UC Davis Health
Sacramento, CA
Department of Pathology and Laboratory Medicine

PROFICIENCY TESTING (PT) SURVEY AND
REFERRAL & COMMUNICATION GUIDELINES **Administrative Procedure 709.A**

PURPOSE:

To provide UCDH Pathology and Laboratory Medicine staff, the Center for Medicare & Medicaid Services (CMS) regulations for referral and proper communication of information regarding Proficiency Testing (PT) Survey samples.

PREFACE:

Any laboratory that intentionally refers its proficiency testing samples to another laboratory for analysis shall have its license revoked for at least one year and shall be subject to fines and penalties to be determined by CMS.
CLIA regulations 42CFR Part 493.801(b)(3) and (4) dictate that laboratories must not engage in any inter-laboratory communications pertaining to the results of PT samples and that laboratories must not send PT samples or portions of PT samples to another laboratory for analysis.

PROCEDURE:

A. Proficiency testing (PT) is the testing of unknown samples sent to a laboratory by a CMS approved PT program, such as CAP. Most sets of PT samples are sent to participating laboratories three times per year. The minimum number of PT challenges for each analyte is twice per year. After testing the PT samples in the same manner as its patient specimens, the laboratory reports its results back to their PT program. The program grades the results using the CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing. CMS and accreditation organizations routinely monitor their laboratories performance.

B. PT is required for only the limited number of tests found in Subpart I (See Appendix A), Proficiency Testing Programs for Non-waived Testing, of the CLIA regulations in 42CFR Part 493. If laboratory performs any of the tests found in subpart I, it must perform PT on each test performed in laboratory. These tests are listed in subpart I as "regulated" analytes. Review the specialty, subspecialty and analytes listed and determine which specialties, subspecialties and analytes are performed in laboratory. Enroll in a CMS approved PT program for each of those tests.

   1. CLIA requires laboratories to assure the accuracy of testing, for all testing performed, whether a test is listed as "regulated" or "unregulated". CLIA requires that, at least twice annually, laboratory verify the accuracy of any test or procedure performed.

      a. If a PT survey is available, it should be used.

      b. If a PT survey is not available, then accuracy of every test or procedure performed must be verified via some other means (See Administrative Procedure 703.A).

C. PT enrollment and participation is required for each CLIA certificate sites. If non-waived testing is offered at more than one site, but the testing is all included under one certificate, laboratory must enroll in an approved PT program(s) for all the regulated analytes covered under that certificate, not for each site. If laboratory has a separate certificate for each site, it must enroll in PT for all regulated tests performed at each site.

D. There are times when the PT program cannot fully evaluate laboratory's samples. Laboratory must verify the accuracy of tests for which PT is required if any of the following occur:

1. When results are submitted to the program after the deadline and are considered a late submission, laboratory grade will be zero.

2. If laboratory did not test PT samples at all, laboratory grade will be zero. When grade does not reflect laboratory's performance because there was no consensus among all laboratories performing the PT sample(s), this will be identified by the PT program as "ungradable" on results report. Laboratory will be assigned an artificial score of "100%", noted as "ungradable", but that does NOT reflect performance, so laboratory will need to check accuracy (See Administrative Procedure 702.A).

E. PT samples must be tested in the same manner as laboratory would test patient specimens. This means testing the PT samples the same number of times as patient specimens, at the same time as patient specimens, by the same personnel that routinely test the patient specimens, and using the same test system that is routinely used for the patient specimens. PT samples should be rotated among the testing personnel in laboratory.

1. Some PT sample preparation may be necessary before testing. In other words, after preparation, PT samples must be treated in the same manner as patient specimens. However, as stated below, NEVER send PT samples out of laboratory for any reason, even if laboratory routinely send out patient specimens for additional or confirmatory testing. ***Sending PT samples to another laboratory for testing is considered PT referral and will cause serious actions to be taken against our laboratory***. The penalties include loss of laboratory's CLIA certificate for at least one year, laboratory director cannot direct a laboratory for two years, and Regents of the University of California (as laboratory owner) may not own or operate a laboratory for two years.

2. Laboratory's name will be listed on the CMS Laboratory Registry on the CMS web site. Be extremely cautious NOT to send PT samples out for a ***"reflex" test***. A "reflex" test is any test listed on Reflex Testing List (See Administrative Procedure 822.A).

F. NEVER discuss PT results with another laboratory and NEVER enter into discussion with another laboratory about their PT results before the PT event cut-off date. This activity may cause the loss of CLIA certificate.

G. If laboratory receives a PT sample from another laboratory, CLIA requires that staff identify them as PT samples, notify supervisor, manager and department Director.

1. Laboratory must notify CAP and/or State Lab Field Services that laboratory has received PT samples from another laboratory.

2. Laboratory must provide the name of the other laboratory and the test(s) requested. DO NOT TEST the samples under any circumstances.

H. Records of all PT testing must keep for minimum of three years (5 years for Transfusion Medicine) from the date of the PT event. These records include:

1. The step by step PT sample preparation and handling, all the steps taken in the testing of the sample. These records should be kept in the technical section performing the analysis.

2. A copy of the PT survey results form used to record and submit your PT results, included the signed attestation statement. These records are kept in the department PT binders. It is also advisable for the testing section to maintain a copy of this document.

3. The PT survey evaluation/performance report. These copies must be maintained for a minimum of 3 years (5 years for Transfusion Medicine) from the date of the PT event. These records must also include any corrective action report resulting from an unsatisfactory or unacceptable score. These records are also kept in the department PT binders.

I. If the same test is performed using two different test systems, PT is required for only the test system, assay, or examination used as the primary method for patient testing at the time the PT survey was performed.

J. The instructions that accompany the PT samples will state the exact date by which laboratory must return PT results to the program. It is very important to return them on time. A late submission will result in a score of zero for the testing event.

K. Review result evaluations with co-workers and medical director. PT survey will include an evaluation for each of the challenges for each test or analyte in the PT event and will detail the performance of each test system used by the laboratories enrolled with their program. This should be done for all PT results, even those with passing scores. If laboratory receive an 80% score, investigation should be performed to determine why one of the five samples was outside the acceptable range of results. Document investigation and what laboratory did to correct the problem that caused the challenge failure.

L. If laboratory do not receive a passing score or have any “unacceptable” result:

1. Re-review the results that were submitted for PT survey for scoring for any obvious errors (this should have been done prior to submitting results to the program). Clerical or transcription errors are considered incorrect results. The director of laboratory as well as the personnel who performed the testing of the PT samples should compare their PT results with the inter-laboratory comparison evaluations provided by the PT program.

2. Laboratory must take remedial actions, i.e., determine the cause of the error or errors, correct it (them), and document your actions. Continually monitor the test system performance, review the results of the quality control materials, and discuss with section medical director to be certain the test system is operating properly and producing accurate results.

3. Write up a Proficiency Testing Investigation and Corrective Action Report, See Administrative Procedure #705.A, *Proficiency Testing: Error Correction and Prevention,* for details. The section supervisor and section medical director must review and sign this report. Any patient samples that were run during this period may need to be reviewed. Depending upon the test system's performance and director's decision, laboratory may need to contact the manufacturer of the test system for assistance.

M. Unsatisfactory PT performance indicates the failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event. Clerical errors are considered a failure. Unsuccessful participation in PT means any of the following:

1. Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

2. Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

3. An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, compatibility testing, unexpected antibody detection, antibody identification) for the same subspecialty for two consecutive or two out of three testing events.

4. If laboratory has never had an unsuccessful performance for any PT analyte, subspecialty, or specialty, the CLIA regulations, under certain circumstances, permit technical assistance and training to take place, rather than a more serious sanction. However, repeated unsuccessful PT performance for that same analyte, subspecialty or specialty may result in laboratory no longer being allowed to perform the failed testing.

N. If laboratory has been required to cease testing an unsuccessful analyte, subspecialty, or specialty, the following must be done to resume this testing:

1. First, demonstrate that laboratory has identified the reason(s) for the unsuccessful performance and corrected it (them). Be sure to document this process.

2. Secondly, when laboratory is certain that it has corrected the problem(s), laboratory must perform two consecutive PT surveys (re-instatement PT) successfully, which will demonstrate correction of the problem(s).

O. If laboratory has been required to cease testing, Medicare and Medicaid reimbursement will be suspended for a six-month period. However, laboratory may purchase re-instatement PT surveys at any time after the problem has been identified and corrected the problem(s) that caused the unsuccessful performance. Laboratory should purchase these PT surveys; these may be obtained from any CMS approved PT program.

P. The laboratory may decide to voluntarily stop testing the unsuccessful analyte, subspecialty, or specialty as soon as it receives the PT results indicating an unsuccessful performance. The regional office CLIA consultant must be notified that testing of the unsuccessful analyte, subspecialty, or specialty has been stopped voluntarily. Complete the CMS Analyte Reporting Selection Notification Form and fax it directly to the PT Provider.

1. This notification must be made before laboratory receives a letter from the CMS regional office imposing a cease testing sanction. The Laboratory must contact PT Monitoring Department for instructions on how to submit the necessary documentation before patient testing is resumed. Laboratory will need to successfully perform two consecutive PT events for the analyte, subspecialty, or specialty that was unsuccessful. Laboratory's Medicare and Medicaid reimbursement will not be affected.

REFERENCES:

- Centers for Medicare and Medicaid (CMS), 42 CFR Part 405, Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), Final Rule, Federal Register. 2003 (January 24):3705 [42CFR493.1236; 42CFR493.801].
- College of American Pathologists (CAP), current accreditation manual
- Clinical and Laboratory Standards Institute (formerly NCCLS) guideline QMS 24: Using Proficiency Testing (PT) and Alternative Assessment to Improve Medical Laboratory Quality (2016).

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PROCEDURE HISTORY

Date	Written/ Revised by	Revision	Approved Date	Approved By
10/08	D. Wright	New	10/08	L. Howell, MD
10/09	D. Wright	Revised	10/09	L. Howell
7/10	D. Wright	Revised (Adnm A)	7/10	L. Howell
01/12	T. Cox	Revised	01/12	L. Howell
09/14	T. Cox	Revised (minor wording)	09/14	L. Howell
09/16	S. Okimura	Biennial Review	09/16	L. Howell
08/18	N. Kaur	Revised:Updated PT record retention term.	08/18	L. Howell Via OnBase
08/20	N. Kaur	Revised	08/20	L. Howell Via OnBase

Appendix A: Regulated Analytes

Participation in proficiency testing is required for analytes listed in the CLIA' 88 regulation and analyzed by non-waived methods. As such, these analytes require enrollment in a Centers for Medicare and Medicaid Services (CMS) approved proficiency testing (PT) program. The frequency for this required PT is five challenges three times per year (exception is Mycobacteriology which requires five challenges two times per year).

All changes to proficiency tests for a regulated analyte must be reported to CMS using the CMS Analyte Reporting Selections Form. This form must be completed and faxed directly to the PT provider.

The following is a general list of the analytes regulated by CMS. For analytes specific to UCDH laboratories, see the CAP website or check with the Quality Assurance Department.

Routine Chemistry

- Alanine Aminotransferase (ALT)
- Albumin
- Alkaline Phosphatase
- Amylase
- Aspartate Aminotransferase (AST)
- Bilirubin, Total
- Blood Gases ($pH/pO_2/PCO_2$)
- Calcium, Total
- Chloride
- Cholesterol, Total
- Cholesterol, HDL
- Creatine Kinase
- Creatine Kinase, Isoenzyme (CKMB)
- Creatinine
- Glucose (excluding devices cleared by FDA for home use)
- Iron, Total

- Lactate Dehydrogenase (LDH)
- LDH, Isoenzyme
- Magnesium
- Potassium
- Sodium
- Protein, Total
- Triglycerides
- Urea Nitrogen (BUN)
- Uric Acid

Endocrinology

- Cortisol
- Free Thyroxine (Free T4)
- Human Chorionic Gonadotropin (hCG) (exluding urine qualitative hCG)
- T3 Uptake
- Triiodothyronine (T3)
- Thyroid Stimulating Hormone (TSH)
- Thyroxine (T4)

Toxicology

- Alcohol (Blood)
- Lead (Blood)
- Carbamazepine
- Digoxin
- Ethosuximide
- Gentamicin
- Lithium
- Phenobarbital

- Phenytoin
- Primidone
- Procainamide (and metabolite)
- Quinidine
- Theophylline
- Tobramycin
- Valproic Acid

Diagnostic Immunology

Syphilis Serology

General Immunology

- Alpha-1-Antitrypsin
- Alpha-fetoprotein (tumor marker)
- Antinuclear Antibody
- Anti-Streptolysin O
- Anti-Human Immunodeficiency Virus (HIV)
- Complement C3
- Complement C4
- HbsAg
- Anti-HBc
- Hbe-Ag
- IgA
- IgG
- IgE
- IgM
- Infectious Mononucleosis
- Rheumatoid Factor

- Rubella

Hematology

- Cell ID/ White Blood Cell Differential (manual and automated)
- Erythrocyte (RBC) Count
- Hematocrit (excluding spun Microhematocrits)
- Hemoglobin (excluding single-analyte instruments)
- Leukocyte (WBC) Count
- Platelet Count
- Fibrinogen
- Partial Thromboplastin Time
- Prothrombin Time

Immunohematology

- Unexpected Antibody Detection
- ABO Group (excluding subgroups)
- D(Rh)Typing
- Antibody Identification
- Compatibility Testing

Microbiology

Bacteriology

- Antimicrobal Susceptibility Testing
- Bacterial Antigen Detection
- Bacterial Identification (aerobic/anaerobic from various sources)
- Gram Stain

Mycobacteriology

- Acid Fast Smears/Culture/ID/Antimycobacterial Susceptibility Testing
- Isolation and identification of mycobacteria by culture

Mycology

- Culture for Yeast or Fungal ID at genus or species level

Parasitology

- Parasite identification (wet mount, concentration and/or permanent stain, immunoassay)

Virology

- Virus Detection (by culture or antigen testing)

For all other 'non-regulated' analytes, CLIA dictates that the laboratory must have a quality assurance plan that establishes the accuracy and reliability of the testing at least twice per year. The CAP Surveys offer a wide array of products to conveniently assist laboratories in fulfilling this requirement. It is also important for laboratories to check with their state and other accrediting agencies they may use as they may mandate additional requirements.