**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 State of California, Department of Health Services (DHS), 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 Management (QM) Department staff reviews the PT Survey subscriptions (generally CAP) with the Technical Directors, Managers and 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.

* 1. Other approved survey agency subscriptions are reviewed, if needed, to meet requirements not met by the CAP Surveys.
	2. Surveys are ordered no later than December 1st of each year.
1. The Laboratory Management receives and reviews the Survey order verification forms for completeness and distributes a copy to all involved Managers and Section Supervisors.

1. In January of each year, the Laboratory Management distributes a Survey

shipment and delivery schedule to each involved Manager and Section Supervisor.

B. Receipt of Surveys:

1. The date Survey kit is received is documented and logged into the Quality Management internal PT tracking system.
2. Survey kits are checked for correct answer sheet and obvious damage or breakage.
	1. Missing answer sheets or broken, missing, or mislabeled samples are reported by telephone to the Survey kit distributor (generally CAP) within 10 days from date of shipment to obtain replacement.
	2. Survey kits with any broken samples are treated as biohazardous waste and disposed of accordingly.
3. The first page of the survey answer sheet is photocopied and maintained by QM for pending survey documentation and follow up. QM writes the date completed survey results must be submitted to the Survey grading agency on the photocopy. This copy is used to monitor that completed Survey results are submitted within stated deadline.
4. A prominent note is attached to the original Survey answer sheet identifying the date the completed results must be reported.
5. Survey samples and result sheets are immediately hand delivered by QM staff to the appropriate testing area Section Supervisor or designee.
	1. In the event that a survey has testing spread across more than one section, Quality Management will provide a section tracking form to clarify the required testing for the sections involved. A copy of this form will be distributed to all sections performing the testing on the survey at the time the survey is distributed.

1) The completed form should be returned to QM at the time results are sent to CAP.

C. Performing and Reporting the Tests:

1. Testing Section Supervisor reviews the answer sheet and 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.

1. The Supervisor selects the primary instrument and method for each analyte.

The highest volume analyzer in the laboratory section may, but need not, be chosen.

1. The primary instrument and method used for Survey testing must be what is

 regularly used to run patient samples.

1. The Supervisor or designee distributes the survey kits to the technologists who

will perform the testing. The section supervisor will distribute surveys to technologists involved in running primary instrument and method analysis so that as many technologists as possible are given the opportunity to perform analysis on PT surveys throughout the year.

 d. Records of technologists’ participation should be kept and can be part of the

 competency and continuing education documentation.

 2. The technologists will immediately 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).

1. The technologist will review the survey instructions, reconstitute and analyze samples per instructions. This process may include accessioning specimens in the 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.

1. The testing personnel will complete the PT answer sheet from LIS or instrument printouts and sign the **Attestation Statement**.
2. A technologist or Supervisor not involved in the analysis or completion of answer sheet will independently review the answer sheet and check for clerical errors.
3. Technical Section Supervisor will check with other sections who performed testing to be sure their data is ready for submission.
4. The Attestation Statement in the answer sheet is signed by the Laboratory Section Director or Designee.
5. The completed Survey results may be entered on-line via the CAP website (preferred method), saving results as they are entered. Finalize on-line submission and print the electronic results form. The printed on-line results form must be reviewed by a CLS not involved with the entry of results on line to check for clerical errors.
6. The answer sheet may also be faxed to CAP or appropriate organization by the due date. If faxed, record the fax date on the first page. (If original answer sheets are mailed, copies of all sheets must be sent to the QM department).
7. All results sheets must be returned to the QM department within a reasonable time. The Technical Section Supervisor must notify QM department of any delay in submitting results.

1. Laboratory QM department records that results have been sent to CAP and that

paper work has been received in the QM department.

D. Graded Survey Evaluation Review and Follow Up:

1. Graded Survey results are received by Laboratory QM, received date is documented, and results are reviewed for:
	1. Satisfactory performance
	2. Unacceptable results
	3. SDI trends and/or shifts (e.g. where 1 of 2 or 3 of 5 results for a single analyte have an SDI > + 1.5).
2. QM sends the graded results forms to the Technical Section with a QM Memorandum cover sheet (**Attachment 1**) to aid the Technical Section Supervisor in reviewing and following up on the results.

**Note CAP requires “Reviews should be completed within one month of the date reports and results become available to the laboratory.”**

1. Satisfactory survey reports are forwarded to appropriate technical Section Supervisor and Director for review.
	1. Section Supervisor or Director reviews the results and comments on any

footnoted results. The Section Supervisor sends the reviewed results form back to the QM department. Completed reports are then sent to the Director of Clinical Pathology, Director of Anatomic Pathology, or Pathology Chair for final review and comment.

b. The Directors return reviewed Survey reports to the Laboratory

Management office for filing.

c. Laboratory Management staff files Survey reports in the correct section of

the Survey manuals.

1. Survey reports with Unacceptable results and/or SDI trend/shift problems are

investigated and corrective action taken as follows:

a. Laboratory QM staff will highlight Unacceptable Results; attach

**Proficiency Testing Investigation and Corrective Action Report** (**Attachment 2**) and forward to appropriate technical section Supervisor. The Supervisor will initiate follow up action immediately.

1. Supervisor works with appropriate technical staff to complete **Proficiency Testing Investigation and Corrective Action Report.**
2. Supervisor reviews Survey report and completed corrective action report

 with section Director.

1. Once the section 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.

1. Supervisor or Director forwards Survey report and corrective action report to Director of Clinical Pathology (Director of Anatomic Pathology for Cytology and Anatomic Pathology Surveys) for final review and comment.
2. If the Director of Clinical Pathology or Anatomic Pathology requires

 additional follow up or corrective action, the **Proficiency Testing Investigation and Corrective Action Report** and the Survey results are returned to the section Director or Supervisor.

1. Director of Clinical Pathology or Anatomic Pathology approves the

 corrective action report and documents review and approval of Survey results by signing last page of Survey report and corrective action report.

1. The Director of Clinical Pathology or Director of Anatomic Pathology's

 Office staff returns approved Survey report and corrective action report to the Laboratory Management office for filing.

1. Laboratory QM staff files original Survey report and corrective

 action report in the appropriate section of the Survey manual.

1. Corrective and preventive action system changes must be documented in the applicable Technical Section procedures and include appropriate staff education. Changes must be monitored to measure the success of implemented changes. A 3 month follow up must be submitted to Laboratory Section Director, Clinical Pathology or Anatomic Pathology Director, and QM department.

E. CAP Survey Exception Report Handling: The CAP Proficiency Survey Program will send a CAP **Survey Exception Report (SER)** when unacceptable results for an analyte occur in any 2 of 3 consecutive challenges, 2 or more unacceptable results for any given analyte in any single survey event and for each unacceptable result in compatibility testing.

1. The Laboratory QM office documents the date CAP **Survey Exception Report**

notification is received.

1. The Survey Exception Reportnotification is photocopied and the date the

completed report must be mailed back to the CAP is hand written on the photocopy. This copy is used to monitor return of completed report by required deadline.

1. The original Survey Exception Reportnotification, referencing Survey reports and

 any previously documented corrective action, are forwarded to the appropriate

section supervisor. The Section Supervisor reviews Survey Exception Reportnotification and works with the appropriate technical staff to complete the report. Supervisor reviews the completed Survey Exception Reportwith the section Director.

1. Once the section Director approves the Survey Exception Reportresponse, the

Director and Supervisor sign and date report and forward report to the Director of Clinical Pathology or Director of Anatomic Pathology for final review and comment.

1. If the Director of Clinical Pathology or Director of Anatomic Pathology requires

additional follow up or corrective action, the Survey Exception Report and the Survey results are returned to the section Director or section supervisor.

1. The Director of Clinical Pathology or Director of Anatomic Pathology approves

the Survey Exception Report and documents review and approval by signing the bottom of the Exception Report.

7. The fully reviewed and approved Survey Exception Report and any attached

documentation are forwarded to the Chair, Department of Pathology and Laboratory Medicine for final signature.

 8. The Chair's office staff returns approved Survey Exception Report and all

accompanying documentation to the Laboratory QM office.

1. The Laboratory QM office staff photocopy Survey Exception Report, write the

mailing/faxing date on the copy and files copy in the correct section of the Survey manual.

1. The original Survey Exception Report is immediately mailed/faxed to the CAP.

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) will continue to be kept in the technical section files.

1. The reviewed survey results and any preventive or corrective action

 documentation are kept for at least 3 years (5 years for Transfusion Surveys).

**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 area Supervisor and Employee Health. 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 CLIA Certificate revocation (and loss of revenue) for at least one year.

5**. No change in Proficiency Testing Agency enrollment is permitted for 1 year.**

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

7. **Any Survey results received late by the grading agency will result in a failure for all analytes in the survey.**

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.

1. 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.
2. Supervisors are expected to verify that the correct methodology is noted as this can also result in proficiency testing failure.
3. 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, February 28, 1992.
* California Business and Profession Code and California Code of Regulations, January 1, 1991
* Joint Commission on Accreditation of Health Care Organizations (JCAHO), current accreditation manual
* College of American Pathologists (CAP), current accreditation manual
* Centers for Medicare and Medicaid (CMS)

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 |

Proficiency Survey Handling Attachment 1 700.A

***M E M O R A N D U M***

DATE:

TO:

FROM: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Manager, Quality & Performance Improvement

**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 errors are noted. Please review, sign and date. You should 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.

\_\_\_\_ Linearity, please review and comment as necessary.

Please return signed documents to me within 3-weeks of the date above.

Thank you.

Proficiency Survey Handling Attachment 2 700.A

**University of California, Davis Health System**

**Department of Medical Pathology & Laboratory Medicine**

# 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 Management Department three months after implementing changes.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Supervising Technologist

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Senior Supervising Technologist

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 M.D. or Ph.D., Director

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Director, Clinical Pathology

|  |  |  |
| --- | --- | --- |
| **PROFICIENCY SURVEY TRAINING MODULE & CHECKLIST 700.A Attachment 3** |  |  |
| CAP PT Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | **Initials** | **Date Completed** |
| Date Received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Due Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
|  |
| **BEFORE TESTING:** |   |   |
| 1. Enter PT Samples in the LIS as appropriate (as per SOP 700.A Section C.1.d). |   |   |
| 2. Review the CAP PT test methods for accuracy and special requirements (e.g. concentration units, method codes), and *share with appropriate section*. |  |  |
| 3. Date and initial the PT specimen vials/LIS aliquots when samples are reconstituted or opened. Place PT samples in refrigerator or freezer as appropriate. |  |  |
| 4. 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:** |  |  |
| 5. 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:** |  |  |
| 6. Testing personnel records CAP results from LIS printouts or test worksheets onto the PT form. |   |   |
| 7. Check for changes in instrument or methodology and record. |   |   |
| 8. Attestation statement: Must be signed by all technologists performing testing. The Laboratory Section Director or designee must also sign the attestation statement (see #15 below). |  |  |
| 9. A CLS or Supervisor not involved in the analysis or completion of answer sheet must recheck the final result form for transcription errors.  |  |  |
| [10. 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.](http://www.cap.org/)  |  |  |
| 11. A CLS /Supv not involved in online result entry checks printed results for transcription errors. |  |  |
| 12. Check with other sections to be sure their data is entered & ready for submission.  |  |  |
| 13. Finalize online submission and print copies of the verification. |  |  |
| 14. Give copies of submitted results to QM Dept. |  |  |
| 15. The Laboratory Section Director or designee must sign electronic copy of attestation page. |  |  |
| **SUPERVISOR - CHECK CAP Website for results, then AFTER RESULTS COME BACK:** |  |  |
| 16. When results are received, address any deficiencies, footnoted results, trends, shifts or other issues; add in acceptability criteria if necessary; troubleshoot if needed.  |  |  |
| 17. Send corrective action follow up to director for signature.  |  |  |
| 18. Provide copy(ies)to QM dept. |  |  |
| 19. If applicable, check that staff has completed Section competency forms. Document PT participation and competency as appropriate. |  |  |