient	□ Problem Prone

Project Leader: _____

Disciplines Involved:_____

Project Dates: :_____

Description:_____

_____

_____

Reason for Performing Monitor: _____

Acceptable Limits: _____

Data Source: _____

Analysis of Data:

_____

_____

_____

Conclusion of Analysis:

_____

_____

Action to Be Taken:

_____

_____

Assessment of Actions Taken (Improvement)**:**

_____

_____

FORM B

EXAMPLE: PREGNANCY TEST LOG SHEET

LOCATION:	
KIT NAME:	
LOT NUMBER:	**EXP. DATE:**
EXTERNAL POSITIVE CONT. LOT#:	**EXP. DATE:**
EXTERNAL NEGATIVE CONT. LOT#:	**EXP. DATE:**

PERFORM EXTERNAL CONTROL ONCE ON EACH KIT		**DATE**	**POSITIVE**	**NEGATIVE**	**TECH INIT.**
KIT LOT#:	**EXP. DATE:**				
KIT LOT#:	**EXP. DATE:**				
KIT LOT#:	**EXP. DATE:**				

DATE	**PATIENT NAME**	**Internal Control "OK"**	**PATIENT TEST RESULT (POS, NEG)**	**TECH INIT.**	**DATE**	**PATIENT NAME**	**Internal Control "OK"**	**PATIENT TEST RESULT (POS, NEG)**	**TECH INIT.**
1					14				
2					15				
3					16				
4					17				
5					18				
6					19				
7					20				
8					21				
9					22				
10					23				
11					24				
12					25				
13					REVIEWED BY:		DATE:		

FORM C

QUALITY CONTROL SHEET

SITE/ UNIT:					**CONTROL LOW: LOT#**								**EXP. DATE:**			
TEST:					**CONTROL HIGH: LOT#**								**EXP. DATE:**			
MONTH/ YEAR:					**TEST STRIPS: LOT#**								**EXP. DATE:**			
					UNACCEPTABLE RANGE (LOW)		**<ACCEPTABLE RANGE >**						**UNACCEPTABLE RANGE (HIGH)**		**CLEAN METER**	**ACTION TAKEN**
							- 2SD	**- 1SD**	**mean**	**+ 1SD**	**+ 2SD**				
			NO tests this day	**LOW Control**												
	Strip #	**CK strip**		**HIGH Control**												
DATE	**OK**	**OK**		**Initial**												
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																
11																
12																
13																
14																
15																
16																
17																
18																

FORM D

TEMPERATURE CHART

Month/Year _____

Dept._____

36-46°F

Refrigerator acceptable = 2-8°C

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Hi																															
46F	8C																															
45F	7C																															
43F	6C																															
41F	5C																															
39F	4C																															
37F	3C																															
36F	2C																															
	Lo																															

64-86°F

Room Temp acceptable = 18-30°C

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Hi																															
86F	30C																															
82F	28C																															
79F	26C																															
75F	24C																															
72F	22C																															
68F	20C																															
64F	18C																															
	Lo																															

*initial in the square corresponding with the date and temperature. For Hi or Lo put initial/ and one of the following:

A – closed door and waited ½ hour to recheck
B – down for repair
C – adjusted temp control, waited ½ hour to recheck
D – defrosted refrigerator
E – Biomed called
O – other written on back of sheet

TABLE 1
Licensing/Accreditation Requirements
Waived Testing

Accreditation Requirements for Waived Testing	Accreditation Inspection Organizations/Agencies			
	TJC*	**CAP***	**MTS/CLIA***	**COLA***
1. Evaluate Waived Testing during inspection process	**YES**	**YES**	**NO**	**NO**
2. Test Method/Performance Verification for Accuracy/ Precision/Reference Range	**YES**	**YES**	Adhere to Good Laboratory Practice and Follow Manufacturers' Instructions	Adhere to Good Laboratory Practice and Follow Manufacturers' Instructions
3. Daily Quality Control (QC)	**Depends**	**YES**		
4. Specific Education Requirement for POCT	**YES**	**YES**		
5. Personnel Training	**YES**	**YES**		
6. Identify Testing and Supervisory Personnel for POCT	**YES**	**YES**		
7. Initial and Annual Competency Assessment	**YES**	**YES**		
8. Performance Appraisal Process	**YES**	**YES**		
9. Continuous Quality Improvement/TQM Program	**YES**	**YES**		
10. Written Standard Operating Procedures (SOP) for: a. Specimen Collection & Preservation b. QC c. Equipment Performance Maintenance d. Instrument Calibration e. Problem & Remedial Action f. Test Performance	**YES**	**YES**		
11. Annual Review of SOP by Director and/or Supervisor of Testing and Laboratory	**YES**	**Site-No Lab-YES**		
12. Patient Test Result Reporting	**YES**	**YES**		
13. Audit Trail Linking Test Results Across to Analyst to QC and to Instrument Problem	**YES**	**YES**		
14. Correlation of Test Results Across Different Instruments and Different Sites	**YES** (Semi-Annual)	**YES**		
15. Proficiency Testing	**NO**	**YES**		
16. M.D. or Ph.D. Scientist with Training is Responsible for Testing	**NO**	**YES**		
17. Monitor Quality and Stability of Reagents	**YES**	**YES**		
18. Linearity and Calibration Verification	**NO**	**YES**		

* CAP: College of American Pathologists MTS: Washington State Medical Test Site Law COLA: Commission on Office Laboratory Accreditation
TJC: The Joint Commission CLIA-88; Waived Testing Chapter: January 2012:

TABLE 2

APPROVED PROFICIENCY TESTING PROVIDERS

Name	Telephone Number
Accutest	(800) 665-2575
American Academy of Family Physicians	(800) 274-7911
American Association of Bioanalysts	(800) 234-5315
American Proficiency Institute	(800) 333-0958
ACP (American College of Physician Medical Lab Evaluation)	(800) 338-2746
California Thoracic Society	(714) 730-1944
College of American Pathologists	(800) 323-4040
EXCEL (CAP)	(800) 323-4040
WSLH (Wisconsin State Laboratory of Hygiene)	(800) 462-5261

WASHINGTON STATE APPROVED ACCREDITATION BODIES

- Washington State Department of Health Office of Laboratory Quality Assurance
  Website: http://www.doh.wa.gov/lqa.htm

- American Association of Blood Banks
  Website: http://www.aabb.org.

- American Osteopathic Association
  Website: http://www.aoa-net.org

- American Society of Histocompatibility and Immunogenetics
  Website: http://www.ashi-hla.org

- The College of American Pathologists (CAP).
  Website: http://www.cap.org

- The Joint Commission
  Website: http://www.jointcommission.org

- COLA
  Website: http://www.cola.org