CLIA Corner

The University of Iowa Hygienic Laboratory

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In This Issue...

Welcome

Kristi and Nancy want to introduce you to the "new" *CLIA Corner* being delivered to you and your laboratory using e-mail and the Internet. For the new *CLIA Corner* to be successful and effective, we need an up-to-date database of e-mail addresses and information. If you received an e-mail about the *CLIA Corner*, but would like your name removed, please contact us. If you like what you are seeing, please feel free to forward the information about the *CLIA Corner* to your co-workers and fellow laboratorians. If you want to be added to our list or have a change of address, contact either Kristi Rotzoll at *krotzoll@uhl.uiowa.edu* or Nancy Grove at *ngrove@uhl.uiowa.edu*. Please include your name, facility or company name, address, phone and fax numbers, and of course, your e-mail address.

Common Deficiencies

This section will focus on three deficiencies that have been cited frequently at surveys within the last few months. Please keep these deficiencies in mind as you prepare for your next CLIA survey.

#1 - Proficiency Testing

Failure to take and document corrective action for any unsatisfactory, unacceptable, and non-graded proficiency testing scores remains one of the most common deficiencies cited at CLIA surveys.

Unsatisfactory proficiency testing is defined as failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event. In most cases, a score less than 80% is considered an unsatisfactory proficiency testing score, with the exception of ABO grouping, Rho typing, and compatibility testing. For these analytes any score of less than 100% is considered an unsatisfactory score.

Unacceptable proficiency testing results are test performance scores where the laboratory has received a passing score (80% in most cases) for a specific analyte, subspecialty or specialty. However, one or more of the individual analytes was incorrect when compared to the program's intended response. It is important to remember that for ***ALL*** unsatisfactory and unacceptable proficiency testing scores the laboratory is required to take and document corrective action including why the laboratory missed the particular analyte, subspecialty, and/or specialty and what steps are being taken to prevent the problem from reoccurring. We have cited numerous laboratories for failing to take and document corrective action when proficiency testing scores are less than 100%.

Non-graded proficiency testing scores occur when the proficiency testing program fails to evaluate the laboratory's results due to a problem beyond the control of the participant. In order for a proficiency testing program to evaluate a laboratory's proficiency testing results there must be at least ten participants in a particular peer group and at least 80% consensus among the participants.

Many times looking at the proficiency testing summary it appears that the laboratory received 100% for an analyte, but further investigation reveals that the results were not evaluated by the proficiency testing program. When this occurs it is the laboratory's responsibility to perform a self-evaluation, by comparing the results your laboratory submitted to the proficiency testing company with the intended results given in the proficiency testing company's summary. If there appears to be a problem, corrective action must be taken to identify the problem and describe what steps are being taken to prevent the problem from reoccurring. In addition, remember anytime the laboratory receives a score of 0% for either failure to participate in a survey or failure to submit survey results on time, the laboratory is required to perform a self-evaluation and document corrective action when applicable.

#2 – Personnel

Assessing and documenting personnel competency, as required by CLIA, is also a common deficiency. CLIA requires that new laboratory testing personnel receive initial training and orientation and demonstrate competency before performing and reporting patient test results. New testing personnel must again demonstrate competency six months prior to their initial competency evaluation. Thereafter, **annual** competency assessments must be performed on all laboratory testing personnel. Remember all training, orientation and competency assessments must be documented. In addition, when a new analyzer, test kit, or test system is put into place, the laboratory must undertake and document training for all laboratory personnel who will perform testing.

#3 - Micro Quality Control

The CLIA regulations state at 42 CFR 493.1256, *"the laboratory must check each batch, lot number, and shipment of reagents, disks, stains, antisera [except those specifically referenced in §493.1261 (a)(3)] and* ***identification systems*** *when prepared or opened for* ***positive and negative reactivity****, as well as graded reactivity, if applicable."* Laboratories that use automated microbial identification systems (e.g. Microscan or Vitek) may be failing to check each biochemical reaction on the identification card or panel by using the appropriate number of organisms. Refer to the manufacturer's package insert for guidance as to which organisms should be tested. There should be **at least** four organisms used to determine the positive and negative biochemical reactivity for both Gram-positive and Gram-negative identification cards and panels. Please remember that these biochemical checks need to be performed at a minimum of once per lot or shipment of identification cards and panels.

Available with this issue are example forms to document proficiency testing corrective action and personnel training and competency. These are ***NOT*** *official or sanctioned CLIA forms, but serve as examples to assist your laboratory in complying with the CLIA regulations. Please feel free to use, modify and revise these forms to fit your facility's needs.*

Frequently Asked Questions

Q: What are the CLIA requirements for performing waived testing?

A: The only CLIA requirement for laboratories performing waived testing is to follow the manufacturer's instructions. The laboratory **must** retain a copy of the **current** manufacturer's package insert for each waived test being performed by the laboratory. Whenever the manufacturer uses phrases such as 'always', 'shall', 'must', and 'required', these are regulatory phrases and the laboratory must follow these instructions. If there are recommendations stated in the package insert (i.e. should, may, or recommend) of the waived test system, it is a good laboratory practice to follow manufacturer's recommendations; however, it is not required by CLIA. Following good laboratory practices will ensure the quality of care you provide your patients. When reading/reviewing the manufacturer's instructions, don't forget to follow the instructions for control and reagent storage and use. For example, the expiration date must be changed when the laboratory or facility opens a new bottle of glucose control used for most waived glucometers. In order to be in compliance with the regulations and follow manufacturer's requirements, the laboratory is required to mark the date on each glucose control bottle when first opened.

Although not required, it is also considered good lab practice for the laboratory to verify the accuracy of the test system (e.g. proficiency testing or split-sample testing), and to perform competency assessments on testing personnel performing waived testing.

Q: I have misplaced my HEW card. How can I obtain a replacement card?

A: For those of you who are not familiar with HEW cards, the Social Security Amendments of 1972 authorized the Department of Health and Human Services [formerly, Health, Education and Welfare (HEW)] to provide an exam for people who had laboratory experience but did not meet the CLIA education and training requirements. The HEW exam was given four times between 1975 and 1977, then again in 1979, 1983, and 1987. The exam concentrated on clinical chemistry, microbiology, hematology, and blood banking. Individuals who received an acceptable score on the exam were issued an HEW card, and then were qualified to perform high-complexity testing.

For HEW replacement cards contact Fanny Reed at 212.367.4338.

We hope you enjoyed the first issue of the new CLIA Corner. We want to hear from you. If you have any questions or comments, please contact our office by phone at 800.421.IOWA or by e-mail at ***ngrove@uhl.uiowa.edu*** *or* ***krotzoll@uhl.uiowa.edu****.*

EXAMPLE

Proficiency Testing Form

Testing Event: _____ Specialty/Subspecialty: _____

Date Received: _____ by _____
Date Reconstituted: _____ by _____
Date Testing Performed: _____ by _____

Please answer the following proficiency testing questions:

	Yes	No
Was the condition of the specimen acceptable? (no hemolysis, not frozen, etc.)		
Were the results sent to the PT company before the due date?		
Were the test results and attestation statements signed by the testing personnel, the laboratory director and/or other designated personnel?		
Have copies been retained of the testing records, the signed attestation statement, PT results and scores from the provider?		
Did the laboratory receive **less than 100%** for any analyte, subspecialty, or specialty? List analyte(s):		
Did the laboratory have any results that were **not graded** by the PT company (either due to lack of participants or lack of consensus)? List analyte(s):		
Did the laboratory receive a score of 0% due to non-participation?		
Did the laboratory receive a score of 0% due to late entry?		
Were results submitted for each **regulated** analyte?		
Did the lab verify the accuracy for each **non-regulated** analyte or for any analyte where PT samples are not available for testing at least twice annually?		
List the **non-regulated** analyte(s) and when the last accuracy verification was performed:		

If any of the answers to the previous questions are in the shaded area(s), corrective action is required. Please complete the Proficiency Testing Corrective Action Form.

Form Completed By: _____ Date: _____

Laboratory Supervisor Reveiw: _____ Date: _____

Laboratory Director Review: _____ Date: _____

EXAMPLE

Proficiency Testing (PT) Corrective Action Form

Testing Event: _____

Analyte(s)/Specialty/Subspecialty:_____

Reported Result(s):_____

Intended Result/Acceptable Range:_____

(1) Identification of Problem (e.g., clerical, technical, etc.):

(2) Corrective Action Taken to Prevent the Problem from Reoccurring:

Form Completed By:_____Date:_____

Laboratory Supervisor Reveiw:_____Date:_____

Laboratory Director Review:_____Date:_____

EXAMPLE

LABORATORY PERSONNEL ORIENTATION & TRAINING

Employee Name_____ **Start Date**_____

Orientation Completion Date_____ Supervisor/Laboratory Director Review_____

Section/Procedure	Review Procedure		Demonstrate/Practice		Competency Met	
	Date	Trainer	Date	Trainer	Date	Trainer
General Procedures/Policies						
• Personnel Standards						
• Specimen Collection, Labeling, Handling						
• Safety Manuals						
• Reporting Critical/Panic Values						
•						
•						
•						
Hematology						
• CBC (Coulter AcT) QC PM Calibration Reporting Test Results Troubleshooting						
• Manual Differentials						
• ESR						
•						
•						
•						
Coagulation						
• INR/Protime using Sysmex CA-500 QC PM Reporting Test Results Troubleshooting						
Chemistry — Routine						
• Dade Dimension QC PM Calibration Calibration verification Reporting Test Results Troubleshooting						
Urinalysis						
• Dipstick						
• Microscopic						
Microbiology						
• Rapid Strep A screen						
• Gram Stains						
• Influenza A & B test						
•						
Immunology						
• Infectious mononucleosis test						
• Helicobacter pylori antibody test						

EXAMPLE

Training Checklist

_____

Test/Test System

Trainee Name:_____Training Date:_____

_____Principles of the procedure

_____Contents of each kit or reagent(s) & storage/expiration requirements

_____Precautions

_____Specimen collection, labeling, handling, & storage requirements

_____Test procedure(s)

_____Interpretation and reporting test results

_____Quality control requirements

_____Maintenance/equipment requirements

_____Calibration/calibration verification

_____Record retention (QA, PM, calibration, patient)

_____Demonstrate competency

Additional Comments_____

_____

_____

Trainer Name:_____

Training Completed & Competency Met Date:_____

Laboratory Director Review
(if applicable)_____Date_____

EXAMPLE

LABORATORY PERSONNEL COMPETENCY ASSESSMENT

Employee Name_____ Annual (year)_____ Semi-Annual (date/year)_____

Competency Assessor_____ Date_____

Laboratory Director Review (as applicable)_____ Date_____

Guidelines (Competency based on direct observations & record review)	**Rapid Strep**			**Throat Culture**			**Urinalysis Clinitek 100**			**CBC Coulter AcT**			**Influenza**								
	Yes	**No**	**NA**	**Yes**	**No**	**NA**	**Yes**	**No**	**NA**	**Yes**	**No**	**NA**	**Yes**	**No**	**NA**	**Yes**	**No**	**NA**	**Yes**	**No**	**NA**
1. Demonstrates good laboratory safety practices, including universal precautions																					
2. Follows specimen collection, labeling and handling procedures																					
3. Properly identifies the specimen before performing test																					
4. Ensures test request contains required information and corresponds to correct specimen																					
5. Performs test according to accepted procedure																					
6. Performs QC, including evaluation of results & corrective action prior to reporting patient test																					
7. Correctly interprets and reports patient test results & corrective action prior to reporting patient test																					
8. Documents and retains all testing records and reports																					
9. Performs required preventive maintenance & troubleshooting																					
10. Participates in proficiency testing																					

Areas of employee competency that requires improvement_____

Training plan and date of completion_____

_____