

## Verifying Laboratory Personnel Qualifications for Non-Waived Testing - A Reminder

by Linda Parisi, DOH/LQA

The Clinical Laboratory Improvement Amendments (CLIA) lists the requirements for various levels of personnel in laboratories that perform non-waived testing. It is the owner's ultimate responsibility to verify that the personnel in their laboratory meet the minimum requirements as defined in CLIA. This documentation must be available during your on-site inspection.

A laboratory performing only moderate complexity tests must have a qualified laboratory director, clinical consultant, technical consultant, and testing personnel. A laboratory performing high complexity testing must have a qualified director, clinical consultant, technical supervisor, general supervisor, and testing personnel. Refer to the complete listing of CLIA personnel standards at [http://www.cdc.gov/clia/regs/subpart\\_m.aspx](http://www.cdc.gov/clia/regs/subpart_m.aspx). A summary of the CLIA personnel requirements can be found on either the Categorized or the Accredited Medical Test Site (MTS) application (<http://www.doh.wa.gov/hsqa/fsl/lqamtslic-types.htm>).

Laboratory Quality Assurance (LQA) and the Accrediting Organizations (CAP, COLA, The Joint Commission, etc.) will review that the laboratory has verified the qualifications of personnel for the laboratory. The laboratory is

required to keep records of the documents used to verify personnel qualifications.

The director's qualifications are reviewed and verified by LQA staff during the application process for a new MTS license and for director changes in an existing MTS licensed laboratory. The laboratory should keep copies of this information on-site.

The qualifications for personnel in all other personnel categories are reviewed by inspectors during the on-site survey process. If the personnel records are kept in the Human Resources Department, alert them prior to the

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### Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website: [www.doh.wa.gov/lqa.htm](http://www.doh.wa.gov/lqa.htm)

Anemia	PAP Smear
ANA	PAP Smear Referral
Bioterrorism Event Mgmt	Point-of-Care Testing
Bleeding Disorders	PSA
Chlamydia	Rash Illness
Diabetes	Red Cell Transfusion
Group A Strep Pharyngitis	Renal Disease
Group B Streptococcus	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness
Lipid Screening	

# Minimum Method Validation Process - Moderate Complexity Testing

by Susan Walker, DOH/LQA

Validation of new instruments must be performed prior to reporting patient results. This validation must be performed at the facility where the instrument is to be used. The following is a brief summary of the validation requirements for moderate complexity testing.

## Accuracy Check

- Analyze two levels of assayed control material ten (10) times each over several days.
- All control values should fall within the expected QC range.
- Calculate the average (mean) for each level. These values should be close to the midpoint of the range.

## Precision Check

- Using a scientific calculator, calculate the standard deviation (SD) and the coefficient of variation (CV) from your accuracy check values for each level.
- Calculate the %CV:  $\%CV = SD/average\ (mean) \times 100$ .
- Determine whether the CV meets the manufacturer's specifications for the test.

**Correlation Study with Patient Samples:** Perform testing on at least ten (10) patient samples for your new instrument that span your reportable range (low – mid – high) and compare these values with your old/current method or with your reference laboratory. The Director must approve the agreement of the results based on the clinical expectations and method accuracy/precision claims.

## Reportable Range Check

- Check the high and low values that represent your reportable range. You may use calibrators (run as patients) or linearity set to do this. You can also use patient specimens that have been tested by a reference method or proficiency testing specimens for this check.
- Analyze, in duplicate, reference materials that reflect the minimum and the upper limits.
- Compare the values. The Director must approve the agreement of the results, based on clinical expectations. These must be used to set the lowest limit and upper limit for reporting patient values.

**Reference Range Check:** The manufacturers usually provide this information. The reference range should be provided with the patient test results. Have your Director review and approve the results. Assure they are appropriate for your patient population.

**Calibration:** Follow the manufacturer's instructions for the calibration of the instrument if required for your instrument.

If your instrument is to use a whole blood fingerstick specimen, please call your surveyor for additional suggestions for completing your validation.

The minimized instrument validation process information has been placed on the LQA website at the following address: <http://www.doh.wa.gov/lqa.htm>.

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## Website addresses:

**DOH home page:** <http://www.doh.wa.gov>

**LQA home page:** <http://www.doh.wa.gov/lqa.htm>

**PHL home page:**

<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

# Personnel Qualifications Verification, cont'd from page 1

Survey that the inspectors will look at personnel files to verify qualifications.

**What records are needed?** Here are some examples of how to verify the qualifications of the testing personnel in a moderate and/or high complexity testing laboratory.

- √ **Moderate Complexity Testing:** The minimum requirement to perform moderate complexity testing is that the person be a high school graduate or equivalent with documentation of training. Please have copies of degrees or transcripts for review for personnel with an associate degree or higher.
- √ **High Complexity Testing:** The minimum requirement to perform high complexity testing is that the person have an associate degree in laboratory science, or medical lab technology, or 60 semester hours in science plus complete an approved laboratory training program. Please have copies of degrees or transcripts for review. To acquire a transcript or copy of a degree from a college or university, contact the school directly for instructions for ordering a transcript or a copy of the degree. If the university or college is no longer in existence, contact the State Department of Education and they should be able to assist.

For individuals who have been grandfathered to perform high complexity testing, document that the individual meets the qualifications noted under CLIA standards: 493.1489, 493.1491.

## Abbott i-STAT Waived Testing Update

In a technical bulletin released by Abbott on February 19, 2009, specimen requirements for using the i-STAT as a waived test device were clarified. The following information is taken from that bulletin:

“The FDA (Food and Drug Administration) has granted waived status for the following i-STAT cartridges:

- Chem8+ (granted September 21, 2007), and
- Crea G, 6+, EC4+, and E3+ (granted November 13, 2008).

**Waived status is applicable only when testing venous samples collected in evacuated tubes with sodium or lithium heparin (green top tubes) with any of the above-listed cartridges with the i-STAT 1 Analyzer (Handheld).”**

**What does this mean to you?** If you collect any other type of specimen (capillary, syringe, line draw, etc.), your testing is categorized as moderate complexity. You must:

- Inform our office of the tests performed;
- Inform our office of the annual test volumes;
- Follow all applicable requirements for moderate complexity testing;
- Participate in a 5-sample proficiency testing program; and
- Undergo on-site inspections.

**What should you do?**

- If you have any questions about this information, contact your Abbott representative for clarification.
- Notify LQA of the non-waived tests performed and test volumes. Use the Test Menu Change Notification Form available on the LQA website (<http://www.doh.wa.gov/lqa.htm>) under Supplemental Material.
- If you need to upgrade your MTS/CLIA license or have questions about regulatory compliance, contact the Medical Test Site licensing program at (206) 418-5600.

# PT Regulation Changes Input Needed

LQA would like your input on possible changes to the CLIA PT regulations in the following areas:

- Suggestions for changes to the list of regulated analytes; and
- Suggestions for revising the criteria for acceptable performance (grading criteria) for regulated analytes including target values and acceptable limits.

Please send your comments to Susan Walker at [susan.walker@doh.wa.gov](mailto:susan.walker@doh.wa.gov) or call 1-206-418-5418 by **February 15, 2010**.

## Calendar of Events

### PHL Training Classes:

(<http://www.doh.wa.gov/ehsphl/phl/training/train.htm>)

#### Advanced Blood Cell Morphology

March 11 Shoreline

#### Specimen Collection for Chemical Terrorism Events

March 24 Shoreline

#### ASCLS-WA Spring Meeting

April 22-24 Seattle

#### Northwest Medical Laboratory Symposium

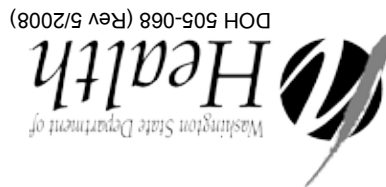
October 21-24 Portland

#### 17th Annual Clinical Laboratory Conference

November 2010 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD 1-800-833-6388).



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