



Lab-Oratory

North Carolina
N.C. Department of Health and Human Services / State Laboratory of Public Health

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"Dear Lab-bey"

Lab-Oratory, September 2007

Number 89

From the Director's Chair

Spotlight on Multi-site CLIA Certificate Program

When the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) were adopted, more stringent requirements were placed on clinical laboratories to ensure the quality of laboratory results that directly impact patient care. These federal requirements defined the qualifications and responsibilities for personnel, including the laboratory director, technical consultant, clinical consultant, and testing personnel. Because of the educational requirements, many local health departments in more rural areas experienced difficulties in recruiting, hiring and retaining qualified laboratory personnel. In the public health system, however, it was deemed important to patient care to be able to provide moderate complexity laboratory services on site, such as vaginal wet mount examinations, urine microscopy and culture for gonorrhea. So how was this challenge approached in North Carolina?



*Leslie A. Wolf, PhD, HCLD (ABB)
Laboratory Director*

The NC State Laboratory of Public Health (NCSLPH) Laboratory Improvement Unit developed a voluntary contract program as a service to local health departments, to fulfill many of the laboratory criteria set forth by CLIA'88. This program has been in existence since 1993 and has provided many benefits to program participants since

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MISSION statement

The State Laboratory of Public Health provides certain medical and environmental laboratory services (testing, consultation and training) to public and private health provider organizations responsible for the promotion, protection and assurance of the health of North Carolina citizens.

Director's Chair cont. from page 1

its inception. The program began with one Laboratory Improvement Consultant stationed in the western part of the state to allow closer contact with participating local health departments. The NC CLIA Contract Program now includes four full-time regional Laboratory Improvement Consultants who serve as Technical Consultants to 48 counties. In addition to providing qualified personnel (Laboratory Director and Technical Consultant), technical oversight, assistance with quality assurance requirements, review of quality control data and record-keeping, development of standard operating procedures and laboratory-related continuing education are provided by NCSLPH staff. The administrative burden and costs of maintaining individual CLIA certificates is reduced by combining multiple health departments on four area certificates. Only one site on each certificate must enroll in proficiency testing and only one site represents the entire multi-site CLIA certificate upon inspection every two years.

Participating local health departments provide a designated laboratory manager, a sufficient number of qualified testing personnel and a clinical consultant, all with clearly defined duties and responsibilities. The on-site laboratory manager is a critical component to the success of the NC CLIA Contract program because of the required daily oversight of all laboratory activities, including monitoring of patient testing, training of new personnel, participation in competency assessments and proficiency testing, as assigned. The laboratory manager

also serves as the key contact with the Laboratory Improvement Technical Consultants when changes in personnel, methods, or instruments are anticipated or when troubleshooting guidance is needed. Ideally, this person is either laboratory trained or has extensive laboratory experience.

There are currently nine states with multi-site CLIA certification for limited public health testing, and the approach varies widely. An Association of Public Health Laboratories (APHL) meeting was hosted by the NCSLPH in March 2007 with representatives from Kentucky, Connecticut, Delaware, Tennessee, Michigan, and Louisiana, as well as staff from APHL and the Centers for Disease Control and Prevention in attendance. It was a great opportunity to learn about the models developed by other states and collectively define a list of best practices, drawing from each of the state public health systems represented. In NC, we are very proud of our strong CLIA Contract Program and found that many elements of our program are considered best practices. Some of these include the following:

- choosing technical consultants with appropriate qualifications and experience
- designating a qualified lead staff person at each local testing site
- ensuring that all sites included on the multi-site certificate understand the impact of one site on the certificate failing to meet CLIA requirements
- using a contract to detail requirements of the program and ensure accountability
- providing standardized forms to document Quality Assurance and Quality Control activities
- conducting proficiency testing annually
- conducting competency assessment of testing personnel annually
- having representation on site during biennial CLIA inspections

For the entire APHL issue brief, please copy and paste the address below into your web browser:

www.aphl.org/about_aphl/products_and_publications/Documents/CLIA_brief_2007.pdf

Dr. Leslie Wolf, Laboratory Director

College of American Pathologist Laboratory Preparedness Survey

The College of American Pathologists (CAP) Laboratory Preparedness Survey (LPS) was developed as a collaborative effort between CAP, the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL). The survey was revamped to provide a more realistic bioterrorism response challenge for the sentinel laboratories. To participate in the survey, sentinel laboratories in North Carolina were required to have protocols in place to function as a Laboratory Response Network (LRN) Sentinel Laboratory and have a properly functioning Class II Biological Safety Cabinet.

Goals of the CAP LPS:

1. To provide LRN Sentinel Laboratories with a realistic bioterrorism agent challenge exercise.
2. To provide an educational survey that will test most aspects of a laboratory bioterrorism response, to include:
 - a. Rule-out and referral of potential bioterrorism agents (both surrogates and attenuated “real” organisms) using appropriate LRN Sentinel Laboratory protocols.
 - b. Notification by the participating LRN Sentinel Laboratory to the nearest LRN Reference Laboratory of potential bioterrorism organisms.
 - c. Knowledge of appropriate packaging and shipping of organisms to the nearest LRN Reference Laboratory.

- d. Knowledge of appropriate laboratory protocols that address the safe handling of highly pathogenic organisms.

In North Carolina, 32 sentinel laboratories registered to participate in the May 2007 College of American Pathology (CAP) Laboratory Preparedness Survey (LPS). Prior to the survey, two of the registered sentinel laboratories informed the NCSLPH that they would not be participating. Safety and liability concerns were provided as reasons for opting out of the survey by one hospital laboratory.

Of the 30 laboratories that participated, 17 contacted their LRN laboratory while 13 did not. Of the 17 that contacted their LRN laboratory, two were asked to send a sample to the closest LRN laboratory for confirmatory testing. This tested the sentinel laboratories capabilities to package and ship a sample to the closest LRN lab in a timely manner.

Comments

- Some laboratories stated that overall the survey was “great”
- Some laboratories said that the survey was a “vast improvement” over previous surveys
- Some laboratories said, “excellent job on the survey isolates”

Concerns

- Laboratories were not aware that they should call their LRN laboratory

- All directions should be included with the kit instructions so that laboratory staff have all information necessary
- Laboratories were not aware that they were given surrogate bugs
- Laboratories were unclear of the proper biosafety level to manipulate the survey agents
- Fear of associated potential hazards
- Liability with regard to incinerating waste off site

Conclusions/Feedback

- Because NCSLPH did not participate in the CAP LPS, we were unaware of the instructions provided to participating laboratories. It would have been helpful if NCSLPH had access to the same information in order to better assist the sentinel laboratories with questions and concerns.
- Some sentinel laboratories expressed concerns that they were not aware of the instructions to call their LRN laboratory. They did note, however, on the CAP LPS response form that they would have called NCSLPH, but did not feel it was necessary to actually make the call for this survey.
- It would have been helpful for all sentinel laboratories to be instructed clearly to call their LRN laboratory so that NCSLPH could test 24/7 response capabilities with regard to communications during a period of time with a high volume of sample submissions.
- It would have been helpful if NCSLPH were notified of all

College of American Pathologist Laboratory Preparedness Survey cont. from page 3

sentinel laboratories that opted NOT to participate in the CAP LPS so we could have an accurate representation of participating laboratories.

- In the future, the NCSLPH plans to participate in the CAP Laboratory Preparedness Survey.
- The NCSLPH plans to encourage our sentinel laboratories to participate in upcoming CAP Laboratory Preparedness surveys to better prepare our state for real biological threat events and to increase our communication abilities.

Abbreviations:

NCSLPH
(North Carolina State Laboratory of Public Health)
BTEP (Bioterrorism and Emerging Pathogens Unit)
CAP (College of American Pathologists)
LPS (Laboratory Preparedness Survey)
APHL (Association of Public Health Laboratories)

Please feel free to contact Holly Lee or Royden Saah if any additional information is needed. The main Bioterrorism and Emerging Pathogens phone number is 919-807-8765.

Submitted by:

Holly Lee, Laboratory Improvement Consultant for the Bioterrorism and Emerging Pathogens Unit at the NCSLPH

NCSLPH Represented at Newborn Screening Symposium

The 2007 Newborn Screening and Genetic Testing Symposium was held May 7-10 in Minneapolis, Minnesota. This annual event is sponsored by the Association of Public Health Laboratories and provides a forum to address changes in the newborn screening testing field and strengthen the role of public health labs in genetic testing. Approximately 400 laboratorians, follow-up professionals and metabolic specialists from 46 states and 17 countries attended the symposium. The NC State Laboratory of Public Health was represented by Dr. Shu Chaing and Ann Grush of the Newborn Screening/Clinical Chemistry Unit. Dr. Chaing is technical supervisor of the unit, and Ann is general supervisor of the Fluoroimmunoassay/Galactosemia/Biotinidase lab.

Among the topics of interest were methodologies and screening algorithms used by other states currently screening for cystic fibrosis. The addition of this disorder to the panel of tests performed by the NC

Newborn Screening Program is presently under consideration, and it is especially helpful and informative to hear from other programs that have successfully implemented such testing. Also of interest was a presentation concerning an upcoming release of revised guidelines for filter paper blood collection by the Clinical Laboratory Standards Institute. More information will be released on this topic as it becomes available.

During their stay, Dr. Chaing and Ann were also able to tour the Minnesota Public Health Laboratory in Minneapolis and the Mayo Clinics in Rochester, Minnesota. The Public Health facility is relatively new, and the tour provided the opportunity to view design and layout schemes that could be applied to the new NCSLPH which is scheduled to be completed in 2010. While at the Mayo Clinics, Dr. Chaing and Ann visited the Molecular Genetics and Biochemical Genetics Laboratories. They also discussed Tyrosinemia I and Congenital Adrenal Hyperplasia testing issues with Dr. Dietrich Matern, Director of the Biochemical Genetics Laboratory. The symposium and tours were very informative, and such opportunities are key to keeping the NC Newborn Screening Program updated on the latest issues in newborn screening.

Submitted by:

*Patty Atwood, BS MT (ASCP)
Supervisor, Hemoglobinopathy Laboratory*

Live Classroom Provides Update on Newborn Screening

The North Carolina State Laboratory of Public Health (NCSLPH) navigated the information highway on June 14th to present an interactive videoconference on newborn screening. Using the North Carolina Public Health Training and Information Network (PHTIN), the State Lab broadcast the program to 200 videoconference sites throughout the state. There were more than 100 participants from local health departments, hospital birthing centers, and physicians' offices.

The live classroom began with an overview of new tests under consideration for the newborn screening panel. Dr. Shu Chaing, supervisor for the NCSLPH, Newborn Screening/Clinical Chemistry Unit, noted that tests for Cystic Fibrosis (CF), Tyrosinemia (type 1) and a second tier of testing for Congenital Adrenal Hyperplasia (CAH) will be added when funding is available. Currently, a newborn in North Carolina is screened for 34 disorders, making North Carolina a national leader in this area.

Since 1999 when the NCSLPH implemented the Tandem Mass Spectrometry Program (MS/MS), more than 1,000,000 babies have been screened for metabolic disorders. Susan Weavil, MS/MS supervisor, said that more than 250 babies with treatable disorders had been detected by this technology since the program's inception. She described the genetics of the most prevalent metabolic disorders, Phenylketonuria and Medium-Chain Acyl-CoA Dehydrogenase Deficiency (MCAD). The class viewed various stages of the MS/MS procedure from specimen punching through sample reconstitution.

Ann Grush, the supervisor of the NCSLPH FluoroImmunoAssay/Galactose/Biotinidase Lab, defined many of the acronyms for newborn tests, including BIO, CH, GAL, and CAH. She began with the most recent test added to the newborn screening menu; i.e. BIO or biotinidase deficiency. In November 2004, the NCSLPH began testing infants for this disorder, which if undetected and untreated may result in seizures, neurological abnormalities and developmental delays. Ann continued to describe other disorders such as CH or Congenital Hypothyroidism. Infants with CH may present with subtle signs, or none, at birth. If the disorder is not detected and treated, irreversible mental retardation and a failure to grow will occur. Another disorder, GAL or classical Galactosemia may cause symptoms that include vomiting, diarrhea, E.coli sepsis and possibly death. Infants that survive Galactosemia may have severe health problems such as mental retardation. Ann distinguished between the two types of CAH or Congenital Adrenal Hyperplasia. An infant with the salt-wasting form of CAH, which has not been treated for the disorder, may experience an acute adrenal crisis. This medical emergency may result in shock or death of the child. The non-salt wasting form (simple virilizing form) of CAH, may be apparent at birth when the sex of the newborn is undetermined ("ambiguous genitalia"). Treatment options for each disorder were discussed.

Ann emphasized the use of the filter paper form as a specimen collection device. She also addressed issues related to completing the filter paper form including the use of the hearing link label by some facilities.

Susan guided a tour of the State Lab website beginning with an introduction to newborn screening, including how and where an infant is tested and the parent's role in the process. She demonstrated how users remotely access the following subjects: disorders detected, conditions tested, specimen collected, reporting, form training, forms and publications, ordering supplies, Lab-Oratory newsletter, SCOPE Guide to Services, lab test results lookup, clinical lab result, FAQs – user and administrator questions, new user registration, notices, clinical lab results, lab results – patient search, patient search results list, printed web report, quick link – DHHS homepage and quick link to NC Public Health homepage.

Common hemoglobin variants, their clinical significance and follow-up requirements were described by Patty Atwood, NCSLPH Hemoglobinopathy supervisor. She discussed the clinical implications of hemoglobin variants that are commonly detected by routine screening and defined the laboratory requirements for follow-up testing of abnormal hemoglobins. Sick cell hemoglobin (Hemoglobin S) is the most prevalent abnormal hemoglobin in North Carolina. In 2006, approximately 100 babies out of the 130,000 tested were positive for sickle cell or sickle cell–Hemoglobin C disease. The irregular, sickle shaped red blood cells are fragile and can result in painful swelling of the hands and feet, increased risk of infections, moderate to severe anemia, and damage to body organs. Patty described other abnormal hemoglobins such as Hemoglobins C,E,D,G

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Live Classroom Provides Update on Newborn Screening cont. from page 5

and Hemoglobin Barts. She also reviewed the inherited disorder thalassemia, which results from decreased production of one or both of the globin chains (alpha or beta chains) that make up hemoglobin. This reduction in globin chain synthesis causes the formation of abnormal hemoglobin molecules, resulting in anemia, one of the characteristic symptoms of thalassemia.

NCSLPH Regional Laboratory Improvement Consultant Lisa Ballance, presented the final lecture on heel puncture collections for newborn screening. She emphasized the goal of the Newborn Screening Program: To provide accurate and timely screening of all infants born in North Carolina through the proper collection and submission of valid blood spot specimens. Lisa described the selection of proper equipment for blood collection, including puncture vs. incision devices. She took the class through the preanalytical process of obtaining the newborn's blood, from the assembly of supplies to the specimen transportation to the NCSLPH for testing. Lisa alerted the class to situations that might cause the rejection of a specimen, such as the presence of tissue fluid in the blood spot on the filter paper form.

The audioconference class concluded with an opportunity for questions from participants. The following is a summary of the questions and answers..

Q. Since the screening of newborns should be done before the infant is transfused, does that include whole blood, platelets, or packed RBCs?

A. The transfusion of platelets or plasma products will not affect newborn screening test results. The transfusion of whole blood or packed RBCs will affect the testing for hemoglobinopathies.

Q. I work with Child Health and we are supposed to get the newborn's results for the chart. When I go on-line to get the results, I am unable to access them as they have already been retrieved (probably by the doctor present at the birth). How can I obtain these results?

A. You must know four identifiers for the infant before you can retrieve results. The identifiers are: infant's last name, mother's first and last names, and the DOB. Usually, if you know the mother's first name, last name and infant's DOB, you will be able to access the infant's newborn screening results.

Q. Is the 24-72 hour period for collecting the newborn blood specimen after the infant's birth or after the first feeding?

A. The period is after the infant's birth. The optimum time for collecting the newborn blood specimen is 48-72 hours after birth. It is preferred that the infant have been fed before the blood is collected but it is not required.

Q. Why is a venous puncture contraindicated for newborns?

A. It is a riskier procedure than the heel stick.

Q. Can the newborn screening form be sent in for testing if the infant's Medicaid number is pending?

A. Yes. Do not delay sending the form to the NCSLPH because of the pending Medicaid number. Call the Newborn Screening Office at 919/733-3937 with the number when it becomes available.

Q. If the infant is being adopted, how much of the birth mother's information must be on the newborn screening form (name, SS#, etc.) and where do you indicate the name of the adoption agency?

A. If the adoption agency or adoptive mother's name is available, put the name of the adoption agency or adoptive mother's information in the place of the birth mother's information. If the adoption information is not available, give the birth mother's information.

Q. If the baby received IV fluids for nutrition at birth and he is returning for a follow-up one month later, must parenteral fluids be checked on the follow-up form?

A. No. Only check parenteral if he is getting IV fluids for nutrition at the time of the repeat collection.

Q. If a newborn has not eaten in the first 72 hours and the blood is collected for the newborn screening, will the specimen have to be recollected once the baby has eaten?

A. No. There is enough protein in the infant's body so that testing can be done. Leave the type of feeding blank on the form.

Live Classroom Provides Update on Newborn Screening cont. from page 6

Q. If a patient presents to the local health department for follow-up testing without a follow-up form, what should be collected?

A. Call NCSLPH Newborn Screening Office at 919/733-3937 to find out what is needed for follow-up.

Q. Has the composition of the filter paper form changed? It doesn't seem to absorb blood as easily.

A. It could be the way the forms are stored. If they are stacked, then the weight of the form may cause the filter paper to compress. It is recommended that the forms be stored in the original wrapping and stacked in a manner that avoids compression.

Q. What do you check on the form for feeding when the infant received nutrition through IV fluids during the first 12 hours of age but was bottle fed (or breast fed) at the time of collection? Do you still check parenteral?

A. Yes. Check parenteral feeding and the appropriate type for bottle or breast since the time period is so close together. Check all that apply.

Q. How critical is it that the filter paper is flat when drying?

A. CLSI (Clinical and Laboratory Standards Institute/ formerly National Committee for Clinical Laboratory Standards) recommends that the blood specimen is allowed to air dry on a horizontally level, nonabsorbent, open surface. However the use of a drying rack is acceptable as long as the blood spots on the filter paper are not heated, stacked or allowed to touch other surfaces during the drying process. Do not use tape to attach the form to a surface. The tape can cause the forms to tear when removed. A thumb tack is an acceptable method for attaching a form to a flat surface such as a cork board, as long as the blood spots are not touching the board. Do not contaminate, bend, fold or wrinkle the forms.

Q. If an infant gets a one time bolus of IV fluids for nutrition, will that affect the newborn screening results?

A. Yes. Be sure to check parenteral for the type of feeding as there is a potential for contamination from amino acids in the fluid and high levels of amino acids in the body.

Q. If the baby is transfused in utero, how do you complete the form?

A. Write the comment IN UTERO on the filter paper form by the question for transfusion. If the date and/or time of in utero transfusion are known, then include that on the form.

Q. Why is penicillin used to treat newborns with Sickle Cell disease?

A. Children with Sickle cell disease are more prone to pneumococcal infections. Oral prophylactic penicillin will aid in preventing severe bacterial infections.

Q. Why are the new labels called hearing labels?

A. Several years ago, the Hearing Program asked the Newborn Screening Program to collaborate in the collection of demographics on newborn infants. The hope was to improve data management using information technology. Since the label was designed by the Hearing Program it is referred to as such.

Q. When will the hearing link labels be available to all facilities?

A. This question must be referred to the Hearing Program.

Q. How long must you wait to collect blood for newborn screening after the infusion of parenteral fluids for nutrition?

A. Do not wait. Collect at the usual schedule. Please make sure to check the box for parenteral feeding.

*Submitted by Colleen Miller, BS MT (ASCP)
Laboratory Improvement Consultant, NCSLPH*

Filter Papers Could Be Past Expiration Date USERS Urged to Check Lab Site For Updates

The filter paper portion of the newborn screening form (DHHS 3105) is imprinted with an expiration date to comply with Clinical Laboratory Improvement Amendments (CLIA) regulations regarding certain specifications in the absorption characteristics of the filter paper. The expiration date consists of a month and year, and forms are considered acceptable for testing until the end of the designated month. This means that any specimen collected and/or received on or after the designated date will be classified "Unsatisfactory," and a repeat specimen will be required. Filter paper forms having no expiration date were issued before the CLIA mandate, and are also unacceptable for

sample collection. Submitters should frequently review their stock of filter forms and discard those nearing the expiration date. These same guidelines also apply to Hemoglobin Electrophoresis form # 1859. Additional forms may be ordered by accessing the NCSLPH web site at <http://slph.state.nc.us/> and selecting "Online Mail Ordering System."

In order to alert submitters to impending expired forms, the lab will post a memo on the NCSLPH web site approximately two months prior to the expiration date. The memos are located by accessing the "Lab Tests Results Lookup" section on the home page. (For those submitters who are not registered to view results

online, a hard copy memo is also distributed with copies of reports that are mailed out during this time.) If a facility uses the web site infrequently to retrieve patient results, it is recommended that the site still be checked monthly for memos to update and inform on issues such as the one discussed.

Regularly checking for this kind of information is one of the many ways the NCSLPH web site can be used as a valuable tool to ensure acceptable specimens and accurate and timely results.

Submitted by:

Patty Atwood, BS MT (ASCP)

Supervisor, Hemoglobinopathy Laboratory

QA Tip Maintenance Log

Each piece of equipment should have a maintenance log. The log should include:

1. Frequency of maintenance: daily, weekly, monthly, etc
2. Equipment ID, such as name, serial number, technical service representative and any other specific information about the instrument
3. Ensure that the maintenance performed and what is recorded meets the manufacturer's guidelines.
4. If the manufacturer changes requirements, make sure that the log is updated to reflect what maintenance is actually being performed.
5. Provide a comment area on the log for detailed notes, if needed.

Lab Test of the Quarter

Serum Electrolytes (Part 2 of 4)

Potassium (K): an alkaline metallic element, atomic no. 19, atomic wt.39.0983, occurring abundantly in nature but always in combination.

-Stedman's Medical Dictionary, 28th Ed.

Potassium Normal Ranges (serum/plasma)

Adult/Elderly:

3.5-5 mEq/L

Child:

3.4-4.7 mEq/L

Infant:

4.1-5.3 mEq/L

Newborn:

3.9-5.9 mEq/L

Critical Values:

Adult:

<2.5 or >6.5 mEq/L

Newborn:

<2.5 or >8 mEq/L

Potassium is a major intracellular cation that is involved in muscle and nerve functions. It also works in conjunction with other electrolytes (sodium, chloride, CO₂) to regulate fluid levels in the body and maintain a stable acid-base balance.

Symptoms of potassium excess (hyperkalemia) include weakness and paralysis, impaired electrical conduction in the heart, and eventual ventricular fibrillation and death. Symptoms of potassium deficiency (hypokalemia) include muscle weakness, dizziness, thirst, mental confusion, and changes in the electrocardiogram.

Submitted by:

Jennifer Anderson, BS, MT(ASCP)^{CM}

Laboratory Improvement Consultant

Causes of Increased Extracellular Potassium (hyperkalemia)

- Excessive dietary intake
- Acute or chronic renal failure
- Aldosterone-inhibiting diuretics
- Burns
- Excessive IV intake
- Hypoaldosteronism
- Crush injury to tissues
- Hemolysis or any destruction of cells
- Transfusion of hemolyzed blood
- Infection
- Metabolic acidosis
- Dehydration

Causes of Decreased Extracellular Potassium (hypokalemia)

- Deficient dietary intake
- Burns
- Diuretics
- Cushing's syndrome
- Licorice ingestion
- Glucose administration
- Renal artery stenosis
- Trauma
- Deficient IV intake
- Gastrointestinal disorders (i.e. diarrhea, vomiting)
- Hyperaldosteronism
- Renal tubular acidosis
- Insulin administration
- Ascites
- Cystic fibrosis
- Surgery

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EDITORIAL

Needle Points

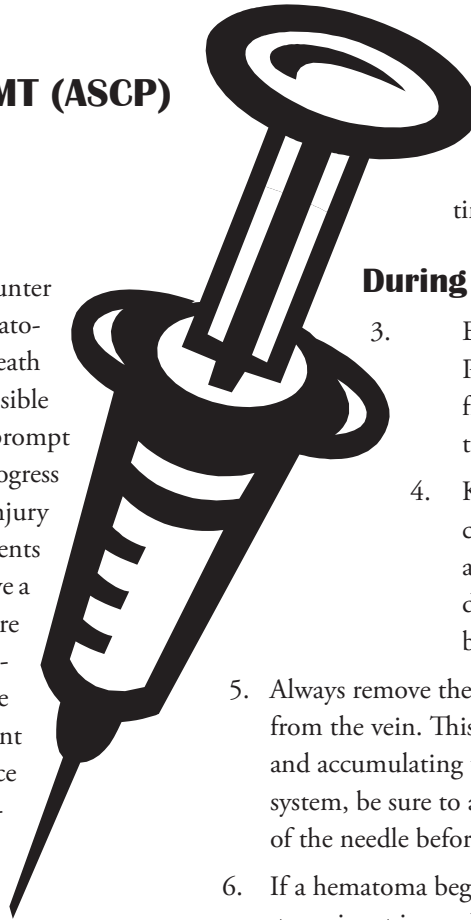
By Lisa O. Ballance, BSMT (ASCP)

Ten Tips for Guarding Against Hematomas

One complication collectors may encounter during phlebotomy procedures is hematoma formation., when blood pools beneath the skin's surface and presents as visible swelling and/or bruising. Without prompt attention, a hematoma can quickly progress into a more serious and debilitating injury for the patient. Most at risk are patients who are on anticoagulant therapy or have a clotting disorder. Also vulnerable are patients with decreased venous elasticity, as seen in the elderly. As healthcare professionals and sentries for patient safety, it is our responsibility to reduce such risks to the lowest degree. Fortunately, the Clinical and Laboratory Standards Institute (CLSI) provides an arsenal of information and the reinforcements we need. Its venipuncture standard outlines several steps that collectors can take before, during and after the procedure to guard against hematoma formation and to halt the process, should it begin.

Before the draw

1. When possible, select a major superficial vein rather than smaller, more fragile ones.
2. Choose an appropriate needle gauge and other collection supplies, based on the selected vein's characteristics. For small or fragile veins, combining a syringe with a smaller bore needle or winged collection set allows the collector to control the amount pulling pressure applied to the vein. Selecting pediatric collection tubes where appropriate also reduces the



blood volume required, minimizing collection time.

During the draw

3. Ensure the needle is fully inserted into the vein. Partial vein penetration may allow blood to ooze from around the needle and into surrounding tissue.
4. Keep the needle assembly still throughout the collection. Move the assembly during the draw and you may bring the needle's beveled edge into direct contact with delicate, unseen structures beneath the skin's surface.
5. Always remove the tourniquet prior to withdrawing the needle from the vein. This prevents blood from escaping from the vein wall and accumulating under the skin. When using an evacuated tube system, be sure to also disengage the last tube filled from the backend of the needle before removing the needle from the patient.
6. If a hematoma begins to form, halt the collection, release the tourniquet immediately and apply firm pressure with a gauze pad.

After the draw

7. Apply adequate pressure to the puncture site using a clean gauze pad rather than cotton balls. Cotton balls aren't recommended for post-venipuncture care since their fibers may dislodge the platelet plug that forms at the puncture site.
8. Observe the site for both superficial bleeding and any mounding or swelling of the surrounding area. Taking 5-10 seconds to perform this two-point check is the best defense against hematoma-related complications. Reapply pressure and repeat the visual check until you are sure bleeding has ceased.
9. For older children and adults, apply a bandage over the puncture site and instruct the patient to leave it in place for at least 15 minutes. Never bandage a patient without visually confirming that the bleeding has stopped.

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Needle Points cont. from page 10

10. Always be on guard for prolonged bleeding and never allow a bleeding patient to leave your care. If a hematoma develops or bleeding continues for more than five minutes, a nurse and the attending clinician should be notified, with the event documented according to facility protocol.

Take the time to protect your patients from the tell-tale signs of a rushed venipuncture. Know the hallmarks of hematoma formation and employ a strategy for prevention that includes providing proper post-venipuncture care. That way, when you're posed with the riddle "What's black and blue and bruised all over?" you can confidently say "Not my patients!".

The Safety Corner

Exposure Control Plan Series— Recordkeeping

An Exposure Control Plan (ECP) must have all of the necessary components to be complete. As we conclude our journey through the elements of an ECP, our last stop is recordkeeping. Three types of records are vital in an ECP – medical records, training records, and a sharps injury log.

All medical records must be kept confidential and held for the duration of employment plus 30 years. These records are not disclosed or reported without the employee's written consent to anyone. Medical records should include:

- Employee name.
- Employee social security number.
- Hepatitis B vaccination record/eligibility/dates.
- A copy of all results of physical exams, medical testing, and follow-up procedures related to vaccination and post exposure.
- Medical consultation, physical, and written opinion report.
- A copy of information provided to the health-care provider.

According to OSHA, training records must be kept for three years. These records must include:

- Dates of the training sessions.
- Contents or a summary of the training sessions.
- Names and qualifications of instructors.
- Attendance roster, including names and job titles.

The last component is the sharps injury log. The employer shall establish and maintain this log for the recording of percutaneous injuries from contaminated sharps. It should protect the confidentiality of the injured employee and shall contain:

- The type and brand of device involved in the incident.
- The work area where the exposure incident occurred.
- An explanation of how the incident occurred.



Hopefully, this journey through the Exposure Control Plan has helped to gain a better understanding of the essential elements. As with any other safety concerns, please call Kristy Breedlove at (919) 733-7186 to gain more information. Look for the next installment of The Safety Corner when we will begin a new series, "What's Right With This Picture"!

*Submitted by
Kristy Breedlove, BS,
Laboratory Improvement Consultant,
NCSLPH*

Exploring Darkfield for Spirochetes

Growing up in rural North Carolina during the sixties, I thought of myself as a budding astronomer. I would spend summer evenings scanning the Milky Way galaxy with my amateur telescope from Sears and Roebuck. Searching the clear, moonless sky, I would marvel upon locating the constellations Sagittarius and Orion amidst the thousands of stars shining in the dark night.

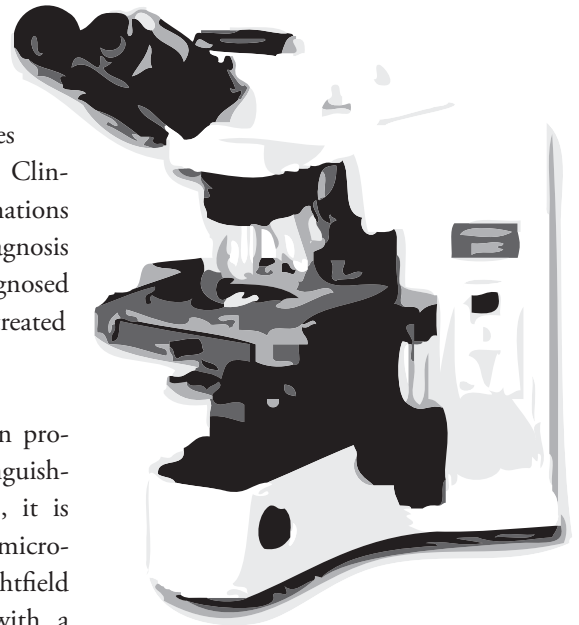
Just as the light from a faint star is enormously enhanced against a dark background, some microorganisms are only visible using darkfield microscopy. *Treponema pallidum*, the causative agent of syphilis is one such microbe. The thin, motile corkscrew shaped bacterium (spirochete) is brightly illuminated by the darkfield examination of fluid from syphilitic lesions. When viewing *T. pallidum* in the “living state”, its characteristic morphology and motility aid in the identification.



This method can provide a definitive diagnosis for primary syphilis because treponemes may be observed before antibodies are detectable by serologic testing. Clinics that perform darkfield examinations may support an earlier syphilis diagnosis because the disease is often diagnosed earlier and the patient can be treated immediately.

Although darkfield microscopy can provide a quick method for distinguishing syphilis from other disorders, it is infrequently used because special microscope equipment is needed. A brightfield microscope must be equipped with a darkfield condenser at an added cost of approximately \$800. However, a number of county health departments are required to use this procedure, as well as serum based serology testing, as part of the North Carolina Syphilis Elimination Project.

The sensitivity of the darkfield examination for *T. pallidum* is approximately 80%. Adequate training, experience and the proper equipment are required to make an accurate diagnosis by darkfield microscopy. Laboratory Improvement will offer Darkfield Microscopy training in 2008. Watch for details in the next issue of LabOratory.



Resources:
Clinical Microbiology Reviews, Jan. 1995.

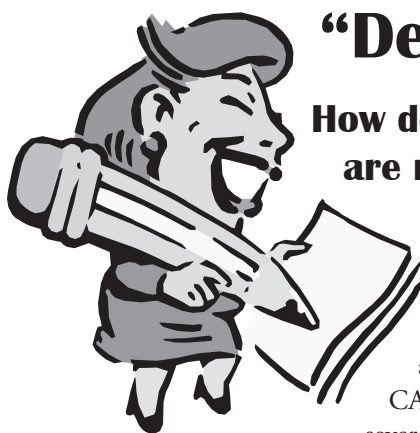
Examination of Specimens by Darkfield Microscopy;
available at <http://www.cdc.gov/std/program/medlab/ApD-PGmedlab.htm>

Submitted by Colleen Miller, BS MT(ASCP)
Laboratory Improvement Consultant

“Dear Lab-bey...”

**If you have a technical laboratory question that you would like to have answered
please submit it to: Jennifer.A.Anderson@ncmail.net.**

The answer to your question may be featured in the next edition of Lab-Oratory.



“Dear Lab-bey”

How do you perform laboratory proficiency testing when there are no commercial PT products available?

Laboratory proficiency testing (PT) is considered to be a form of external quality assessment (QA) and should be implemented with internal quality control (QC) procedures in order to ensure that patient results are reliable and accurate. In addition, periodic PT is required by laboratory oversight agencies such as CLIA and CAP. PT materials for many laboratory tests are available commercially but there are several types of tests that may not have proficiency testing programs available. These tests may include but are not limited to:

- Newly developed tests
- Certain drugs
- Tests associated with container-analyte interactions
- Tests in unusual matrices
- In vivo tests
- Uncommonly performed/esoteric tests
- Tests associated with PT material problems
- Tests that require extensive manipulation of the sample
- Hazardous or fastidious microbiological organisms

If there is no PT material available then an alternative assessment procedure must be developed and implemented. The most common procedures are:

- Split-sample testing (a single biologic sample is divided into aliquots and tested on different analyzers, by different laboratories, or by different analysts and the results are compared)
- Split-specimen testing (two biologic specimens are obtained at the same time from the same source and are both tested on different analyzers, by different laboratories, or by different analysts and the results are compared)

In addition, the following techniques may also be utilized:

- Audit sample testing (aliquots of patient specimen are frozen and analyzed periodically over time and results are compared)
- Analysis of the manufacturers calibration material or trueness control material
- Analysis of interlaboratory quality control data
- Analysis of patient data (reference ranges, delta checks, etc.)
- Reevaluation of morphologic analysis (glass slides reviewed by supervisory personnel or review of unknown glass slide sets.)
- Direct observation of technique dependent tests
- Clinical correlation studies
- Utilize surrogate organisms (in place of dangerous organisms)

This procedure must be documented in the procedure manual and include frequency, evaluation methods, limits of acceptable ranges, and corrective action if results are unacceptable. In addition, PT results and corrective actions must be documented and records retained for inspection purposes and to identify trends over time.

Submitted by Jennifer Anderson, BS, MT(ASCP)^{CM}, Laboratory Improvement Consultant

Serewitz SA, et al. “Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline.” GP29-A, 22(26). Wayne: Clinical and Laboratory Standards Institute; 2002.

Kudos!

The NCSLPH continues to recognize exemplary employees by awarding the State Lab Employee of the Month. Employees are encouraged to nominate co-workers who demonstrate great work ethics and always lend a helping hand. Our latest recipients are:

- July** Susie Lavendar, Cancer Cytology
- August** Beverly Boyd, Virology/Serology
- September** Crystal Poppler, Lab Improvement

Congratulations to all of our winners and thank you for your contributions to the NCSLPH!

Barbara Moore retired April 30, and Jona Medlin from the NCSLPH Chemical Terrorism section retired this summer. Enjoy your retirement, Barbara and Jona!

One of our regional Bioterrorism employees, Sayed Muaz Khalil, will be beginning a PhD program this fall. Congrats!



Becky Lee has been promoted to Cytotechnologist II.

Valerie Johnson, Processing Assistant III, celebrated the birth of a new baby daughter June 21. Congratulations, Valerie!

Congratulations to Ann McKenzie, who was awarded North Carolina Public Health Association Laboratorian of the Year on September 27, 2007!

Please contact Kristy Breedlove at (919) 733-7186 or kristy.breedlove@ncmail.net if you would like to recognize a co-worker at your facility.

QA Tip Proficiency Testing

You missed a PT - did you:

- 1. Review the report for information about overall performance for the event? Occasionally, there may be problems with the samples used by the PT providers.**
- 2. Re-run the sample, if possible?**
- 3. Review the QC and equipment maintenance for clues? For example, has there been a shift in the QC? Does the equipment show a positive or negative bias since the last maintenance or calibration?**
- 4. Evaluate any score less than 100%, according to your QA policy? After investigating the error, did you write up the corrective action and submit it to the QA office?**



The North Carolina State Lab of Public Health would like to welcome the following new employees. We hope they will find their service with us rewarding.

The Cancer Cytology CytoPrep Lab welcomes the following:
Cheryl Williamson – MLA II and, LyTeasha Bass – MLA III.

Cancer Cytology welcomes Sola Ogunniyi – Cytotechnologist I.

Erin Gragg has joined FIA/ Biotinidase/Galactosemia section, and John Bunting has moved to the Rabies Department.

Rachael Gast has completed the EID program at SLPH and is no longer with us—good luck to Rachael!

EDITORIAL board

Holly Lee, Bioterrorism and Emerging Pathogens; **Patty Atwood**, NBS/CC;
Susie Lavender, Cytology; **Brenda Webber**, Cytology; **Jennifer Anderson**, Lab Improvement;
Kristy Breedlove, Lab Improvement; **Colleen Miller**, Lab Improvement;
Crystal Poppler, Lab Improvement; **Janice West**, Lab Improvement; **Vanessa Campbell**, Virology/ Serology



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