PROFICIENCY SURVEY HANDLING **Administrative Procedure 700.A**

PURPOSE:

Department of Pathology and Laboratory Medicine will maintain documented enrollment and **successful** participation in **approved** proficiency testing (PT) for each specialty, subspecialty and analyte for which a proficiency test is available, and for which the Laboratory seeks or has approval by the California Department of Public Health (CDPH), and the Centers for Medicare and Medicaid (CMS) to receive reimbursement. This procedure details the processes used by the Laboratory to meet these requirements.

PROCEDURE:

A. Enrollment:

1. Between September and December of each year, Laboratory Quality Assurance (QA) section staff reviews the PT Survey subscriptions (generally College of American Pathologists -CAP) with the section medical directors, managers and/or Section Supervisors to verify that the surveys to be purchased for the next year cover all laboratory testing for which proficiency testing is available, and to assure that all regulatory requirements are met.

    a. Other approved survey agency subscriptions are reviewed, if needed, to meet requirements not met by the CAP Surveys.
    b. Surveys should be ordered no later than December 1st of each year.
    c. If laboratory has separate CLIA certificates for more than one site, PT must be ordered for each CLIA site.

2. The Laboratory QA section receives and reviews the order verification forms for completeness and distributes a copy to all involved managers and/or Section Supervisors.

3. In January of each year, the Laboratory QA section distributes a survey shipment and delivery schedule to each involved manager and/or Section Supervisor.

4. Laboratories must enroll and participate in one approved program for one (1) year before designating a different program.

5. Laboratories operating under a new CLIA certificate and/or new regulated testing must enroll in PT as soon as possible and complete the PT for the remainder of the year.

B. Receipt of Surveys:

1. The date the survey kit is received is documented and logged into the QA internal PT tracking system.

2. Survey kits are checked for obvious damage or breakage and temperature.

a. Samples that are broken, missing, or mislabeled are reported by telephone to the survey kit distributor (generally CAP) within 10 days from date of shipment to obtain replacement.
b. Survey kits with any broken samples are treated as biohazardous waste and disposed of accordingly.
c. Survey kits that are received at incorrect temperature are reported to the survey kit distributor to obtain replacement if necessary.

3. The first page of the survey kit instructions is stamped with received date. A photocopy is made and maintained by QA for pending survey documentation and follow up.

4. For surveys received from CAP: Result forms are printed from the CAP website.

5. Survey samples are immediately delivered by QA staff or lab courier to the appropriate testing area Section Supervisor or designee.

    a. In the event that a survey has testing spread across more than one section, QA will send e-mail notification to all involved Section Supervisors/designees to clarify the required testing for each section involved.

C. Performing and Reporting the Tests:

1. Testing Section Supervisor or designee (e.g. CLS specialist) reviews samples to determine the tests to be performed, checks for accuracy, correct methodology, and special requirements (e.g. concentration units), and initiates testing as soon as possible.

    a. The supervisor or designee selects the primary instrument and method for each analyte. The highest volume analyzer in the laboratory section may, but need not, be chosen.
    b. The primary instrument and method used for survey testing must be what is commonly used to run patient samples.
    c. The supervisor or designee assigns the survey kits to the laboratory staff who will perform the testing. The Section Supervisor or designee distributes surveys to staff involved in running primary instrument and method analysis so that as many laboratory staff as possible are given the opportunity to perform analysis on PT surveys throughout the year.
    d. Staff working at multiple CAP/CLIA sites may not be assigned samples from the same survey kit.
    e. Staff are prohibited from accessing proficiency reports under other CLIA certificates than one by which they are employed.
    f. Records of staff participation should be kept and can be part of competency documentation.

2. Laboratory staff will test samples and treat them exactly as patient samples are tested. (Survey samples must be tested singly if patient samples are tested singly, in duplicate only if patient samples are tested in duplicate).

    a. Laboratory staff will review the survey instructions, reconstitute and analyze samples per instructions. This process may include accessioning specimens in the Laboratory Information System (LIS) in some cases. Survey must always be treated and run as a patient sample.

3. After testing is completed, the technical section will store any remaining samples until the survey results have been returned and reviewed. These stored samples may be used to assist in any further investigation.

4. The testing personnel will complete the PT answer sheet from LIS or instrument printouts and sign the **Attestation Statement** (For CAP surveys: attached to the kit instructions booklet).

    a. For Surgical Pathology related CAP PT, the designated surgical pathologist will interpret/review the glass slides according to present practice and will fill-in the answers for the appropriate questions in the answer sheet.

5. Laboratory staff or supervisor not involved in the analysis or completion of answer sheet will independently review the answer sheet and check for clerical errors.

6. Technical Section Supervisor or designee will check with other sections who performed testing to be sure their data is ready for submission.

7. The Attestation Statement in the answer sheet is signed by the Laboratory Director or qualified designee with written delegation from Lab Director.

8. The completed survey results may be entered on-line via the CAP website, saving results as they are entered. Finalize on-line submission by the due date and print the electronic results form. The printed on-line results form must be reviewed by a staff not involved with the on line result entry step to check for clerical errors.

9. NOTE: Results cannot be faxed, mailed or emailed to CAP.

10. A copy of the signed survey Attestation must be returned to the QA department within a reasonable time. The technical section Supervisor should retain all results sheets for documentation purposes. The technical Section Supervisor must notify QA department of any delay in submitting results.

11. Laboratory QA department uses QA PT tracker to document that results have been sent to CAP.

D. Graded Survey Evaluation Review and Follow Up:

1. Graded Survey results are received by laboratory QA, received date is documented, and results are reviewed for:
    a. Satisfactory performance
    b. Unacceptable results
    c. SDI trends and/or shifts (e.g. where 1 of 2 or 3 of 5 results for a single analyte have an SDI $\geq \pm$ 1.5).

2. QA sends the graded results forms to the technical section with a QA Memorandum cover sheet (**Attachment 1**) to aid the supervisor or designee in reviewing and following up on the results.

3. Satisfactory survey reports are forwarded to appropriate technical section for review.
    a. Section general supervisor, CLS specialist or Director reviews the results and comments on any footnoted results. The Section Medical Director or designee signs the results form and sends the reviewed results form back to the QA department.
    b. Laboratory QA staff files the reviewed and signed survey reports in the correct section of the survey manuals.

4. Survey reports with unacceptable results and/or SDI trend/shift problems are investigated and corrective action taken as follows:

    a. Laboratory QA staff will highlight Unacceptable Results; attach **Proficiency Testing Investigation and Corrective Action Report** (PTCAR, **Attachment 2**) and forward to appropriate technical section general supervisor. The supervisor will initiate follow up action immediately.
    b. Supervisor works with appropriate technical staff to complete the PTCAR.
    c. Supervisor reviews survey report and completed corrective action report and forwards to Section Medical Director for review
    d. If the Section Medical Director requires additional follow up or corrective action, the **PTCAR** and the survey results are returned to the section general Supervisor.
    e. Once the section Medical Director approves the corrective action report, the director and supervisor document review of survey results by signing and dating review page of survey report and corrective action report.
    f. Supervisor or section Medical Director forwards survey report and corrective action report to QA section.
    g. Final report will be signed by Section Supervisor, Medical Director and Quality Assurance Supervisor.
    h. Laboratory QA staff files original survey report and corrective action report in the appropriate section of the survey manual.
    i. Corrective and preventive action system changes are documented in the applicable technical section procedures if applicable, and include appropriate staff education. Changes must be monitored to measure the success of

implemented changes. A three month follow up is submitted to Section Medical Director and QA department.

E. CAP Proficiency Testing Compliance Notice (PTCN) Handling:

The CAP Proficiency Survey Program will send a **Proficiency Testing Compliance Notice (PTCN)** for failure to enroll, participate, or for unsatisfactory performance. When appropriate, a summary of scores (Proficiency Testing Exception Summary-PTES) for the most recent four PT testing events is included with the PTCN. Laboratory will be required to document corrective action and respond to the CAP if requested. Actions to correct the compliance issue will vary by the type of notice. (Refer to Administrative Procedure- 701.A)

1. The Laboratory QA office documents the date CAP **PTCN notification** is received.

2. **PTCN** due dates are monitored by entering information into the QA CAP Tracker. The tracker is monitored by QA staff.

3. The original **PTCN** notification, referencing survey reports and any previously documented corrective action, are forwarded to the appropriate Section Supervisor. The Section Supervisor reviews **PTCN** notification and works with the appropriate technical staff to complete the corrective action report. Supervisor forwards the corrective action report to the section Medical Director for review.

4. If Section Medical Director requires additional follow up or corrective action, the **PTCN** and the survey results are returned to the Section Supervisor. Once the section Medical Director approves the **PTCN** response, the Medical Director and supervisor sign and date the report.

5. This reviewed and approved **PTCN** and any attached documentation are forwarded to the CLIA Laboratory Director (Chair) for final approval and signature. The Chair's office staff returns approved **PTCN** and all accompanying documentation to QA department.

6. The original **PTCN** is immediately mailed/faxed/or emailed to the CAP, submission date is entered into the CAP tracker and documents are filed in the correct section of the survey manual by QA staff.

F. Record Retention:

1. A copy of the survey answer sheet with signed attestation statement is kept with survey results. Section records (worksheets, instrument printouts or tapes and report forms) are kept in the technical section files.

2. The reviewed survey results and preventive or corrective action documentation are kept for at least three (3) years. Transfusion Medicine survey documentation is kept for five (5) years.

NOTES:

1. All Surveys must be handled using **Universal Precautions.**

2. The Laboratory must release and the Proficiency Testing Agency must send results to the Centers for Medicare and Medicaid (CMS) and the California Department of Health Services, Laboratory Field Services.

3. Laboratory accidents resulting in staff injury must be reported to Supervisor and Employee Health, following Lab Admin P&P 230.A Injury or illness in the workplace. The survey agency will provide instructions concerning prophylaxis.

4. There can be **NO** inter-laboratory communications about the survey test results until after the reporting date of that survey. **CLIA regulations strictly prohibit referral of proficiency testing specimens to another laboratory with a different CLIA number**. This prohibition applies even if the second laboratory is in the same health care system and takes precedence over the requirement that PT specimens be handled in the same manner as patient specimens. Violations result in penalties including loss of laboratory's CLIA Certificate for at least one year (and loss of revenue), A person who has owned or operated a laboratory that has had its certificate revoked is not eligible within two years of the revocation date to own or operate a laboratory.

5. CMS has reiterated that laboratories are not permitted to test PT samples on multiple instruments unless that is how the laboratory routinely tests patient specimens.

6. Any outside laboratory submitting survey samples to UCDH Department of Pathology and Laboratory Medicine for testing must be reported to Centers for Medicare and Medicaid (CMS). Reporting is required.

7. **Any Survey results received late by the grading agency will result in a score of zero for the testing event.**

8. Incorrect entry due to transcription error by participant or failure to complete questionnaire/answer sheet correctly, **CANNOT** be corrected. Errors made by the survey grading agency will usually be re-evaluated and a corrected survey report returned.

9. Satisfactory performance requires at least a score of 80% (4 out of 5 correct) for each regulated analyte, 100% for transfusion analytes and 80% overall (100% overall for transfusion) for each survey. Unsatisfactory performance will result in the suspension of accreditation and or reimbursement.

10. Unsatisfactory PT performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

11. Unsuccessful participation in PT means any of the following:

    a. Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events (this term is generally used by CMS inspectors).
    b. Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.
    c. 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.

12. Supervisors are expected to verify that the correct methodology is noted as this can also result in proficiency testing failure.

13. Supervisors will ensure that all personnel who participate in PT surveys are familiar with testing, reviewing, reporting, and follow up for survey results. **Attachment 3 - Proficiency Survey Training Module & Checklist** will be used as documentation of training and will be maintained by Section Supervisors.

REFERENCES:

- 42 CFR Part 405, Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), Final Rule,
- California Business and Profession Code and California Code of Regulations
- The Joint Commission (TJC) accreditation manual
- College of American Pathologists (CAP), 2020 All Common Checklist
- College of American Pathologists (CAP), 2020 Laboratory General Checklist
- Centers for Medicare and Medicaid (CMS)
- College of American Pathologists, CMS Directive Regarding Testing PT Samples on Secondary Instruments/Methods, October 28,2015

PROCEDURE HISTORY

Date	Written/ Issued by	Revision/ Annual Review	Approved Date	Approved By
10/92	D. O'Sullivan	New	10/16/92	K. Sazama, M.D., J.D.
10/93	D. O'Sullivan	Annual Review	10/14/93	K. Sazama, M.D., J.D.
5/94	D. O'Sullivan	Revised	5/94	R.D. Cardiff, M.D., Ph.D.
4/96	D. O'Sullivan	Annual Review	4/96	R.D. Cardiff, M.D., Ph.D.
10/96	D. O'Sullivan	Annual Review	10/96	R. Green
11/97	D. O'Sullivan	Annual Review	11/97	R. Green
11/98	D. O'Sullivan	Annual Review	11/98	R. Green
6/00	D. O'Sullivan	Annual Review	6/00	R. Green
5/01	D. O'Sullivan	Annual Review	5/01	R. Green
7/02	D. O'Sullivan	Annual Review	8/02	R. Green
5/03	D. O'Sullivan	Annual Review	5/03	R. Green
2/04	D. O'Sullivan	Revised	2/04	R. Green
9/04	D. O'Sullivan	Revised	9/04	R. Green
10/05	D. O'Sullivan	Revised	10/05	R. Green
9/06	D. O'Sullivan	Annual Review	9/06	R. Green
9/06	D. O'Sullivan	Annual Review	9/06	R. Green
11/06	D. O'Sullivan	Annual Review	11/06	R. Green
11/07	D. O'Sullivan	Annual Review	11/07	R. Green
04/08	D. Wright	Revised	04/08	R. Green
4/09	D. Wright	Revised	4/09	L. Howell
6/10	D. Wright	Revised	6/10	L. Howell
9/10	D. Wright	Revised	9/10	L. Howell
11/10	D. Wright	Added 30 day time	11/10	L. Howell
05/12	T. Cox	Revised: 2nd reviewer; added attachments	05/12	L. Howell
10/14	T. Cox	Revised: added separate survey each	10/14	

Date	Written/ Issued by	Revision/ Annual Review	Approved Date	Approved By
		CLIA site; defined unsuccessful survey		L. Howell
09/16	E.Villadolid/ S. Okimura	Updated to current CAP process and references	10/16	L.Howell
08/18	N. Kaur	Revised: Changed SER to PTCN; Removed attachment 4	09/18	L.Howell via OnBase
10/19	N. Kaur	Revised: Added AP slide review by pathologist	10/19	R. Edwards Via OnBase L. Howell Via OnBase
09/21	E. Karanja	Revised: Added staff at multiple CLIA sites, edited references and attachments	09/21	L. Howell via OnBase
02/22	B. Brownlow	Revised: Updated workflow to reflect changes to CAP workflow (no results sheets)	02/22	L. Howell via OnBase

Proficiency Survey Handling **Attachment 1 700.A**

M E M O R A N D U M

DATE:

TO:

FROM: _____
Quality Assurance Department

RE*:* **Proficiency Testing Follow Up**

Please carefully review the attached Proficiency Testing results and take action indicated. ***Please comment on any highlighted section of the evaluation.***

____ No proficiency testing exceptions are noted. Please review, sign and date. Also review these results for any trends, shifts, or possible signs of future system problems. See attached bulletin for error prevention information.

____ Review all footnoted test results using the summary report and note next to the results whether the test result is acceptable or not. If not, note what has been done to follow up and improve the accuracy of the test results.

____ One or more proficiency testing errors require investigation and follow up. Please use the attached form and guidelines to document corrective action.

____ Final Critique, for your information only, no action or response needed.

____ Quality Cross Check, please review and comment as necessary.

Please return signed documents to me within reasonable time of the date above (Within 3 weeks is recommended)

Thank you.

Proficiency Survey Handling **Attachment 2 700.A**

Proficiency Testing Investigation and Corrective Action Report

Proficiency Survey Number _____ ( ) Result "Unacceptable"
Test Procedure _____ ( ) Result Exceeds Fixed Criteria
Specimen Number(s) _____ ( ) SDI trends and/or shifts

Description of Problem Identified by Investigation:

Evaluation of Related Patient Results: Did reason for deficiency affect patient results?
YES / NO
If yes, identify volume and describe affect and follow up action.

Describe Prospective Intervention Plan to Minimize or Prevent Deficiencies:
Include in system changes such as what procedure(s) are being rewritten and how staff is being retrained.

Describe how system changes will be monitored to measure success of corrective action:

Submit a summary of the "system change" monitoring results to the Quality Assurance Department three months after implementing changes.

_____ Date:_____
Section Supervisor

_____ Date:_____
Section Director (MD or PhD)

_____ Date:_____
Quality Assurance

PROFICIENCY SURVEY TRAINING MODULE & CHECKLIST **Attachment 3 700.A**

CAP PT Name: _____

Date Received: _____ Due Date: _____

	Initials	Date Completed
BEFORE TESTING:		
1. Enter PT Samples in the LIS as appropriate (as per SOP 700.A Section C).		
2. Review the CAP PT test methods for accuracy and special requirements (e.g. concentration units, method codes), and *share with appropriate section*.		
3.**Testing Personnel**: Attest that they have not performed the same Proficiency Testing Survey at another CAP Accredited Facility or CLIA site. Notify Section Supervisor immediately, if you have performed the same PT elsewhere. *DO NOT PROCEED WITH TESTING*.		
4. Date and initial the PT specimen vials/LIS aliquots when samples are reconstituted or opened. Place PT samples in refrigerator or freezer as appropriate.		
5. Place aliquot of sample in freezer as appropriate. Where sample volume permits, this should be done when sample is reconstituted or opened. Otherwise, the sample should be frozen according to routine testing procedures.		
TESTING:		
6. READ INSTRUCTIONS. Barcode CAP samples if indicated, and perform CAP Survey testing in a regular run in the same manner as patient testing.		
AFTER TESTING:		
7. Testing personnel records CAP results from LIS printouts or test worksheets onto the PT form.		
8. Check for changes in instrument or methodology and record.		
9. Attestation statement: Must be signed by all technologists performing testing. The Laboratory Director or designee must also sign the attestation statement (see #15 below).		
10. A CLS or Supervisor not involved in the analysis or completion of answer sheet must recheck the final result form for transcription errors.		
11. For supervisor: Go online to www.CAP.org and enter results for the survey. E-lab solutions – proficiency testing – result form – select survey – view – view/edit. Save as you go, but don't submit yet. Print results.		
12. A CLS /Supv not involved in online result entry checks printed results for transcription errors.		
13. Check with other sections to be sure their data is entered & ready for submission.		
14. Finalize online submission and print copies of the verification.		
15. Give copies of submitted results to QA Dept.		
16. The Laboratory Director or designee must sign electronic copy of attestation page.		
SUPERVISOR - CHECK CAP Website for results, then AFTER RESULTS COME BACK:		
17. When results are received, address any deficiencies, footnoted results, trends, shifts or other issues; add in acceptability criteria if necessary; troubleshoot if needed.		
18. Send corrective action follow up to section medical director for approval and signature.		
19. Provide copy(ies)to QA dept.		
20. If applicable, check that staff has completed Section competency forms. Document PT participation and competency as appropriate.		

Proficiency Testing Three Month Follow Up **Attachment 4 700.A**

Reason for Corrective Action:

Department _____ ( ) Result "Unacceptable"
Proficiency Survey _____ ( ) Clerical
Test Procedure _____ ( ) SDI trends and/or shifts

Description of Problem Identified by Investigation:

Describe the system change(s) that have been implemented:

Describe how system change(s) will be monitored to measure success of corrective action:

Describe the effectiveness/results of the system change(s) since implementation:

_____ Date:_____
Section Supervisor

_____ Date:_____
Section Director (MD or PhD)

_____ Date:_____
Quality Assurance