

Proficiency Testing for 2011

by Leonard Kargacin, DOH/LQA

Proficiency testing (PT), required under Medical Test Site rules 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 2011. Page 6 contains a list of the currently approved PT agencies. Call the programs for a free copy of their 2011 PT brochure or visit their websites. Your current PT provider will automatically send you a PT order form and catalog for 2011. Early enrollment guarantees that you will receive samples for the first testing event that occurs between January-March 2011.

- 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 5-sample proficiency testing program applies to you.

Failure to participate in PT results in a score of 0% for each analyte. This is a failure, and may jeopardize your ability to continue testing patient specimens.

Information needed to enroll: Complete the 2011 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 # (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.

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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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- Visit the LQA website (www.doh.wa.gov/lqa.htm) for 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 they want 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 5-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.

Deleting tests during the year:

- Notify our office within 30 days.

Temporarily discontinuing tests during the year:

- Notify our office 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, medical test site rules and much more. The website address is <http://www.doh.wa.gov/lqa.htm>.

If you have other questions regarding proficiency testing, contact Leonard Kargacin at (206) 418-5416.

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LQA home page: <http://www.doh.wa.gov/lqa.htm>
PHL home page:
<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

TIPS for Proficiency Testing Success

Improve your chances for successful participation in PT by considering the following suggestions:

- ✓ **Release Results:** Notify the PT provider to send copies of PT results for each analyte to the Office of Laboratory Quality Assurance.
- ✓ **Handle PT samples like patient samples, but DO NOT** refer them to your reference laboratory 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.
- ✓ **Make sure all testing personnel perform PT during the year:** Share or rotate the samples among all staff who perform the test.
- ✓ **Be timely:** Always be sure to meet the deadline for returning your results.
- ✓ **Review your graded results:** Review your graded PT results with your lab director. Document corrective action for scores below 80%. Evaluate ungraded results.

Tips for Shipping Infectious Substances

What is Rigid Outer Packaging?

by Chuck Talburt & Shelley Lankford, DOH/PHL

What is the rigid outer packaging? It is the third and final part of a certified triple-pack shipping system. Because it is part of a certified shipping system, you must never mix packaging components from different manufacturers for Category A, infectious substances. Mixing packaging components voids the system's certification.

Effective in 2006, federal regulations defined that the outer container must be made of a rigid material and be in good condition. It must display certification labeling that complies with the United Nations (UN) certification code for infectious substances on an exterior surface.

Certified packaging systems are generally very rugged in nature and can be reused several times. Selection of certified shipping systems that allow the internal components to be autoclaved prior to re-use is a wise choice. The exterior of the rigid outer container, where all the required remaining labels are placed, degrades after multiple uses from re-labeling and in-transit damage. It is advisable to purchase additional rigid outer containers to replace older damaged ones.

The rigid outer container may be used to hold several secondary containers. Employ some type of cushioning or securing of the secondary container(s) to prevent it from shifting while the package is in transit. Place the list of contents inside the outer container, around the secondary container or on top.

If the specimens must remain refrigerated or frozen while in transit, utilize a certified packaging system designed with a Styrofoam-lined rigid outer container. Place absorbent material on the inside bottom area of the Styrofoam lining to absorb any atmospheric moisture condensation inside due to the low internal temperature. You do not want the package to appear to be leaking because of internal moisture condensation!

If you are using solid carbon dioxide (dry ice) as a refrigerant, you **MUST** make provisions for the carbon dioxide gas created during the sublimation process to escape safely. Otherwise, the package could become a bomb from accumulated gas. Remember to secure the secondary container to prevent movement inside the foam-lined rigid outer container as the dry ice sublimates in transit. Regulations require that the manufacturer of a packaging system either print the closure procedure on the outer container or provide printed instructions.

There are different triple packaging certification requirements for the outer packaging for shipping Category A or Category B infectious substances. A packaging system certified for Category B infectious substances must be able to withstand a drop of 4 feet without leaking. A packaging system certified for Category A infectious substances must be able to withstand a drop of 30 feet without leaking. Make sure you use the correct shipping system for the category of infectious substance you plan to ship!

No labels used on the outer container must be handwritten. Labels can be computer generated or purchased commercially. The size of the labels must meet the minimum size requirements and varies with the type of label being generated (please check regulations).

Category B Infectious Substances labeling requirements include:

- Shipper's address
- Consignee's address
- The UN3373 diamond-shaped label with "Biological Substance, Category B"
- A "Responsible Person" label must be on the outer packaging and around the secondary container if you use United States Postal Service (USPS). With other carriers, it can be on either location. NOTE: When shipping a Category B

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specimen, the person named as the “Responsible Person” needs to be available during normal business hours.

Category A Infectious Substances labeling requirements include:

- Shipper’s address
- Consignee’s address
- The UN2814 or UN2900 label with the total weight of the specimen indicated
- A Centers for Disease Control and Prevention (CDC) Infectious Substance label (with the CDC’s 800 area code emergency response phone number on it)
- The Responsible Person’s name and phone number. This must be a person available on a 24-hour, seven-day-a-week basis who is knowledgeable about the infectious substance being transported.
- If dry ice is included in the container, the rigid outer packaging must include a Class 9 Miscellaneous Dangerous Goods label. List the weight of the dry ice inside the package in kgs. on the label and include the words “Dry Ice” or “Carbon Dioxide, Solid” and “UN1845.” The weight of the dry ice must be in kilograms and must not exceed 200 kilograms unless an exception is granted.
- There are weight/volume restrictions that govern whether or not the package can be transported in the cargo hold of a passenger aircraft. If restrictions apply, the package requires an orange “Cargo Aircraft Only” label if transported by air.
- All Category A infectious substance shipments require a properly completed “Shipper’s Declaration of Dangerous Goods” form.

If you follow these rules regarding your outer containers, you will be compliant with the latest shipping regulations. For additional information on outer packaging or if you are having trouble with packaging your specimens, you can contact us via email at phl.training@doh.wa.gov or by phone at 206.418.5404.

Laboratory Guidelines for Acute Diarrhea

A critical area of concern in the current cost-conscious health care environment is optimization of service delivery. Over-utilization of laboratory testing can lead to needless and costly treatment for the patient. Under-utilization can result in a misdiagnosis and delays in treatment. To address inappropriate or unnecessary use of laboratory testing services, the Clinical Laboratory Advisory Council established a process for developing practice guidelines for clinical laboratory testing. The guidelines are for educational purposes only.

The intent of the guidelines is to help laboratorians answer questions on appropriate test ordering. The guidelines are useful to clinicians as a review of a typical test-ordering pattern for asymptomatic patients. The guidelines are a compilation of existing data, not original work by the Council. The Council elected to summarize existing information into simple, easy-to-use flow-charts. Once the Council identifies a test as a candidate for a guideline, a Council workgroup is formed to develop a proposed guideline. The draft guideline is reviewed by the entire Council, members of the state’s laboratory community, and appropriate medical professional societies. Comments from the reviewers are evaluated by the Council workgroup and incorporated into the final document. The finalized guideline is disseminated to all clinical laboratories and other interested parties through this newsletter.

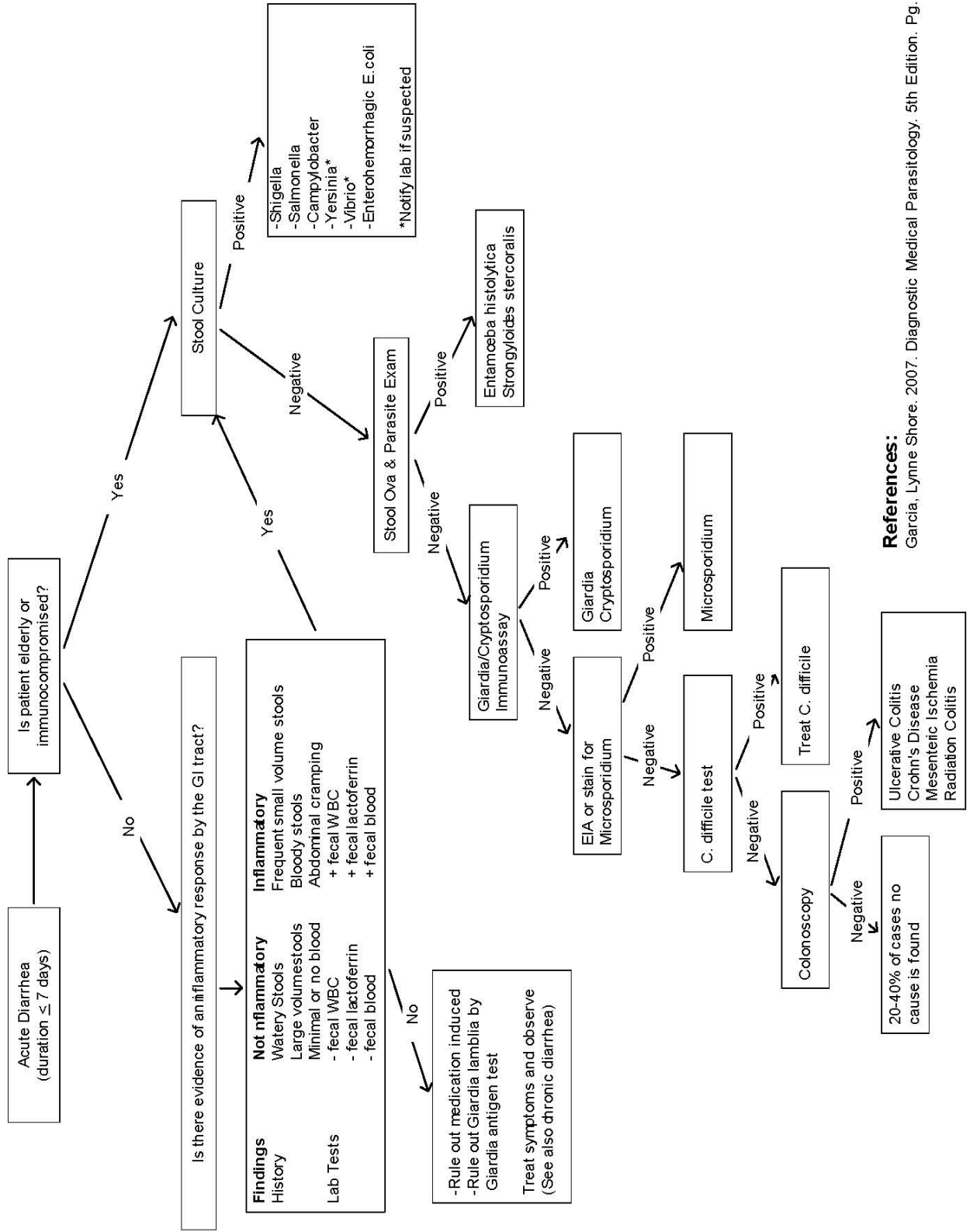
FOR EDUCATIONAL PURPOSES ONLY: The guidelines should be used strictly as guidelines. The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.

Guidelines developed by the Council are listed on page 1 of each issue of the Elaborations newsletter. This issue contains the Laboratory Guidelines for Acute Diarrhea on page 5.

Laboratory Guidelines For Acute Diarrhea

Suggested Physician Ordering Plan for the Laboratory Examination of Stool Specimens
 Washington State Department of Health Clinical Laboratory Advisory Council
 Originally published: October 2010

FOR EDUCATIONAL PURPOSES ONLY
 The individual clinicians in the best position to determine which tests are most appropriate for a particular patient.



References:

Garcia, Lynne Shore. 2007. Diagnostic Medical Parasitology. 5th Edition. Pg. 1057.

Approved PT Providers

- Accutest** (800) 356-6788
<http://www.digitalpt.com>
- Amer. Acad. of Family Physicians** (800) 274-7911
<http://www.aafp.org/pt.xml>
- Amer. Assoc. of Bioanalysts** (800) 234-5315
<http://www.aab.org/>
- American Proficiency Institute** (800) 333-0958
<http://www.api-pt.com/>
- ASIM Medical Lab Evaluation** (800) 338-2746
<http://www.acponline.org/mle/>
- California Thoracic Society** (714) 730-1944
<http://www.thoracic.org/sections/chapters/ca/pt-program.html>
- College of American Pathologists/EXCEL**
(800) 323-4040
<http://www.cap.org/apps/cap.portal>
- WSLH** (800) 462-5261
<http://www.slh.wisc.edu/pt/>

For answers to your PT questions, go to the LQA website at www.doh.wa.gov/lqa.htm or call Leonard Kargacin at (206) 418-5416.

Calendar of Events

PHL Training Classes:

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

Basic Course in Blood Cell Morphology

January 13 Shoreline

Packaging and Shipping of Infectious Substances

February 10 Shoreline

Intestinal Parasitology: A Two-Day Course

February 23 & 24 Shoreline (Tentative Date)

2011 ASCLS-WA Spring Meeting

April 28-30 Vancouver, WA

Northwest Medical Laboratory Symposium

October 12-15 Seattle

18th Annual Clinical Laboratory Conference

November 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.

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).

