## Performing Proficiency Testing

**PURPOSE**

External proficiency testing is mandatory for each specialty area in which testing is performed under the Clinical Laboratory Improvement Act of 1988. Proficiency test samples are processed and analyzed by routine test methods and personnel to the same level as patient specimens to demonstrate competency, accuracy, and reproducibility. The laboratory must maintain an average score of 80% to maintain licensure. If the Molecular Diagnostics Laboratory fails to maintain an overall score of 80%, appropriate training and technical review must be performed to correct the problems associated with the proficiency failures. The section technical director and/or designee will review the proficiency program.

**POLICY STATEMENT**

* Alternative performance assessment (ASA) must be performed twice per year on tests for which external PT is not available
* Per the *Federal Register,* sharing of PT results with another laboratory prior to evaluation is not permitted even in the same health care system. PT specimens cannot be referred to another laboratory.
* Handle each sample as if it were a patient sample using the same approach and procedures for processing, testing and reporting of results.
* An average score of 80% must be maintained for licensure.

**ABBREVIATIONS**

* CAP: College of American Pathologists
* GASDN: Group A strep PCR
* PT: Proficiency test
* PTCN: Proficiency Testing Compliance Notification
* WSLH: Wisconsin State Laboratory of Hygiene

**SOURCE**

 CAP, #1802101 – 01 WSLH, ID #: 2005499

 325 Waukegan Road 465 Henry Mall

 Northfield, IL 60093-2750 Madison, WI 53706-1578

 (800) 323-4040 opt#1, then 3 (800) 462-5261

 FAX 1-866-329-2227 FAX 1-866-240-4687

## SAFETY CONSIDERATIONS

1. Standard precautions
2. Use of engineering controls: Refer to MB 3.01 Engineering Controls to Prevent Nucleic Acid Contamination

**PROCEDURE A:** Follow the activity below for handling proficiency samples

# General Information

|  |  |  |  |
| --- | --- | --- | --- |
| **Activity** | **Step** | **Action** | **Related Doc** |
|  | 1 | Process, test and submit results before deadline stated on the instruction form. |  |
|  | 2 | Store samples at 2-8°C until processing can be performed.  |  |
| **General information** | 3 | If the kit is incomplete or contains damaged samples, contact CAP or WLSH within 10 days of the shipment date for replacement samples.* Provide CAP #1802101 – 01 and contact information
* WSLH ID number: 2005499
 |  |
|  | 4 | Treat all samples as potentially infectious. Wear gloves when handling. |  |
| **Hotline** | 5 | Call CAP or WLSH if there is a laboratory accident in which the employee is exposed to the survey material* **CAP Hot Line 1-800-443-3244, CAP #1802101 – 01**
* **WSLH 1-800-462-5261, WSLH ID#: 2005499**
 |  |
| **Rotation** | 6 | Distribute the specimen into the daily workflow.* Rotate testing among all personnel that perform the procedure.
 |  |
| **Freeze** | 7 | Freeze residual sample at – 70°C. |  |

**PROCEDURE B:** Follow the activity below for processing, testing and reporting samples

# Testing and resulting samples

|  |  |  |  |
| --- | --- | --- | --- |
| **Activity** | **Step** | **Action** | **Related Doc** |
|  | 1 | Accession each sample in Sunquest and generate label |  |
| **Testing** | 2 | Reconstitute the proficiency samples according to the instructions provided with each survey. |  |
|  | 3 | Test each sample with the regular workload according to written procedures |  |
| **Record** | 4 | Record results in computer. |  |
|  | 5 | Transcribe the results onto the CAP/WLSH result form.

|  |  |
| --- | --- |
| **If** | **Then** |
| Result determined | Fill in appropriate bubble |
| Test not performed | Follow instructions whether to leave result field blank or not |
| Submitting results | Check accuracy prior to filing online or faxing |
| Corrections needed | * Can be made any time prior to due date
* Must be made online if submitted originally online
 |
| Analytical problems | Refer to CAP kit instructions for exception codes |

 |  |
| **Signatures** | 6 | Testing personnel and section technical director must sign the result form attesting the PT samples were integrated into the routine workload. |  |
| **Online submission** | 7 | CAP: A personal web account must be established before entering results online.  Once established, enter and approve results by the due date printed on the Result form.WSLH: PT Central Login: 2005499 PT Central Password: 2055499 | [www.cap.org](http://www.cap.org)[www.wslhpt.org](http://www.wslhpt.org) |

**PROCEDURE C:** Follow the activity below for reviewing graded PT results and PT results that were not graded because of lack of consensus, educational challenge or failure to submit results before the due date

# Review of PT results

| **Activity** | **Step** | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| **Who** | 1 | The section technical director and/or designee will review all final survey results and document with signature and date reviewed. |  |
| **Graded Results****Trouble-shooting PT failures**  | 2 | Evaluate unacceptable results to detect and correct any problems identified.

|  |  |
| --- | --- |
| Step | Action |
| a | Involve the individual(s) who originally processed the sample |
| b | Gather survey documentation including QC records, instrument reports, incomplete and completed worksheets, reagent lots, etc. |
| c | Use PT Exception Investigation Checklist to help evaluate a possible source of error. |
| d | Retest the original sample if possible to determine if problem repeats. |
| e | Review patient results for acceptability at the time of PT testing. |
| f | Investigate a potential root cause, i.e., insufficient training, lack of communication, improper equipment, etc. |
| g | Document and communicate corrective action to prevent future failures. |

NOTE: If repeat testing yields incorrect results, CAP may instruct the laboratory to cease patient testing. Send tests out as applicable until approval to start testing again is attained.  | [PT Exception Checklist](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/Res/212405.pdf) |
|  | 3 | If documentation must be sent to CAP, complete a Proficiency Testing Compliance Notification (PTCN) Form | [PT Compliance Notification (PTCN) Form](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/Res/212406.pdf) |
|  | 4 | Submit completed PTCN form and documentation to section technical director for review. |  |
| **Ungraded results** | 5 | Review and document that the ungraded results were reviewed and compared to the participant consensus response using statistics and evaluation criteria provided in the *Participant Summary*.  |  |
|  | 6 | Investigate an ungraded result that was not in agreement with the participant consensus response as if it were an unacceptable result. Refer to step 2. |  |

**PROCEDURE D:** Follow the activity below for alternate proficiency testing

**Alternate Performance Assessment (APA)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Activity** | **Step** | **Action** | **Related Doc** |
| **Testing Methods** | 1 | When external proficiency testing is not available, perform alternate PT on five samples to revalidate the test twice per year using one of the following methods:

|  |  |
| --- | --- |
| Step | Action |
| a | Split samples with an established in-house method |
| b | Use previously assayed patient samples or controls in matrix |
| c | Split sample analysis with a reference or other laboratory |

 | Generic APA Form: Appendix A |
|  | 2 | Test each sample with the regular workload according to written procedures |  |
| **APA Form** | 3 | Document results on the Alternate PT form and in the computer; submit to section technical director and/or designee for review |  |
| **Signatures** | 4 | Testing personnel and section technical director must sign the result form attesting the PT samples were integrated into the routine workload. |  |
| **Results** | 6 | Investigate discrepant results that were not in agreement with the intended response as if it were a graded PT unacceptable result. Refer to Procedure C, step 2. |  |

### **REFERENCES**

1. Daly, J., Section 14. Quality Assurance, Quality Control, Laboratory Records and Water Quality. InLynne S. Garcia (ed) *Clinical Microbiology Procedures Handbook,* Third edition2010, American Society for Microbiology, Washington, D.C., pg. 14.2.4.
2. Persing, D. H., et al., Molecular Microbiology *Diagnostic Principles and Practice,* Second Edition, 2011, American Society for Microbiology, Washington, D.C., pg. 885 – 898.
3. CLIA-88 Final rule. *Federal Register*. 1992 (Feb 28): 7146[42cfr493.801 (b) (3).
4. CLSI *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline, Second Edition*, Feb 2007, GP27-A2, Vol. 27 No. 8, Wayne, Pa.

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| --- | --- |
| Historical Record |  |
|   | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1.0 | P. Ackerman | 4/25/97 | Initial Version |
| 1.3 | P. Ackerman | 6/23/07  | Added Biohazard warning, WLSH address and phone no., statement regarding sharing or referral of PT specimens, CAP; Online reporting and WLSH Fax reporting |
| 1.4 | P. Ackerman | 6/10/09 | Reformatted procedure; added molecular specific information; hyperlinks to supporting documents. |
|  | 5 | P. Ackerman | 8/18/11 | Reformatted procedure; changed version to whole number |
|  | 6 | P. Ackerman | 9.20.14 | Updated WSLH online login/password for result entry |
|  | 7 | P. Ackerman | 06.07.2016 | Updated Medical director to Technical Director; reformatted for CMS; updated logo |
|  | 8 | P. Ackerman | 3.27.17 | Removed FAX information; changed Alternate Profiency Testing (APT) to Alternative Performance Assessment (ASA) |
|  | 8 | J. Laramie | 03.27.17 | Biennial review: 05.02.2018 JL |
|  | 9 | J. Laramie | 9.3.18 | Updated graded results section to include notes related to repeat failures.  |

**APPENDIX A: Alternate Performance Assessment (APA) Generic Form**

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| Molecular Biology Department**Test: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | Performed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Date Tested** | **APT ID No.** | **Original Lab Result\*** | **Reference Lab No.\*** | **APT Test Result** | **Interpretation** | **Comments** |
|  |  |  |  |  | **­\_\_Accept \_\_Reject** |  |
|  |  |  |  |  | **\_\_Accept \_\_Reject** |  |
|  |  |  |  |  | **\_\_Accept \_\_Reject** |  |
|  |  |  |  |  | **\_\_Accept \_\_Reject** |  |
|  |  |  |  |  | **\_\_Accept \_\_Reject** |  |
| **\* Technical Specialist or designee will fill in the original lab number and result after APA testing is completed** |
| **Corrective Action** |
| **Management Review** | **Name** | **Signature** | **Date** | **Review Comments** |
| Technical Specialist/designee |  |  |  |  |
| Technical Director | Phillip Heaton PHD |  |  |  |