

ELABORATIONS

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Waived Testing: Good Laboratory Practice Guidelines & Recommendations

by Lori Hudson, DOH/LQA

With the advancement of technology and the boom of waived test kits on the market, 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.

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.

The term "waived" means that the test is waived from 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.

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	Lipid Screening
ANA	PAP Smear
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

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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 contained a study revealing 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.

Waived Test Common Performance Problems

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>.

Tips for Shipping Infectious Substances: Labeling the Package

by Laura Kentala & Shelley Lankford, DOH/PHL

One of the largest challenges of shipping infectious substances is the proper labeling of all of the shipping containers. All three layers of your triple packing must have labels.

The primary and secondary containers are straightforward because they only have one label each. The outer container is the challenge because it needs several labels depending on the shipping categories of the specimens.

Primary & Secondary Labeling Requirements: The label required on the primary container is the patient name or number that corresponds to the laboratory or history form. The secondary container label is the biohazard label. This label has a minimum size of 2 inches and must have an orange background.

Many of the labels are the same whether the substance is Exempt, Category A, or Category B. In addition, each category requires a set of specific labels. The one requirement all labels have in common is that they all must be machine printed. Only certain label markings, such as dry ice weight, can be hand written.

Outer Container Labeling Requirements: The outer container labels required for all categories are:

1. UN certification label - this label is printed by the manufacturer. It shows that the entire system has been checked against breaking and leaking.
2. Shipper's address - this should include name and full address.
3. Consignee's label -this is the name and full address of the person who will be receiving the package.

Category A and B Specific Label Requirements: Refer to this website for Category definitions: <http://hazmat.dot.gov/regs/rules.htm>. Click on Hazardous Materials Regulations (Title 49 CFR Parts 100-185) and go to 173.134.

Category A outer containers require the first three labels mentioned above plus:

1. UN2814 or UN2900 - This label will read "Infectious Substance, Affecting Human Category A UN2814." Write the weight of the material on the label. Remember, the proper shipping name is no longer required on this label.
2. Infectious Substance - This diamond-shaped label has the hazard symbol on top and states "Infectious Substance, in case of damage or leakage contact..... CDC 1-800-212-4124." Make sure your labels have

the 1-800 phone number for the CDC listed.

3. Directional Arrows – This label must be placed on opposite sides of the container. Usually these are already printed on the containers. The arrows can be red or black.
4. Responsible Person - This person must be knowledgeable about the organism that is being shipped. This can be a person in your facility or a private company that you have hired to perform this duty. The name and phone number must be connected to a live person who can be reached 24 hours/7 days a week. There are several companies in the United States that perform this service.

Category B outer containers require the first three outer container labels mentioned above plus:

1. UN3373 - This is a diamond-shaped label that must be at least 2 inches square and have letters that are 6mm point font.
2. "Biological Substance, Category B" - This label must be attached on the lower edge of the UN3373 label.
3. Optional: Directional Arrows - Arrows that are on a Category B container are OK, but not required.

If you are shipping by USPS, you must have a "Responsible Person" label. This must contain the name of a person who can either answer questions about this package or find a person who can answer questions. The phone number must be on this label as well, but the phone only has to be manned during usual working hours. If you are shipping by other carrier, this information may be inside the outer container or on the airway bill.

Exempt Specimens:

1. "Exempt Human Specimen"- This label is needed when shipping exempt specimens. There are no UN numbers designated for exempt specimens.
2. Optional: Directional Arrows- Arrows that are on "Exempt" containers are OK, but not required.

The most important thing to remember about labeling is that all labels must be machine printed. Make sure that the labels are the correct size for the container size and the category of specimens you are shipping. Making a simple checklist for each category is a great tool to help make sure no label will be forgotten.

For additional information on labeling, you can contact us via email at phl.training@doh.wa.gov, or by phone at 206-418-5404.

Urine Culture Growth / No-Growth Update

Is your laboratory performing urine cultures for growth/no-growth only and/or colony count only?

Effective January 1, 2009, you are required to participate in a 5-sample proficiency testing PT program from one of the approved PT providers.

The list of approved PT providers can be found on the LQA website: <http://www.doh.wa.gov/lqa.htm>.

Calendar of Events

PHL Training Classes:

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

Basic Microscopy
August 6 Shoreline

Northwest Medical Laboratory Symposium

October 15-18 Portland

15th Annual Clinical Laboratory Conference

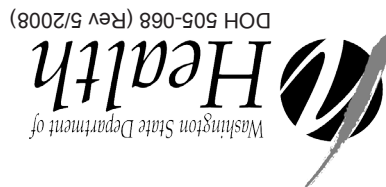
November 10 Seattle

2009 ASCLS-WA Spring Meeting

April 2009 Spokane

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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