

Waived Blood Glucose Monitoring Systems

The Department of Health/Lab Quality Assurance received a letter from the Centers for Medicare & Medicaid Services (CMS) regarding off-label use of waived blood glucose monitoring systems (BGMS). The notification is dated November 21, 2014 and is effective immediately.

The following is a summary of some key points contained in the official CMS memorandum. Two attachments contain frequently asked questions regarding this memorandum. The links are found at the conclusion of this article.

Memorandum Summary

- “Off-Label Use” of BGMS: Using a test outside of its Food and Drug Administration (FDA)-approved or cleared intended use, limitations or precautions, as indicated in the manufacturer’s instructions, is considered “off-label use.” “Off-label use” applies whether the test is waived or non-waived. It means that the test is considered modified and therefore defaults to a high-complexity test under the Clinical Laboratory Improvement Amendments (CLIA) regulations. This will require all laboratories using the device for an “off label use” to meet all applicable CLIA high-complexity requirements.
- Frequently Asked Questions (FAQs): Included with this memorandum are FAQs prepared by Centers for Medicare & Medicaid Services (CMS) and FAQs prepared by the FDA, respectively that provide responses to key questions.

Background: This memorandum is specifically directed toward a discussion of BGMS, but the information it

Inside This Issue

-
- 2-3 Proficiency Testing for 2015
 - 3-4 Blood Glucose Monitoring Systems, cont’d
 - 5 Approved PT Providers/Calendar of Events
-

contains is applicable to all waived and non-waived laboratory testing and describes already existing regulations and interpretive guidance.

The CLIA statute, section 353 of the Public Health Services Act (codified at 42 U.S.C. 263a), provides that the examinations and procedures a laboratory performs with a Certificate of Waiver are those that have been approved by the FDA for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result; 42 U.S.C. § 263a(d)(3) (emphasis added). The CLIA statute further states that these include “methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible,” or those that “the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly.” The CLIA regulations support these requirements as described at 42 CFR §493.15(b).

Laboratories issued a Certificate of Waiver (CW) have no continued on page 3

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the [LQA website](#).

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

Proficiency Testing for 2015

Proficiency testing (PT), required under Medical Test Site rules WAC-246-338-050, is a source of external quality control. Although labs perform daily internal quality control with their test systems, external quality control provides important interlaboratory comparisons to determine the accuracy and reliability of your testing procedures.

It is time to enroll in PT for 2015. Page five contains a list of the currently approved PT agencies. Call the programs for a free copy of their 2015 PT brochure or see their websites. Your current PT provider will automatically send you a PT order form and catalog for 2015. Early enrollment guarantees that you will receive samples for the first testing event that occurs between January and March 2015.

- Shop around for prices and test groups.
- In order to cover all tests performed in your laboratory, it may be necessary to enroll in PT with more than one company.

Urine Culture Growth / No Growth Reminder: Does your laboratory perform urine cultures for growth/no growth only and/or colony count only? If so, participation in a five-sample proficiency testing program applies to you.

Failure to participate in PT results in a score of 0 percent for each analyte. This is a failure, and may jeopardize your

ELABORATIONS is a free monthly publication of the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and Office of Laboratory Quality Assurance (LQA).

Secretary, DOH: John Weisman, DrPH, MPH
 Health Officer: Kathy Lofy, MD
 Director, PHL: Romesh Gautam, PhD
 Program Manager, LQA: Susan Walker
 Editor: Leonard Kargacin (253) 395-6747
 Circulation: Leonard Kargacin (253) 395-6747

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:

ELABORATIONS
 Laboratory Quality Assurance
 20425 72nd Ave S Ste 310
 Kent, WA 98032

e-mail address: leonard.kargacin@doh.wa.gov

NOTE: Letters to the editor may be published unless specified otherwise by the author.

Website access:

[Department of Health](#)
[Laboratory Quality Assurance](#)
[Public Health Laboratories](#)

ability to continue testing patient specimens.

Information needed to enroll: Complete the 2015 order form in the PT brochure with the following information:

- Name (use the name exactly as it appears on your MTS license)
- Address
- CLIA ID number (primary means of identifying your lab)
- MTS license number (see your MTS license)
- Select the appropriate program for your lab (you may have to enroll in several modules and/or companies to cover all analytes)

NOTE: Authorize the PT agency to send copies of your results to the Washington State Department of Health Office of Laboratory Quality Assurance. Do this for each analyte!

Regulated analytes:

- Five sample modules shipped three times per year are required for all regulated analytes.
 - The LQA website (www.doh.wa.gov/lqa.htm) has a listing of the regulated analytes.
 - PT participation is required for all non-waived tests for influenza A and B, and direct strep antigen.
 - Some manufacturers of waived test kits include instructions for moderate complexity testing in the same package insert. This allows the laboratory to choose whether
- continued on page 3

Tips for Proficiency Testing Success

Improve your chances for successful participation in PT:

- **Release results:** Notify the PT provider to send copies of PT results for each analyte to LQA.
- **Handle PT samples like patient samples, but do not refer them to your reference/main lab for further study.** Do not run them multiple times.
- **Retain all raw data:** Save data showing the workup of PT samples, instrument printouts, worksheets, and log sheets.
- **Attestation statement:** Keep a copy of the form signed by the director and personnel who tested the samples.
- **Make sure all testing personnel perform PT during the year.**
- **Be timely:** Always be sure to meet the deadline for returning your results.
- **Review your graded results:** Review the graded PT results with your lab director. Document corrective action for scores below 80 percent. Evaluate ungraded results.

Proficiency Testing for 2015, cont'd from page 2

it wants to perform the test as a waived test following the waived test requirements or as a moderate complexity test following these requirements. If the laboratory chooses to perform the test as a moderate complexity test, it must participate in a five-sample PT program three times per year.

Non-regulated analytes: Test all non-waived tests (other than the regulated analytes) using one or a combination of the following:

- A two-sample PT program from one of the proficiency testing providers, or
- Blind samples with known values, or
- Split samples with another lab, or
- Split samples with another instrument or method, or
- Two analysts perform microscopic tests and compare results, or
- Kodachromes of microscopic tests, or
- Correlate patient results with clinical history.

Adding tests during the year:

- Notify our office within 30 days.
- Enroll in PT for regulated analytes before you start testing patient samples.

Discontinuing tests during the year:

- Notify our office within 30 days of discontinuing the tests.

Temporarily discontinuing tests during the year:

- Notify our office within 30 days if you temporarily discontinue a test.
- Use the appropriate action code from your PT provider if you temporarily discontinue a test at the time of a PT challenge.
- When you reinstate the test, notify our office.

LQA website: The [LQA website](#) contains additional information regarding proficiency testing, applications, licensing, practice guidelines, surveys and checklists, MTS rules and much more. If you have other questions regarding proficiency testing, contact Veronica Bush at 253-395-6782.

Waived Blood Glucose Systems, cont'd from page 1

regulatory requirements for routine surveys, personnel qualifications, experience or training, quality control (QC), proficiency testing (PT), record-keeping, quality assessment (QA), or laboratory director responsibilities. These laboratories are allowed only to perform waived tests, but they must also meet the following requirements under CLIA:

- Enroll in the CLIA/MTS program and obtain a license;
- Pay the applicable certificate fee of \$150 biennially; and
- Follow manufacturers' test instructions for test performance.

The BGMS that have been cleared by the FDA, as waived for home use, were originally designed as consumer devices, intended for use in monitoring glucose levels in an individual patient diagnosed with diabetes. However, over time, the use of BGMS has expanded to include use in healthcare facilities and, in turn, use in patient populations that the manufacturer's studies and performance standards, which were used to evaluate these BGMS for home use, did not address.

This means that, when the manufacturer's instructions contain limitations indicating that the BGMS has not been evaluated or cleared for use in critically ill patients, the use of BGMS on critically ill patients will be considered "off-label" use, and, for purposes of the CLIA/MTS regulations, will automatically default to high-complexity testing. Facilities may continue to use their waived BGMS on patients as long as they follow the manufacturer's instructions.

Waived Blood Glucose Systems, cont'd from page 3

Manufacturers' Instructions: The CLIA/MTS laboratories must read and follow all of the manufacturer's instructions for waived test systems, including BGMS. This includes any instructions that the manufacturer may include regarding the system's intended use, limitations and precautions. Note that manufacturers' instructions vary in format, and some information may be found in different sections. Moreover, manufacturers' instructions may be updated or changed, and instructions from different manufacturers for the same type of testing may not be the same.

Off-Label Use or Test Modification: Based on a laboratory's needs and the unique population it serves, there may be instances when a laboratory chooses to modify an FDA-approved or cleared test system 42 CFR §493.1253(b)(2)). For the purposes of this memorandum, a "laboratory modification" means any change in intended use, adjustments to the precautions, limitations or other sections of the manufacturer's instructions. These changes are considered "off-label" use of a commercial test system and are not supported by the manufacturer's clinical data, or approved or cleared by the FDA.

Among other requirements, the CLIA regulations at §493.1253(b)(2) require all laboratories that modify an FDA-cleared or approved test system to establish performance specifications for that test system (i.e., accuracy, precision, analytical sensitivity, analytical specificity including interfering substances, reportable range of test results, reference intervals and any other performance characteristic required for test performance).

An example of off-label use would be using a BGMS to perform a blood glucose test on a patient whose hematocrit or oxygenation level is below the range indicated in the manufacturer's instructions. Results of blood glucose testing in this situation may lead to clinical interventions that could cause patient harm.

Laboratory Options for CLIA/MTS Compliance for Waived Blood Glucose Monitoring Systems

- The laboratory and the facility may continue using their BGMS as long as they follow the manufacturer's instructions.
- If a facility wishes to use a BGMS off-label (e.g., in a critically ill patient population when a manufacturers' instructions contain a limitation on critically ill patients), laboratories with a Certificate of Waiver may:
 - Obtain a categorized or accredited MTS license;
 - Establish the performance specifications; and
 - Meet the additional regulatory requirements for high-complexity testing and any applicable state regulations.
- Note:** Personnel requirements for non-waived testing are found in Subpart M. The specific requirements for high-complexity testing personnel are located at 42 CFR §493.1489.
- Identify and use a point-of-care glucose device from the [FDA CLIA database](#) without patient population limitations in the manufacturer's instructions.
- Note:** Laboratories should contact the manufacturer directly to confirm that they have the most current package insert and what populations their device can be used within..
- Submit blood glucose specimens from patients whose clinical conditions do not meet those described in the intended use or limitations sections of the manufacturers' instructions to a laboratory capable of doing the testing.

Effective Date: Immediately.

Pertinent links

- [Frequently asked questions prepared by CMS](#)
- [Frequently asked questions prepared by the FDA](#)
- [FDA Test Complexity Website](#)
- For a more complete explanation of the common components of a manufacturer's instructions, please refer to [Appendix B](#), in the Center for Disease Control and Prevention's Ready? Set? Test! Booklet at the following link,

Approved PT Providers

[Amer. Acad. of Family Physicians](#) (800) 274-7911

[Amer. Assoc. of Bioanalysts](#) (800) 234-5315

[American Proficiency Institute](#) (800) 333-0958

[ASIM Medical Lab Evaluation](#) (800) 338-2746

[California Thoracic Society](#) (714) 730-1944

[College of American Pathologists/EXCEL](#)
(800) 323-4040

[WSLH](#) (800) 462-5261

For answers to your PT questions, go to the [LQA web-site](#) or call Veronica Bush at (253) 395-6782.

Calendar of Events

Training Classes:

[2015 ASCLS-WA Spring Meeting](#)

April 23-25, 2015 Olympia

[2015 Northwest Medical Laboratory Symposium](#)

October 14-17, 2015 Seattle

[22nd Annual Clinical Laboratory Conference](#)

November 2015 Tukwila

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.

1-800-833-6388).

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)

DOH 505-068 December 2014



Kent, WA 98032

20425 72nd Ave S Ste 310

Washington State Department of Health

ELABORATIONS