

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Patient Safety: Lab Pre-Analytic Errors – Part II

by Linda Parisi, DOH/LQA

The pre-analytic phase of laboratory testing includes the collection, handling, and processing of laboratory specimens. Errors introduced into a specimen during this phase of testing can alter patient test results.

In the January issue of *Elaborations*, we discussed the physiologic variables that influence specimens. In this issue, we will address phlebotomy site selection variables that influence specimens, procedural errors that affect specimen quality, and errors associated with specimen handling.

Site selection variables that influence specimen composition include:

- Damaged veins, healed burn sites, and tattooed areas may have impaired circulation and yield erroneous results.
- Tattooed areas may contain dyes that can interfere with laboratory test results.
- Edematous areas are hard to palpate and specimens may contain tissue fluids that yield inaccurate test results.
- Venipuncture at the site of a hematoma or the surrounding area can result in a specimen that is contaminated with hemolyzed blood. This specimen is unsuitable for testing.

- For mastectomy patients, draw blood from the arm on the side opposite from the mastectomy site. If the lymph nodes were removed as part of the mastectomy, the area is susceptible to infection and can cause changes in the composition of the blood.

Procedural Errors that Affect Specimen Quality: The method of specimen collection can affect the quality of the specimen.

- Prolonged tourniquet application can cause venous stasis (stagnation of normal blood flow) resulting in hemoconcentration. The decreased plasma volume can cause an abnormal increase in nonfilterable blood components such as RBCs, enzymes, iron, and calcium.
- Allow sufficient time for the blood to clot prior to centrifugation.
- Inadequate mixing of anticoagulant tubes can lead to microclot formation and erroneous results.

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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

Lab Pre-Analytic Errors, continued from page 1

- Inadequate mixing of gel separation tubes may prevent the additive from functioning properly, and clotting may be incomplete.
- Hemolyzed specimens can result if the patient has hemolytic anemia, liver disease, or a transfusion reaction.
- Hemolyzed specimens can be the result of procedural errors including:
 - Vigorous mixing of tubes with additives
 - Drawing blood from a vein with a hematoma
 - Pulling the syringe plunger too quickly
 - Using a small-bore needle
 - Using a large Vacutainer tube with a butterfly needle
 - Improper fit of the syringe needle can cause frothing of the blood specimen
 - Forcing blood from a syringe to Vacutainer tubes
 - Failure to wipe the first drop of blood which may contain alcohol
 - Excessive squeezing at the venipuncture site
- Partially filled tubes will not have the proper blood-to-additive ratio and test results may be inaccurate.
- Using the wrong disinfectant at the venipuncture site can result in contaminated specimens.
 - Using povidone-iodine to clean a puncture site can cause erroneously high levels of uric acid, phosphate, and potassium.

- Not allowing the correct antiseptic dry can inhibit bacterial growth in blood cultures.
- Microbial contamination of blood cultures can occur with improper cleaning.
- Powder from gloves can contaminate tubes and blood specimens.
- Fingerprints, urine from wet diapers, and alcohol residue have been cited as sources of contamination of filter paper containing newborn screening samples.

Sources of pre-analytical errors in specimen handling:

Improperly handled specimens are not always easy to detect. Having and following written specimen handling policies and procedures is essential. The policies and procedures should address specimens that are sent to another laboratory as well as specimens tested in your facility.

- Rough handling of specimens during transport may cause hemolysis or tube breakage.
- Transport tubes with stoppers up.
- Transport non-blood specimens in leakproof containers with secured lids.
- Some analytes like bilirubin, B12, B2, B6, carotene, folate, urine porphyrins, porphobilinogen, and Vitamin C are broken down by light. Protect the specimens from light to prevent falsely decreased values.
- Some analytes such as blood gases, ammonia, lactic acid, plasma rennin activity, and glucagon require chilling. Immerse these specimens in a slurry of crushed ice and water to slow down the metabolic process.
- Cryoglobulins, cold agglutinins, and cryofibrinogen require that the specimen remain at body temperature after collection.
- The Clinical and Laboratory Standards Institute (CLSI) states that it is advisable to separate most serum and plasma specimens from the cells within two hours from the time of collection. If specimens cannot be delivered to the laboratory in the specified times, the serum or plasma should be separated.

NOTE: Refer to the specimen collection and handling protocols from your reference laboratory for specific information about referral tests. Call your reference laboratory if you are unsure of the proper specimen handling protocol.

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

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>

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Tips for Shipping Infectious Substances

What is an “Outer Packaging”?

by Paul Marbourg & Shelley Lankford, DOH/PHL

What is an “Outer Packaging”? It is the outer packaging of a certified packaging shipping system. Because it is part of a *certified* shipping system, you must never mix packaging components from different manufacturers. This practice will void the system’s certification.

As of 2006, federal regulation defined that the outer container must be made of a rigid material and be in good condition. It must be certified by the US Department of Transportation (DOT), and must display the United Nations (UN) certification code 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 the secondary from shifting while the package is in transit. Place the list of contents inside the outer container, either 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 carbon dioxide (CO₂) as a refrigerant, you **MUST** make provisions for the CO₂ gas to escape safely. Otherwise, the package could explode. Remember to secure the secondary container to prevent movement inside the foam-lined rigid outer container as the dry ice evaporates in transit. New regulations require that the manufacturer of packaging systems either print the closure procedure on the outer container or have printed instructions with your shipment.

There are *different* triple packaging certification requirements for shipping Category A or Category B infectious substances. A packing system certified for Category B infectious substances must be able to withstand a drop of 4 feet without leaking. A packing 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!

All labels used on the outer container must **not** be handwritten. They can be made on your computer, so you do not need to buy special labels, but there are minimum size requirements. The label requirements for shipping Category B infectious substances include:

- Shipper’s address,
- Consignee’s address,
- The UN3373 diamond with “Biological Substance, Category B,”
- A “Responsible Person” label must be on the outer packaging as well as on the lab forms if you use United States Postal Service (USPS). It can be on either location with any other carrier. **NOTE:** When shipping a Category B specimen, the Responsible Person needs to be available during normal business hours.

The label requirements for shipping Category A infectious substances include:

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What is an “Outer Packaging”? continued from page 3

- Shipper’s address,
- Consignee’s address,
- The UN2814 (or UN2900) label with the total weight of specimens inside the package,
- 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. For Category A infectious substance, the Responsible Person must be a live person available on a 24-hour seven-day-a-week basis.
- If dry ice is included in the container, the outer rigid packaging must include a Class 9 Miscellaneous Dangerous Goods label. List the weight of the dry ice inside the package on the label and include the words “Dry Ice” **or** “Carbon Dioxide Solid” **and** “UN1845”.
- 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 a “Cargo Aircraft Only” label.
- All Category A infectious substance shipments require a properly filled out “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.

Specimen Collection Protocols for Patients Involved in a Chemical Incident

by Paul Marbourg and Shelley Lankford, DOH/PHL

A chemical incident can result from an act of terrorism or from an industrial accident involving chemicals. Specimen collection during a chemical incident involves many healthcare professionals. Physicians, nurses, emergency department personnel, phlebotomists, and laboratory personnel can all be responsible for collecting blood and urine specimens.

It is important that the specimen collection personnel know there are specific protocols to follow when responding to a chemical event. This article discusses the state and federally mandated protocols specific to chemical exposure events.

There are three main types of chemical exposure addressed here:

- **Nerve Agents:** Exposure to nerve agents such as methylphosphonothioate (VX), Soviet VX (SVX), sarin (GB), soman (GD), and cyclosarin (GF) most likely would occur from an act of terrorism, but could also result from a leak at a weapons storage facility. Patients with exposure to nerve agents generally exhibit rapid onset of acute symptoms.
- **Toxic Industrial Chemicals:** Exposure to toxic industrial chemicals could happen anywhere in our state from a variety of sources. Patients with exposure to toxic industrial chemicals generally exhibit rapid onset of acute symptoms.
- **Food-borne or water-borne toxins:** Exposure to food-borne or water borne toxins such as incapacitating agents (LSD or BZ), Botulinum toxin, ricin, or heavy metals such as thallium, mercury, or cadmium may be more difficult to diagnose initially since the onset of symptoms may be insidiously subtle instead of acute.

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Chemical Incident Specimen Collection, continued from page 4

Blood and urine specimen collection and handling procedures are the same regardless of the type of chemical associated with the exposure. Specimen collection must be performed using CDC mandated protocols. The protocols require the collection of both blood and urine specimens from each patient and are specific to the type of specimen (blood or urine) being collected. Only urine specimens are collected for children, unless directed otherwise by your LHJ, state DOH or the CDC.

It is critical to draw the specimen tubes for chemical exposure testing in the proper order. This protocol is necessary for the most accurate testing results. The correct draw order is:

- lavender top (EDTA) tubes,
- **then** the gray top (oxalate/fluoride) tube or the green top (heparin) tube.

Blood Specimen Collection: Collect a minimum volume of 12 mL in either three 4 mL or four 3 mL EDTA lavender-top tubes. After the EDTA draw, collect 4 mL of blood in a gray or green-top tube. Label each tube with patient information. On the lavender top tubes, place numbers (1-3 or 1-4) to indicate the exact order of draw. The draw order is very important for testing purposes. If you have bar-coded patient identification labels, place bar-coded labels on each tube such that when the tubes are upright, the barcodes look like a ladder. **Do not use** gel separators. Mix the contents of the tubes by inverting 8 to 10 times. Store the patient specimens between 1 to 10°C. *Do not freeze the blood specimens.*

Urine Specimen Collection: Collect 25 to 50 mL of urine into a screw cap urine cup. Label each urine cup with patient information. If a bar-code label is used, it should be placed so that it looks like a ladder when the cup is upright. If the collection method was other than “clean catch,” indicate on the cup how the specimen was collected. Freeze and store the upright cups at -70°C with dry ice or in a low temperature freezer.

Submit an Empty Specimen Container! You **must** include an empty, unused specimen container from each container lot number used for collection for both blood and urine specimens. These “blanks” are necessary for background subtraction during specimen analysis. Specimens may not be analyzed without the container blanks.

Specimen Collection for Chemical Incidents Training Course: The collection of urine and blood specimens may seem to be a simple and standard practice. However, the CDC mandated changes from the standard blood draw protocols are important to insure accurate results. A short two hour “Specimen Collection For Chemical Incidents” course has been developed and will be presented in your region this spring or early summer. Course brochures are already being distributed in your area. If you are interested in attending and do not receive a brochure, please send an email request (including your location) to PHL.training@doh.wa.gov or call Margaret Hoff at (206) 418-5402.

Lab Pre-Analytic Errors, continued from page 2

Summary: Pre-analytic errors can cause serious harm to the patient – up to and including death, either directly or indirectly. It is critical to have established written procedures and policies, and to adhere to them. The phlebotomist must implement and practice excellent quality control throughout the entire pre-analytic phase including patient identification, communication with the patient, selecting the site, choosing the correct equipment, determining any special patient considerations, ordering the tests, labeling the specimen, and processing the specimens.

Errors can have devastating consequences for the patient. The laboratory should have a process in place to identify, capture, assess, and investigate deviations from procedures and policies. Most laboratory employees are dedicated, caring, and competent in their duties, but it is the ultimate responsibility of the medical director and the laboratory management team to maintain trained and competent employees so the potential of pre-analytic errors remains low and patient outcomes are favorable.

Sentinel Laboratory Guideline for Packing & Shipping

The Association of Public Health Laboratories (APHL) provided the following information.

The American Society for Microbiology (ASM) has revised the *Sentinel Laboratory Guideline for Packing and Shipping Infectious Substances*, authored by Larry Gray, PhD and James Snyder, PhD. This guideline was revised to reflect current packing and shipping guidelines and requirements to assist Sentinel Level Clinical Microbiology Laboratories. Download a free copy of the revised Guideline from this website:

<http://www.asm.org/ASM/files/LeftMarginHeaderList/DOWNLOADFILENAME/000000001202/PackingandShipping1-08.pdf>

A couple points of reference:

Page 17: Resources for training your employees

Page 26-37: Flow charts, images & shipping containers

Venipuncture Techniques Training Course

Monday, April 14, 2008

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 is six hours in length and will be held at the Washington State Public Health Laboratories in Shoreline, WA. There will be 0.6 CEU credits awarded at the completion of 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 April 1, 2008 registration deadline. **For more information or an application, please contact** Ronnie Staats at rstaats@u.washington.edu or (206) 685-9848.

Proficiency Testing: Have you enrolled for 2008?

The first proficiency testing (PT) events for 2008 will be shipped soon. If you hold a MTS license that is Categorized or Accredited, you should have already enrolled in PT for 2008. If you have not enrolled, you must do so immediately so you do not miss the first event. Failure to participate in the 1st event will result in a “zero” score for the event. This is considered unsatisfactory performance and can jeopardize your ability to continue to perform patient laboratory tests in your facility. Please refer to page 6 of this newsletter for a list of the CLIA approved PT providers and contact information. If you have already enrolled in PT, thank you!

NOTE: If you hold a MTS license that is either “Certificate of Waiver” or “Provider Performed Microscopic Procedure (PPMP)”, enrollment in PT is not required.

Laboratory Quality Assurance Websites

by Leonard Kargacin, DOH/LQA

The Office of Laboratory Quality Assurance (LQA) has many resources available through its Web site. All of the materials listed in this article are available on the LQA Web site at <http://www.doh.wa.gov/lqa.htm> and scrolling down the listing on the left hand side of the screen to **Links and Extras**.

Supplemental Material (*Select the sidebar “Supplemental Material”*):

Educational materials:

- Biannual Verification of Accuracy Suggestions
- Calibration & Calibration Verification Compliance Guide
- Good Laboratory Practices with Waived Test Systems
- Instrument Validation Requirements
- Medical Test Site Survey Checklist (All Specialties)
- Pre-Inspection Self-Assessment Checklists
 - Aerobic Cultures
 - Chemistry Testing – Moderate Complexity Only
 - Dermatology Testing
 - Gram Stains
 - Hematology Testing – Moderate Complexity Only
 - Microscopic Examinations
 - Moderate Complexity Testing Kits
 - Proficiency Testing or Biannual Verification of Accuracy
 - Quality Assurance Plan Development
 - Who Can Order and Interpret Laboratory Tests

Forms (*Select the sidebar “Supplemental Material”*): Contains forms to notify LQA of changes in personnel and test menus.

Newsletters (*Select the sidebar “Newsletters”*): Contains copies of the Elaborations newsletter from the past three years.

Practice Guidelines (*Select the sidebar “Practice Guidelines”*): Copies of all practice guidelines developed by the Clinical Laboratory Advisory Council are located here.

Updates (*Select the sidebar “Updates”*): This tab will contain any updated information about the Medical Test Site (MTS) licensing program.

- Calibration & Calibration Verification Compliance Guide
- Laboratory Conference Program Flyer
- Revised Medical Test Site Rules
- Who Can Order and Interpret Laboratory Tests

Other Links (*Select the sidebar “Other Links”*): Links to the following are included under this tab:

- Continuing Education Opportunities
- Laboratory Professional Organizations
- Laboratory Personnel Certification
- Laboratory Accrediting Agencies
- Laboratory Training Programs
- Proficiency Testing Companies
- Miscellaneous Links
 - Centers for Disease Control and Prevention (CDC)
 - Centers for Medicare and Medicaid Services (CMS)
 - Clinical and Laboratory Standards Institute (CLSI)
 - Clinical Laboratory Improvement Amendments (CLIA)
 - Clinical Laboratory Initiative
 - Department of Labor & Industries - Safety Information
 - Food and Drug Administration (FDA)
 - Washington State Public Health Laboratories

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 Intestinal Parasites (2-Day Class)
February 13-14 Shoreline

2008 ASCLS-WA Spring Meeting
April 24-26 Lynnwood

Northwest Medical Laboratory Symposium
October 15-18 Portland

15th Annual Clinical Laboratory Conference
November 2008 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.