

ELABORATIONS

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Waived Testing: Good Laboratory Practice Guidelines & Recommendations

by Lori Hudson, DOH/LQA

As technology advances and the number of waived test kits on the market increases, it is important to review the requirements and good laboratory practice guidelines for waived tests.

Under CLIA, tests are categorized by their complexity into four groups: Waived, PPMP, Moderate, and High.

A waived test is a testing procedure that does not have to meet some of the requirements applied to higher complexity tests. For instance, site inspections are not routinely performed, proficiency testing is not required, and personnel qualifications are not established.

Waived tests are simple lab procedures with negligible likelihood of erroneous results and no reasonable risk of patient harm if performed incorrectly. Waived tests are also those tests that are cleared by the Food and Drug Administration (FDA) for home use.

Requirements for Waived Testing: Waived-testing laboratories must obtain a Medical Test Site license, indicate the tests they perform, and pay the appropriate fee. The waived testing personnel must follow the most current manufacturer's test instructions (package insert) exactly as written.

The Package Insert is your guide to performing the test accurately. Read the package insert carefully, focusing on the intended use, storage of the kit, proper handling of the

kit and test devices, specimen collection, performing the test, procedural notes, quality control, expected results, result interpretation, limitations of the procedure, and precautions and warnings.

Intended Use describes what is being measured and whether it is qualitative or quantitative.

Storage of the kit and reagents discusses storage of the kit (keep refrigerated? keep out of sunlight? etc.).

Proper handling of the kit and test devices discusses how to handle the kit and test devices once opened (i.e., test strips are valid for 30 days once opened).

Specimen collection discusses the acceptable types of specimens and acceptable anticoagulants, if applicable.

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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

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	

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Performing the Test: It is very important to follow the instructions **exactly** as written. Do not modify the test, and adhere to the timing specified.

Procedural Notes: This section is where to find additional information about performing the test (i.e., “do not open the foil pouch until ready to test, avoid cross contamination, warm to room temperature before use,” etc.).

Quality Control may vary between kits, but usually involves testing external and internal positive and negative controls, and electronic function checks.

- External controls (usually included in the kit) are tested like a patient sample. Compare the control results to the expected values printed on the vial or product insert.
- Internal (procedural) controls ensure that the reagents are active, that reagents and samples are added correctly, and the test performs according to specifications. These controls typically include a colored line or dot for the positive control and the expected appearance of the background for the negative portion.
- Electronic controls are reusable devices such as cartridges or cassettes used to check the instrument performance specifications.

Expected Results or Reference Range: This section informs the user of the normal range of patient results.

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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>

Results and Interpretation: This section informs the user of the intended results: positive, negative, invalid, quantitative results if applicable, and the reportable range of the method.

Limitations of Procedure discusses the limitations of the test, such as the cause of false positives or negatives, or measuring range limitations.

Precautions and Warnings: Examples of these might be “do not use past expiration date” or “do not mix components of different lots or kits.”

Good Laboratory Practice for Waived Tests: On November 11, 2005, the Centers for Disease Control and Prevention (CDC) published a report titled “Good Laboratory Practices for Waived Testing Sites” in the *Morbidity and Mortality Weekly Report* (MMWR Volume 54/ RR-13). This report revealed that although most waived testing is performed correctly, a number of quality-related concerns were found in all three phases of the testing process (pre-analytic, analytic, and post-analytic).

Implementation of Good Laboratory Practices

- Correlate test results with patient presentation, history, and diagnosis.
- Participate in a proficiency testing or split sample program.
- Keep records of employee training – document that new employees read the entire product insert; keep documentation of employee training and periodic competency assessment.
- Keep a log of results, kit lot number, expiration date, quality control results, and patient test results to detect potential problems.

Common Problems Performing Waived Tests

1. Testing samples not approved for the kit by the FDA or CDC (for instance, using a waived strep antigen testing kit for perianal testing when it has only been cleared for throat samples)
2. Using the test incorrectly (i.e., mononucleosis tests may be waived for whole blood, but serum or plasma testing is moderate complexity)
3. Failing to maintain records (maintain a current product insert for the testing)

Although waived testing is considered simple, all test results are important to the provider and the patient. For more information, contact the Office of Laboratory Quality Assurance: (206) 418-5600 or go to our website at: <http://www.doh.wa.gov/lqa.htm>.

Venipuncture Techniques Training Course

Tuesday, August 18, 2009

This course is designed for the health care worker who is new to blood drawing, or for anyone who wants a “refresher” to learn the very latest in venipuncture procedures and techniques. Sylvia Crawford, Registered Phlebotomist (ASCP), teaches the course.

Course objectives are to understand techniques for best vein selection; to perform a successful venipuncture; to exercise appropriate use of equipment; proper handling of blood specimens, and to understand biohazard safety techniques and OSHA regulations. The course lasts six hours and will be held at the Washington State Public Health Laboratories in Shoreline, WA. Attendees are awarded 0.6 CEU credits for completing this course.

Please register online at <http://www.seattlestdhivptc.org>. The registration fee is \$150. If paying by check, please make it payable to University of Washington and send it to the Seattle STD/HIV Prevention Training Center at 901 Boren Ave., Suite 1100, Seattle, WA 98104. To pay by credit card, go to: <http://www.seattlestdhivptc.org> and download the Payment by Credit Card form. Complete and fax it to (206) 221-4945 Attn: Ronnie Staats, before the August 7, 2009 registration deadline. For more information or an application, please contact Ronnie Staats at rstaats@u.washington.edu or (206) 685-9848.

Swine Flu Virus (H1N1) and West Nile Virus

by Yolanda Houze, DOH/PHL

Swine Flu Virus (H1N1): The DOH thanks all of the laboratories in Washington for their assistance in the recent Swine Flu outbreak. We appreciate your cooperation. The lessons learned from this outbreak are valuable in helping us better handle future outbreaks. Visit this website for the latest information about Swine Flu: <http://www.doh.wa.gov/ehsphil/Epidemiology/CD/swineflu/sfluresources.htm>

West Nile Virus: From its first identification in 1999 in New York City through 2008, 47 states and the District of Columbia have reported 11,807 cases of West Nile neuroinvasive disease (WNND), including encephalitis, meningitis, and acute flaccid paralysis. Nearly 10% of these cases were fatal. Despite the spread into the Pacific and Northwest states, Washington has remained relatively unaffected. Only six locally acquired human cases of WNV infection have been reported in Washington; of these, only two were WNND.

If the experiences of seven recently affected western states are any indication and if similar conditions exist in Washington, hundreds of WNND cases could be expected here. Because of Washington's similar ecology and vectors, the potential for a large-scale epidemic here is real. Therefore, it is essential to plan for epidemiologic surveillance, laboratory testing, and coordination with environmental health and communications.

Additional information regarding WNND will be available as the season progresses. In the interim, here are a couple of helpful websites:

- <http://www.doh.wa.gov/ehp/ts/Zoo/WNV/WNV.html>
- <http://www.doh.wa.gov/EHSPHL/epitrends/09-epitrends/09-06-epitrends.htm>

Good Laboratory Practices for Molecular Genetic Testing

CDC released recommendations for best practices in genetic testing for heritable diseases and conditions in the June 12, 2009 issue of MMWR; 58(RR06); 1-29.

Refer to the following website for more information:

<http://www.cdc.gov/mmwr/>

Calendar of Events

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

Basic Microscopy

August 12 Shoreline

Venipuncture Techniques (see page 3)

August 18 Shoreline

Northwest Medical Laboratory Symposium

October 21-24 Seattle

16th Annual Clinical Laboratory Conference

November 9 Seattle

2010 ASCLS-WA Spring Meeting

April 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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