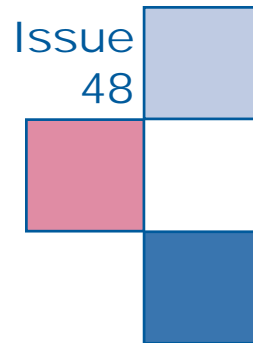
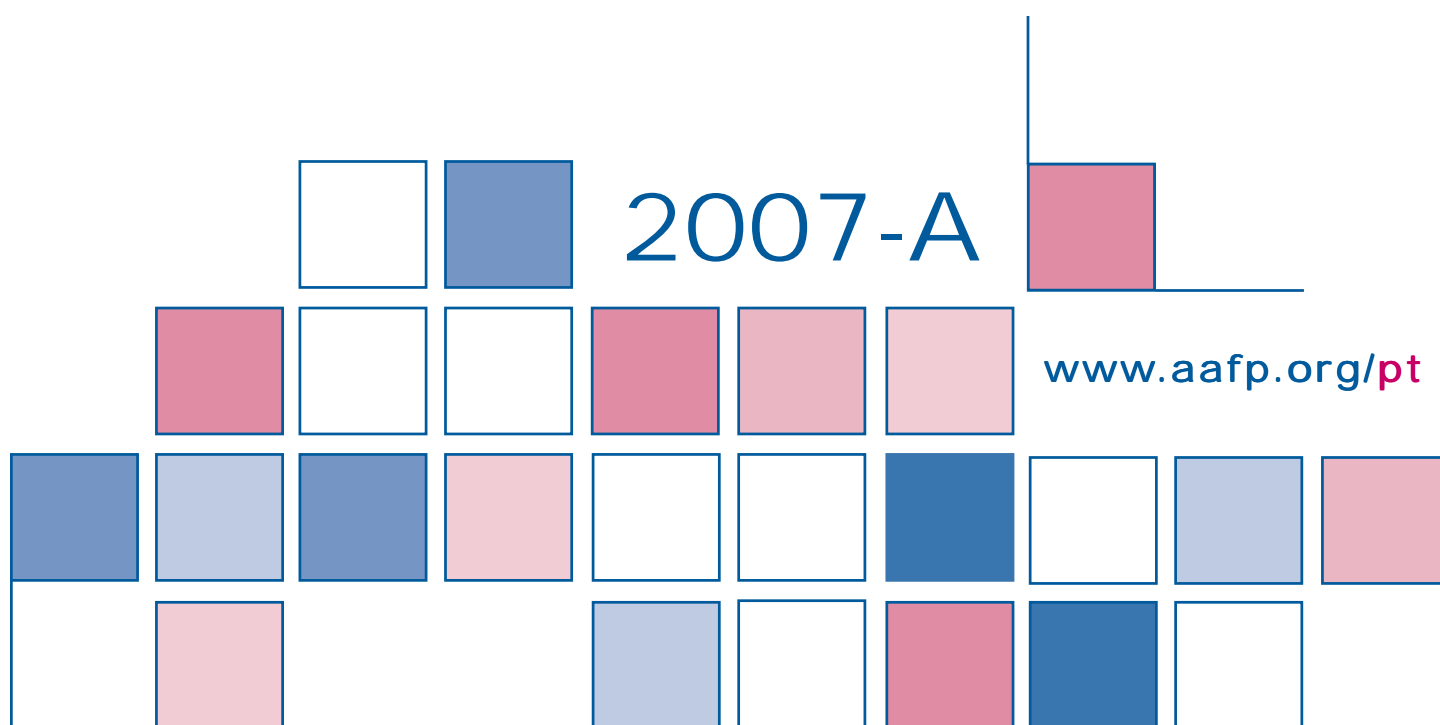


P.O.L.



Insight

A Continuing Education Publication for the
Physician Office Laboratory



In This Issue:

Safety for the POL

Autoimmune Disease
Testing

Preparing for a
Laboratory Inspection



Accreditation Statements

AAFP Physician's Proficiency Testing Program has been reviewed and is acceptable for up to 12 Prescribed credits by the American Academy of Family Physicians. AAFP accreditation begins 3/5/07. Term of approval covers three events offered within one year from this date with option for yearly renewal.

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Published by the American Academy of Family Physicians, 11400 Tomahawk Creek Parkway, Leawood, KS 66211-2672.

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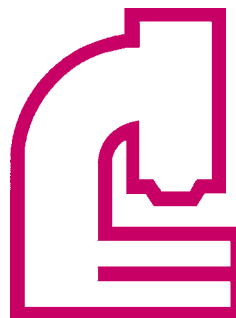


Table Of Contents

■ Safety for the POL	4-7
■ Autoimmune Disease Testing	7-10
■ New Product Announcements	10
■ Preparing for a Laboratory Inspection	11-13
■ CME Questions	13-15
■ CME Test Sheet	16

ATTENTION PHYSICIANS AND
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Personnel !

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AAFP member physicians may contact AAFP's CMER Department (800-274-8043) and request a complete transcript of their CME. Transcripts for non-Academy member physicians are mailed at the end of each year and are available upon request at 800-274-7911.

Verification of CME hours earned for laboratory personnel is mailed in January and July each year. Laboratory personnel are mailed P.A.C.E.® certificates at the end of the year (January 2008). Verification is also available upon request (swilliam@aafp.org or 800-274-7911, extension 4145). Allow 7-10 business days for requested transcripts.

CME Learning Objectives

Following completion of the self-instructional material, the participant will be able to:

1. Perform a laboratory safety audit and identify and correct OSHA safety violations.
2. Understand the purpose of laboratory surveys, know how the surveys proceed, organize data for a smooth survey, avoid survey pitfalls, and develop a plan of corrective actions.
3. Define autoimmunity, describe the most common types of autoimmune disease, discuss the diagnostic criteria for SLE, and identify common laboratory tests and expected results for diagnosis of autoimmune diseases.

To earn the CME, answer the questions included with this issue of the *Insight*, using the form included, or submit the test online at www.aafp.org/pt – click on Continuing Medical Education.

2007-A CME Answers

1.	A	13.	A	25.	B
2.	D	14.	D	26.	D
3.	B	15.	C	27.	A
4.	A	16.	B	28.	B
5.	C	17.	A	29.	A
6.	B	18.	B	30.	B
7.	A	19.	A	31.	D
8.	B	20.	C	32.	D
9.	A	21.	D	33.	B
10.	C	22.	B	34.	B
11.	D	23.	A	35.	A
12.	A	24.	A		

P.A.C.E.® Due Dates and Course Codes

Event 2006-B	May 31, 2007	254-002-06
Event 2006-C	September 30, 2007	254-003-06
Event 2007-A	February 28, 2008	254-001-07

■ Safety for the Physician's Office

By Terry Jo Gile, MT(ASCP)MA, Ed.
The Safety Lady, www.safetylady.com

Joe works in Dr. Jones' office laboratory. Joe wears scrubs when collecting the blood from patients and performing lab tests. He uses a non-safety type needle with a multiuse holder. He recaps the needle and throws it in a sharps container with the lid off and the sharps container overflowing. All of his waste goes into the regular trash. He only puts the patient's last name on the label because he knows all of Dr. Jones' patients since he has worked there for 17 years. On occasion when he has to send a test to a reference lab, he sticks it in a zip bag along with the requisition and mails it in a flimsy cardboard box. One day a compliance officer from the Occupational Safety and Health Administration (OSHA) makes an unannounced visit to Dr. Jones' laboratory.

Does this sound like your practice? If so, then you need an immediate safety audit to make sure you don't write a huge check to OSHA. Each violation can generate as much as \$7,000 per violation per day. So how does this office add up?

✓ **Not using a safety needle** – this requirement has been around since November of 2001. Employees are to evaluate the safety needles on the market and select one that meets most everyone's needs. You must document this evaluation and retain those evaluations for 3 years.

✓ **Not using a single use needle holder** – this has been the practice since 2004 although a lot of controversy has surrounded the practice. The bottom line is that OSHA is currently fining facilities for not disposing of both the used needle as well as the attached needle holder.

✓ **Recapping the needle** – this must never be done unless medical practice dictates it such as when doing a fine needle aspirate.

✓ **Overflowing sharps container** – sharps containers must be disposed of when three-fourths full or every month whichever comes first.

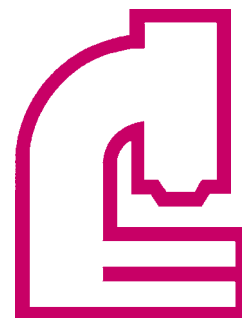
✓ **Biohazard waste in the regular trash** – this has been forbidden since 1991. Waste must be segregated into five waste streams - chemical waste, biohazard waste, sharps, regular trash and items to be recycled.

✓ **Labeling of the patient's tube with only the last name** – Tubes must be labeled at the time of collection and both the first and last name of the patient, and the initials of the phlebotomist as well as the tests to be performed and some practices request that the patient's birth date also be on the label. Your practice must have a policy of what is to be on the label whether you do the testing in house or send it out to a reference lab.

✓ **Sending out tests in a flimsy cardboard box** - Tests to be sent out must be packaged according to the Department of Transportation requirements which have changed for 2007. Diagnostic specimens are now classified as biological specimens and the blood tube must be individually wrapped in bubble wrap, placed in a leak proof zip bag that has an absorbent in it that will soak up at least five times the amount contained in each tube in the package. So, if you have three 10ml. tubes in the bag you would need an absorbent that would be able to handle a spill of 150mls. of liquid. The zip bag must then be placed into a sturdy cardboard box that can withstand a four foot drop.

These seven violations alone could result in a minimum of \$49,000 in fines *each day* they are not corrected. Can your practice afford this? If not, read on.

Each medical office practice needs to conduct an annual safety audit and keep the information on file until the next audit is done. The following is an audit template that asks the necessary questions. How does YOUR office lab measure up?



Laboratory Safety Audit Checklist

GENERAL

- Do employees receive safety training at the time of hire and annually thereafter?
- Do you have the required OSHA poster #3165 displayed where all employees are likely to see it?
- Is there a current listing posted of emergency contacts with phone numbers?
- Are bloodborne pathogen and chemical spill kits maintained in accessible locations?
- Is there signage indicating the location of these spill kits?
- Are noise levels below 85 decibels?
- Do employees understand what to do if they sustain an exposure to blood and body fluids?
- Is annual safety training provided to all employees and attendance documented?
- Have all employees been offered Hepatitis Vaccine free of charge and has this information been documented?
- Are floors wet mopped daily?
- Are certain computers and telephones designated as clean/dirty?
- Has initial and routine air monitoring been performed to determine exposure levels (eg: formalin, xylene, etc.), if necessary?
- Have you looked in each and every cabinet for unlabeled containers and labeled them correctly?
- Are chipped or cracked glassware disposed of in a rigid container?
- Is the refrigerator for food clean and defrosted?
- Is the microwave oven clean?
- Are workstations disinfected with an appropriate Environmental Protection Administration (EPA) registered disinfectant at the end of each shift?



HOUSEKEEPING

- Are all work areas, floors and storage areas maintained in a neat and orderly manner?
- Are all work surfaces decontaminated with an appropriate disinfectant at the end of each work shift and when grossly contaminated with blood and body fluids?
- Is broken glass picked up by tongs or forceps and disposed of in an appropriate container?
- Do spill clean-up procedures include soaking up the spill with absorbent material such as paper towels, decontaminating the area with an appropriate disinfectant and disposing of the contaminated materials appropriately?
- Is storage no more than 24 inches from the ceiling in a non-sprinkled area and no more than 18 inches from a sprinkler head?
- Are heavy objects stored on lower shelving?
- Are aisles free of trash and other debris?
- Are biohazard receptacles for blood or other potential infectious materials separate from regular trash?
- Is trash removed at least daily?
- Are main access hall corridors 48 inches wide?
- Do employees wear safety glasses with side shields (or goggles) in case of splash hazards?
- Does the task require the use of additional face protection such as a mask or a chin length face shield?
- Do shoes cover the entire foot and are made of leather or vinyl?
- Do employees wear fluid resistant (withstanding a minimum of 10 lbs./sq. in. of pressure) full length lab coats or cover gowns with long sleeves, knitted cuffs and closed in the front while in the work area?
- If these coats/gowns are reusable, are they laundered by a hospital or outside laundry service?
- Do employees remove their lab coats/gowns when leaving the lab or exam environment?
- Do employees wear appropriate gloves when performing laboratory testing, patient examination or phlebotomy?
- Are gloves available in appropriate sizes for all workers at risk for exposure?
- Are hypoallergenic gloves and liners available to workers who are allergic to latex?
- Are gloves removed when leaving the laboratory environment?



Documentation

- If you perform lab tests in your office, do you have copies of the *Federal Register* for January 31, 1990, Vol. 55, No. 21, pp 3327-3335 (Chemical Hygiene) and December 6, 1991, Vol., 56, No. 235, pp 64175-64182 (Bloodborne Pathogen) and NCCLS document M29-A2?
- Are safety training records on all employees kept three years?
- Are medical records on all employees kept for the duration of employment plus 30 years?

BLOODBORNE PATHOGENS

- Is the bloodborne pathogen written program available, current and has it been reviewed within the last year?
- Do employees understand what Standard Precautions (formerly Universal Precautions/Body Substance Isolation) means?
- Are lab coats and gloves removed before leaving the work area?
- Are hands washed before leaving the work area?
- Have employees been offered Hepatitis B vaccine free of charge within 10 days of hire?
- Are sharps containers available and used?
- Are sharps containers disposed of when three-fourths full?
- Do employees store food in a refrigerator specifically for food and not for specimens?
- Is this refrigerator labeled "For Food Only"?
- Do employees refrain from eating, drinking, smoking, applying cosmetics and lip balm or manipulating contact lenses in the work area?
- Have employees responsible for shipping biological and infectious specimens been trained in accordance with the Department of Transportation (DOT) regulations?

CHEMICAL HYGIENE

- Do employees know where the Material Safety Data Sheets (MSDS) are located?
- Are the MSDS accessible to employees during all working hours?
- Do employees know how to use the MSDS to look up spills and first aid for a chemical they use?

- Are old MSDS archived for 30 years?
- Has the chemical inventory been performed and updated in the last 12 months?
- Is there a list of carcinogens, mutagens and teratogens?
- Are all manufactured chemical containers labeled with the appropriate chemical identity and hazard warning information?
- Do transfer containers of chemicals properly labeled with a HIMS label or plain label with the name of the chemical, concentration, route of entry, health hazard, physical hazard, target organs effected, lab name, lot number and expiration date?
- Are flammable or toxic chemicals kept in closed containers when not in use?
- Are chemicals stored away from heat, sunlight or reactive substances?
- Do employees understand how to properly store chemicals?

ELECTRICAL

- Is electrical equipment grounded with the use of three pronged plugs?
- Are electrical cords free of any frayed edges?
- Are extension cords prohibited from use?
- Are multi-plug adapters prohibited?
- Are receptacles properly wired?
- Are electrical outlets located near wet locations, such as sinks, protected by a ground-fault circuit interrupter (GFCI)?
- Are heat sources and liquid chemicals kept away from outlets, cords and equipment as much as possible?
- Are light fixtures in working order?
- Have employees been trained in how to handle shock injuries?
- Are electrical panels kept cleared within three feet in front of breaker panels?
- Are electrical circuit breakers and panels labeled with a current listing of equipment powered by each unit?

EYEWASH/SHOWER

- Are eyewash stations located within 100 feet of where hazardous chemicals are used?



- Is the eyewash in good working condition?
- Are the eyewash stations checked weekly and the eye covers disinfected with 10% bleach?
- Is there a sign indicating the location of the safety shower above the station?
- Are the safety showers checked monthly?
- Are floor drains near showers flushed monthly?
- Are all safety checks to showers documented?

FIRE

- Do fire exits have an exit sign that is illuminated by a reliable light source?
- Are stairwells and emergency exits accessible and free of obstructions?
- Do all employees know where the fire extinguishers are located?
- Are all fire extinguishers easily accessible and not blocked?
- Have all employees received fire extinguisher training including the opportunity to actually use the extinguisher in a real or simulated practice?
- Do employees understand what type of extinguisher is needed (A, B or C) for each class of fire?
- Have fire extinguishers been serviced within the past year?
- Do employees know what the acronym RACE and PASS stand for? (Hint: Rescue/ Alert/Confine/ Extinguish and Pull/Aim/Squeeze/Sweep)

Autoimmune Disease Testing

By Toni Clinton, PhD, BCLD(ABB), MT(ASCP)
Assistant Medical Director, American Esoteric Laboratories-Memphis, Assistant Professor, Departments of Pathology & Clinical Laboratory Science; University of Tennessee-Memphis

Autoimmune disease is estimated to affect one out of every five Americans (American Autoimmune Related Disease Association; AARDA)¹. As the baby boomer generation creeps into its mid-50's and early 60's, this number is projected to rise. Autoimmunity is more prevalent in an aging population. As the number of potential affected individuals increases, the need and demand for testing will increase. This article will review the most common autoimmune disorders and discuss test methods for diagnosis and management.

- Has each employee performed at least one full evacuation to the triage area annually?
- Are evacuation routes posted in visible locations?
- Does staff know how to respond to a fire drill and what evacuation route to use?

WASTE MANAGEMENT

- Is there a recycling program in place that includes paper, plastic, glass, cans, alcohol, formaldehyde, solvents, etc.?
- Is all waste disposed of properly according to federal state and local authorities?
- Have employees been trained as to what can be discharged down the sewer?
- Does the facility have a discharge permit or letter of acknowledgment from the wastewater treatment facility?
- Have employees responsible for shipping hazardous waste been trained in accordance with the Department of Transportation (DOT) regulations?
- Are waste management records (manifests, waste analysis results, inspection records, training records) retained on-site for at least three years?
- Has the use of mercury been eliminated?

Sources:

1. Gile, T. J. *Complete Guide to Laboratory Safety*, HCPRO 2004
2. OSHA Compliance Document CPL2-2.69
3. US Department of Labor, final rule Part II, Federal Register 29CFR
4. 1910.1030 Bloodborne Pathogens, December 6, 1991

The AARDA defines autoimmunity as a physiological situation in which the patient's immune cells begin to attack the individual's own cells¹. The effect can either be one of cell destruction, a disruption in organ function, or even a stimulation of cell or organ growth¹. Generally speaking, women are more susceptible to autoimmune diseases than men. Women of childbearing age are particularly susceptible. Other factors may also influence the development of autoimmune disease. Stress, genetics, and certain environmental triggers have all demonstrated a relationship to autoimmune disease².

Autoimmune diseases may be classified as either organ-specific or systemic. Targeted organs tend to be the thyroid (Hashimoto's),

adrenals (Addison's disease), and pancreas (Type I diabetes). These types of disorders frequently have a strong genetic component, and they often present in patients with a history of viral infection². Systemic autoimmunity is most commonly associated with antibodies directed against "self" antigens. Those antigens may be found either in the nucleus or within the cell itself. The classical antigen-antibody reaction occurs, causing the creation of immune complexes which cause tissue damage in those sites where the appropriate antigens are found. Lupus (Systemic Lupus Erythematosus; SLE), scleroderma, Sjögren's Syndrome and mixed connective tissue disease are several examples.

Grave's disease, a thyroid disorder, is the most commonly occurring autoimmune disease in the US, followed by rheumatoid arthritis, Hashimoto's thyroiditis, and then Type I diabetes. Other disorders with lower incidence rates include pernicious anemia, multiple sclerosis, lupus (SLE), and Sjögren's Syndrome³.

Historically, diagnosis of autoimmune disease has relied upon an indirect immunofluorescence technique utilizing a HEp-2 cell line as a substrate. Cells are incubated with patient samples and then stained with immunofluorescent markers to detect nuclear and cytoplasmic autoantibodies. Patient

samples that react positively with the substrate Hep-2 cells can be serially diluted in order to obtain a titer of autoantibodies. Of particular importance are the staining patterns observed on the Hep-2 cells. Table 1 provides detail concerning the staining pattern, the associated antigen, and the suggested disease⁴.

Although considered the "gold standard" for autoimmune disease diagnosis, this technique is inherently error prone. Hep-2 immunofluorescent testing requires a fluorescent microscope as well as careful, precise handling and pipetting. Reading and interpreting the stained slides requires training and practice. This assay is time consuming and as such is not feasible in high volume laboratories. Reproducibility from lab to lab can be an issue, especially when testing is first implemented. Assessment of staining patterns and intensity are quite subjective, and although the assay is very sensitive it lacks specificity. Low titers have been reported in as high as 30% of the "normal" patient population⁵. Generally, a titer of > 1:160 is considered positive. However, that number varies greatly from clinician to clinician.

In the mid-1970's, antinuclear antibody profiles were first described⁶. Researchers demonstrated that specific antibodies were associated with individual autoimmune disorders.

These findings led to the development of antibody-specific assays which are now commonly used to help diagnose the most prevalent autoimmune disorders. Table 2 lists the most common nuclear antigens and their associated autoimmune disorder⁶. Multiple antibodies may be present in any given disorder, but there is some disease-associated specificity. Testing for these antibodies is often used to follow up or confirm a positive Hep-2 cell screen, which can be very non-specific.

Traditional enzyme immunoassay (EIA) with or without an automated plate reader is the most common

Table 1:
Hep-2 Cell Immunofluorescent Assay Staining Patterns

Pattern	Description	Disease Association
Homogeneous	Diffuse, uniform staining of Hep-2 cell nuclei; antibodies to DNA-histone complex	SLE; drug-induced SLE
Peripheral	Outline pattern staining of the nucleus; indicative of anti-DNA antibodies	Active SLE
Speckled	"Spotted", diffuse staining; reflects the presence of non-DNA nuclear antibodies; Associated with histone, Sm antigen, nuclear RNP, Scl-70, SSA, SSB	SLE; Mixed Connective Tissue Disease; Sjögren's Syndrome; Scleroderma; Polymyositis
Nucleolar	Homogeneous staining of the nucleolus; ribonuclear protein staining	Scleroderma
Centromere	Anti-centromere antibodies	Scleroderma
Cytoplasmic	Staining only in the cytoplasm; Associated with Jo-1 antigens	Polydermatomyositis



method used to detect and quantify these autoimmune antibodies. A more recent method is termed "Multiplexing". Color-coded beads are coated with specific auto antigens and then mixed with a patient's sample and a fluorescent dye. The bead-serum-dye slurry is then analyzed using a laser cytometer which detects both the type of bead (antigen) as well as the concentration. The latter technique is most commonly utilized in larger laboratories who receive a high volume of samples to screen.

Three of the most common systemic autoimmune disorders are described below.

Systemic lupus

erythematous (SLE) is a multi-system disease that affects all the major organs. Patients can exhibit auto antibodies to multiple nuclear antigens including Sm, RNP, double-stranded DNA, chromatin, and SSA. Diagno-

sis is often complicated by the fact that the disease can occur in overlap with other autoimmune disorders, most notably mixed connective tissue disease and Sjögren's Syndrome. There are 11 criteria for the diagnosis

of SLE which are presented in Table 3⁷. A definitive diagnosis requires four. A homogeneous pattern on a Hep-2 cell assay is most commonly associated with SLE, but speckled patterns are also observed. Double-stranded DNA antibodies are found in 60% of patients, and they are most associated with active disease⁷. Antibodies to the Sm antigen are found in 20% - 30% of patients⁷. Lupus-like symptoms can appear in patients taking certain medications (procainamide, quinidine, and methyldopa). An important distinguishing characteristic between this drug-induced lupus and classical lupus is that the former will develop antibodies to histone, but not to double-stranded

Table 2:

Anti-Nuclear Antibody Profiles

Antigen	Hep-2 Cell Assay Pattern	Disease Association
Double stranded DNA	Peripheral	SLE
DNA-histone complex	Homogeneous	SLE; Drug induced SLE; MCTD
Sm (Smith)	Speckled	SLE
RNP (ribonucleoprotein)	Speckled	SLE; MCTD; Sjögren's Syndrome; Scleroderma; polymyositis
SSA (Ro)	Speckled	SLE; Sjögren's Syndrome
SSB (La)	Speckled	SLE; Sjögren's Syndrome
Jo-1	Speckled	Polydermatomyositis
Scl-70	Speckled	Scleroderma
Centromere	Speckled	Scleroderma
Nucleolar RNA	Nucleolar	Scleroderma

Table 3:

Criteria for Diagnosis of Systemic Lupus Erythematosus

Criteria	Definition
Macular rash	Fixed erythema; flat or raised ("wolf" mask)
Discoid rash	Erythematous raised patches
Photosensitivity	Skin rash as a result of unusual reaction to sunlight
Oral ulcers	Oral or nasopharyngeal ulceration
Arthritis	Non-erosive arthritis involving 2 or more peripheral joints; characterized by tenderness, swelling, or effusion
Serositis	Pleuritis or evidence of pleural effusion; Pericarditis
Renal disorder	Perisistent proteinuria (.3+ or >0.5 g/day)
Neurological disorder	Seizures; Psychosis
Hematologic disorder	Hemolytic anemia with reticulosis; Leukopenia; Lymphopenia; Thrombocytopenia
Immunological disorder	Positive LE cell prep; Anti-DNA antibodies; Anti-Sm
Anti-nuclear antibody	Abnormal titer; in the absence of drugs know to be associated with drug-induced SLE



DNA⁷, which is characteristic of traditional lupus.

Scleroderma, or systemic sclerosis is an autoimmune disorder that affects between 75,000 to 100,000 patients in the US. Approximately 75% of those patients are women⁷. This disease is characterized by thickening (sclerosis) of connective tissue. "scleroderma" refers to the scarring of the skin that can occur. Systemic organ involvement (GI tract, kidneys, heart, lung) may also occur. One complication of systemic disease is the loss of GI mobility, particularly the esophagus, which limits the patient's ability to eat and digest food. Vascular complications caused by vasoconstriction in the fingers (Raynaud's phenomenon) and in some cases a complete restriction of blood flow are not uncommon. This disease is most commonly associated with the Scl-70 antibody⁸.

Sjögren's Syndrome is inflammation of the salivary glands and tear ducts, and it is caused by deposition of immune complexes into those glands. Patients complain of dry mouth and eyes, difficulty swallowing, and sore eyes. Joint pain and stiffness are also commonly reported. Nearly 90% of patients are women, and over one half of those patients present with another autoimmune disease. SLE, rheumatoid arthritis, and mixed connective tissue disease are the most prevalent. Antibodies to the SSA and SSB antigens are characteristic of the disease. Hep-2 cells will stain with either a speckled or homogenous pattern⁷.

Sources:

1. Peterson, P. "Assuring accuracy in autoimmune disease testing." *Advance*. April 1999.
2. King, D. "Experts predict advances in autoimmune disease testing." *Advance*. February 2001.
3. Jacobson, DL et al. *Clinical Immunology Immunopathology*. 1997.
4. Sack, KE and Fye, KH. "Rheumatic diseases". *Medical Immunology*. Lange Medical Books; New York. 2001.
5. Blumenthal, DE. "Tired, aching, ANA-positive: Does your patient have lupus or fibromyalgia?" *Cleveland Clinic Journal of Medicine*. February 2002.
6. Peebles, CL. "Antinuclear antibody profiles." *Clinical Laboratory News*. November 2005.
7. Lutz, CT. "Diagnosing SLE: What UPCMD.com says." *CAP Today*. June 2001.
8. Khan, AI, et al. "Systemic sclerosis (scleroderma)." *Lab Medicine*. November 2005.

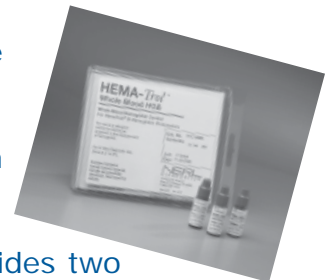
New Laboratory Quality Improvement Tools from AAFP-PT



AAFP-PT is pleased to introduce two new quality improvement tools to compliment your Proficiency Testing Program.

Guarantee valid urine dipstick and whole blood hemoglobin results with **Sentry® Urine Dipstick Controls** and **Hema-Trol® Whole Blood Hemoglobin Controls** manufactured by NERL Diagnostics.

The urine dipstick controls are packaged in a convenient ready-to-use liquid format which may be stored at room temperature. This product is suitable for use with automated strip readers and provides two levels of control.



The hemoglobin controls are designed for use with Hemocue® B and HemoCue 201 Plus® photometers. The product contains three control levels (low, normal, high) and offers a 2-year expiration dating with 60 days stability after opening.

For more information, or to order, please call (800) 274-7911, ext. 4146.

POL Microscopy Atlas 3rd Edition (2007)



The Third Edition of the **Physician Office Laboratory Microscopy Atlas** is now available. This newly-updated version features over 150 photographs of cellular elements (including urine sediment, wet preps, nasal smears, gram stains, and peripheral blood smears) commonly found during microscopic examinations in the POL. It also contains descriptions and clinical associations of the elements in the photograph, along with procedures for preparing and performing the examinations.

The *Atlas* is also available as a combo which includes the *Atlas CD-ROM (2nd ed.)*. Call (800) 944-0000 or order on-line at www.aafp.org/pt.

■ Preparing for a Laboratory Inspection

By M. Ann Bachman, MT(ASCP), CLC(AMT)
 DoctorsManagement Director, Compliance
 Department; AAPOL Executive Director

The Clinical Laboratory Amendments of 1988 (CLIA '88), enforced by the Department of Health and Human Services (DHHS), established biennial inspections for clinical laboratories performing tests of moderate or high complexity, now collectively known as "nonwaived." The purpose of the CLIA regulations, including inspections, is to improve the quality of laboratory testing in all settings.

The initial surveys were considered educational in nature, and surveys continue to include an educational aspect. However, corrective actions are often required, and some CLIA surveys may even result in sanctions. Early statistics showed significant improvements from one inspection cycle to the next, indicating effectiveness of the CLIA regulations in achieving quality improvement. Deficiencies decreased by 40% following round one, and have decreased further with each round.

As the laboratory community has become increasingly compliant with the more basic requirements, the CLIA surveyors look deeper. This may mean delving into documentation to determine, for example, if the laboratory director is providing necessary direction and continuing education and if documentation is complete. Sometimes this results in a citation for something that was not addressed in previous surveys, even though nothing has changed. This is frustrating for some laboratorians, who thought they were in compliance.

Routine inspections are currently limited to nonwaived laboratories. However, any laboratory is subject to an inspection triggered by a complaint or if DHHS determines a need. DHHS is now conducting surveys in 2% of waived laboratories because of significant problems found during a pilot project which was triggered by complaints. Surveyors may evaluate waived tests while surveying nonwaived laboratories and are more likely to do so if problems are found in the nonwaived testing. Subsequent re-inspections of waived laboratories have shown improvement of 74%.

Advance notice of up to two weeks precedes most surveys for physician office laboratories. However, larger laboratories accredited by the Joint Commission of American Health Care Organizations may experience no-notice surveys. Most surveys are conducted approximately three months prior to the certificate's expiration date to give the laboratories time to implement required corrective actions and maintain certification. However, no laboratory should ever wait until inspection time to get organized.

Organize your data! Expect to be asked for all records for the past twenty-four months. The inspector cannot possibly read all that material, but they prefer to personally select what they will read. Clear a desk or table for the surveyor and gather all the necessary materials in advance, perhaps the evening before the survey.

Before the surveyor arrives – and every day! – clean the laboratory thoroughly and discard all expired supplies and reagents. If tubes or occult blood cards are typically found in exam rooms, check those as well. Check your fire extinguisher and your eyewash stations to ensure that they are operational.

Upon arrival, the surveyors introduce themselves and provide credentials. They will verify the laboratory ownership and personnel list. They will request your test menu and annual test volumes for nonwaived tests, so have those lists and numbers ready. If you don't maintain an ongoing test count, count the tests performed in a three-month period and multiply. It may not be precise, but it will serve this purpose. Also have your report from your previous survey, along with your response and your corrective actions, especially any that you did not have to submit to the surveyor or agency.

Personnel files (paper or electronic) should be immediately available for everyone involved in the laboratory. For the physician director, this means the license to practice medicine in the state where the laboratory is located. For the technical consultant, credentials and an evaluation should suffice. For testing personnel, files should contain documentation including training records, an annual competency evaluation and documentation of the highest level of *formal* education. This may be a college degree, a high school diploma or transcript, or a GED. Unfortunately licenses and certificates won't count. For example, for a medical technologist, the state



med tech license or national registry is nice but does not fulfill the requirement. If an individual cannot locate his or her high school diploma, request an official transcript from the Board of Education in the county where the school is located.

Documentation of hepatitis B vaccination must be available but should be in a more confidential file, such as the OSHA-required employee medical files. Annual continuing education records may be in personnel files or elsewhere – they are not confidential. Attendance sheets are generally accepted.

Installation records should be readily available for all instruments acquired since the most recent inspection, even if the new instrument is a replacement or an exact duplicate. Installation records are now much more involved than previously and must show that your testing personnel participated in the calibrations and correlation studies.

Manuals should be current, comprehensive, and signed by the laboratory director. This includes your procedure manual, package inserts if referenced in the procedure manual, manufacturer's user guides, Quality Assessment manual if separate from your procedure manual, and a current manual from your reference lab(s). Your procedures must include site-specific information, such as corrective actions for unacceptable QC results and the course of action to take if you are unable to run a patient test for any reason.

All procedures discontinued since the last inspection should be dated ("Discontinued xx/xx/xxxx") and separated from the active procedures. They could be filed in a section tabbed "Discontinued Procedures," placed in a pocket of the binder, or stored in a file cabinet. They must be kept for a minimum of two years from the date discontinued.

Calibration and calibration verification records should be ready for the surveyor to review. If they are buried with other data, they might be difficult to retrieve, delaying the survey while you search. All **maintenance** records and service reports should also be separate from other data, maybe with calibration records or at the front of monthly data. Printout of maintenance or background counts should be kept if the information cannot be retrieved electroni-

cally. Include temperature and humidity logs and documentation of water quality checks if applicable.

Quality control records for two years may be organized by test, by specialty or by date, and may be kept electronically, in binders or in folders. Make sure you include corrective actions for those occurrences when control values are unacceptable.

Have your **Proficiency Testing records** organized and ready for the surveyor to evaluate. You should have your proficiency testing provider send a copy of the report to the surveyor, but you must also keep all signed attestation statements, handwritten records and instrument printouts, even after you get your grade of 100%. Less than 100%? Show documentation of your investigation and corrective actions, even if you only missed one. For unregulated analytes, split-specimen testing must be done at least twice each year, so be prepared to show documentation of that as well.

The surveyor will want to review some **patient records**, whether you have paper charts or electronic health records. They need to be able to verify that you have written requests for all tests and that all tests ordered have been resulted and charted. Instrument printouts may be placed in the charts or stored in the laboratory. Do not be concerned about your patient's privacy or your own HIPAA policies. This is a required government function, a part of quality improvement, and is specifically allowed by the HIPAA regulations.

After the surveyor has exhausted your pile of documents, he or she will summarize the findings and will provide guidance for any required corrective actions. You will receive a written report within a few business days. If you have corrective actions requiring you to submit documentation to the surveying agency, you will receive detailed instructions. You **MUST** respond within the specified time frame. This doesn't necessarily mean you must have your corrective actions completed by that time, but that you must submit your *plan*.

The plan of corrective actions must specify *how* you plan to correct the problem, *who* is responsible for ensuring that the corrective actions are implemented, and *when* the corrective actions will be completed. Unless the report specifies



that the corrective actions must be completed by a certain date, give yourself ample time. For example, if you must revise your procedure manual, give yourself at least three months. Then, don't be surprised if the surveyor appears at your door on that very day you specified!

Laboratory surveyors are there to look after your patients' best interests. The proof is in the paperwork, so get organized and stay organized. Treat every day as if you knew you were being inspected that day. Don't be terrorized by a laboratory inspection, but consider it an opportunity to find areas for improvement.

Sources

1. Personal Experience
2. Publication 7, Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services
3. CMS- 2226-F: 42 CFR 493 Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule on January 24, 2003
4. Waived/PPMP Laboratory Project
5. <http://www.cms.hhs.gov/CLIA/>

2007-A CME Questions

The material necessary to review to answer the following questions may be found in this issue of the *P.O.L. Insight* and the *AAFP-PT Handbook* or on the AAFP-PT website (<http://www.aafp.org/pt> and click on Continuing Medical Education). The Test Sheet may be found on page 16 of the *P.O.L. Insight*. The Accreditation information may be found on the inside cover of this issue.

1. True or False: Safety violations can generate up to \$7,000 in fines per day.
 - A. True
 - B. False
2. Which of the following are safety violations:
 - A. Using a multi-use needle holder
 - B. Placing biohazard waste in the regular trash for disposal
 - C. Storing food in the specimen refrigerator
 - D. All of the above
3. True or False: It is acceptable to recap a needle if your hands are full.
 - A. True
 - B. False
4. True or False: Specimen shipping packaging must contain an absorbant.
 - A. True
 - B. False
5. Old MSDS must be archived for _____ years.
 - A. 2
 - B. 5
 - C. 30
 - D. 50
6. True or False: Employees may take personal labs coats home for laundry.
 - A. True
 - B. False
7. True or False: New employees must be offered Hepatitis B vaccine within 10 days of hire.
 - A. True
 - B. False
8. True or False: A chemical inventory must be performed every 18-24 months.
 - A. True
 - B. False
9. True or False: "RACE" stands for "Rescue/Alert/Confine/Extinguish" in fire safety terms.
 - A. True
 - B. False

10. Items in storage should be no closer than ____ inches to a sprinkler head
 - A. 6
 - B. 12
 - C. 18
 - D. 24
11. Eyewash stations must be located within _____ feet of hazardous chemicals.
 - A. 10
 - B. 25
 - C. 50
 - D. 100
12. True or False: Autoimmune disease affects one of every five Americans.
 - A. True
 - B. False
13. True or False: Autoimmune diseases are classified as either organ-specific or systemic.
 - A. True
 - B. False
14. Autoimmune conditions can result in:
 - A. cell destruction
 - B. disruption of organ function
 - C. stimulation of cell or organ growth
 - D. All of the above
15. The most commonly occurring autoimmune disease in the U.S. is:
 - A. Hashimoto's thyroiditis
 - B. Type I diabetes
 - C. Graves Disease
 - D. Rheumatoid arthritis
16. Systemic autoimmune disease is associated with antibodies directed against:
 - A. viral antigens
 - B. "self" antigens
 - C. toxins
 - D. bacteria
17. True or False: The historic "gold standard" for autoimmune diagnosis is indirect immunofluorescent staining.
 - A. True
 - B. False
18. A "nucleolar" immunofluorescent staining pattern is associated with:
 - A. lupus
 - B. scleroderma
 - C. Polydermatomyositis
 - D. Sjögren's syndrome
19. True or False: Specific antibodies are associated with individual autoimmune disorders.
 - A. True
 - B. False
20. Diagnosis of SLE requires matching ____ of 11 criteria.
 - A. 5
 - B. 11
 - C. 4
 - D. 2
21. Antibodies to the DNA-histone complex are associated with:
 - A. SLE
 - B. Scleroderma
 - C. Mixed connective tissue disease
 - D. both A & C



22. True or False: Sjögren's syndrome is primarily a disease of males.
 - A. True
 - B. False
23. True or False: Certain medications can produce lupus-like symptoms
 - A. True
 - B. False
24. True or False: Raynaud's phenomenon is a complication of scleroderma.
 - A. True
 - B. False
25. True or False: Immunofluorescent staining procedures can be easily performed in the POL.
 - A. True
 - B. False
26. Patients with Sjögren's syndrome complain of:
 - A. Dry eyes or mouth
 - B. Joint pain
 - C. Difficulty swallowing
 - D. All of the above
27. True or False: The purpose of laboratory inspections is to improve laboratory quality.
 - A. True
 - B. False
28. True or False: Laboratories rarely show quality improvement between inspections.
 - A. True
 - B. False
29. True or False: Inspectors may evaluate waived testing while inspecting a non-waived lab.
 - A. True
 - B. False
30. True or False: Waived laboratories are never subject to inspection.
 - A. True
 - B. False
31. Inspectors may ask to see:
 - A. Personnel files
 - B. Financial records
 - C. Procedure manuals
 - D. A & C
32. A corrective action plan should include:
 - A. How you plan to correct the problem
 - B. Who is responsible for implementation
 - C. When the actions will be completed
 - D. All of the above
33. True or False: You do not need to investigate proficiency testing failures if you only miss one.
 - A. True
 - B. False
34. True or False: Inspectors are not allowed to review patient records due to HIPPA regulations.
 - A. True
 - B. False
35. True or False: All manuals should be signed by the laboratory director.
 - A. True
 - B. False



AAFP-PT CME Test Answer Sheet

ALL INFORMATION MUST BE COMPLETED TO OBTAIN CREDIT

2007-A (submit by February 28, 2008 to obtain credit)

Fill in the circles for the correct answers:

Please print:

Individual AAFP #: _____

(All participants in the AAFP-PT are now assigned a 7-digit AAFP number; AAFP-member physicians should use their AAFP-ID number; non-member physicians and laboratory personnel are assigned an Id number the first time CME is submitted)

Lab AAFP #: _____

(All labs enrolled in AAFP-PT are assigned a 7-digit AAFP number. The Lab Id number may be found on the Order Confirmation and on evaluations.)

Name (Last) (First) (Initial)

Street

City / State/ Zip Code

Fax Number

Address or Fax change Name change

Select one if you are a physician:

- FP IM
 PED OB/GYN
 Other

Select one if you are laboratory personnel:

- MT MLT Nurse Practitioner
 RN LPN Physician Assistant
 Med. Assist. Laboratory Manager
 Laboratory Consultant Other

	<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>
1.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
30.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Evaluation: please fill in bubble between 1 & 5 – 1 denotes poor, 5 denotes excellent:

1. To what extent were the objectives achieved?
poor ① ② ③ ④ ⑤ *excellent*
2. To what extent did the AAFP-PT education program *content* relate to the program's objectives?
poor ① ② ③ ④ ⑤ *excellent*
3. Rate your overall degree of satisfaction with this education program.
poor ① ② ③ ④ ⑤ *excellent*
4. In what general area of laboratory practice would you like to receive educational materials? (please mark all that apply).
 - CLIA and/or regulatory. requirements
 - Good laboratory practices
 - Test Procedures
 - Technical Subjects
 - Business/Financial Aspects
 - Other, please specify _____



Return to: AAFP-PT Education Program
11400 Tomahawk Creek Parkway
Leawood, KS 66211-2672
or Fax to 913-906-6079

Important: Keep a copy of the completed form for your records. Documentation of CME hours earned is mailed to lab personnel in July and January. Allow 7-10 business days for requested transcripts.