Holyoke Medical Center
575 Beech Street
Holyoke, MA 01040

Policy: 401.ADM.4.03

Laboratory

Category 3

Proficiency Testing

Purpose

To define the system used in the laboratory to meet CAP and CLIA regulations.

Principle

It is the policy of the Laboratory to subscribe to proficiency surveys as mandated by CLIA-'88 and the College of American Pathologists (CAP) to evaluate the effectiveness of procedures.

Procedure

1. On an annual basis the laboratory manager will circulate the CAP SURVEY book and the Wisconsin State Laboratory of Hygiene(WSLH) book to all departmental supervisors who will determine, in conjunction with the pathologist who oversees the department, which surveys are appropriate to cover all testing for their area.

2. The laboratory manager will order the surveys for the year. (See order form which follows this policy for current year.)

3. Surveys will be delivered to the appropriate department by the pathology secretary.

4. Test will be assigned to technologists by the department supervisor.

5. All proficiency materials will be treated the same as patient samples.

6. The technologist or supervisor will complete the answer form (per department policy); testing technologist will sign the attestation statement and the department supervisor will also sign the statement as the pathologist's designee. The supervisor will ensure the response is mailed, or submitted on line, within the time frame indicated for the survey.

7. In order to resolve problems all survey material and a photocopy of responses submitted will be maintained until the results are received from CAP or WSLH.

8. Technologist's participation in proficiency testing will be documented by the supervisor

as addressed in the Personnel Assessment policy.

9. All unacceptable survey results should prompt a timely evaluation as to the specific reason(s) for the unacceptable result, and an action plan should be developed to reduce the likelihood of recurrence. Survey results should be reviewed for any trends that may indicate problems. All documentation of the evaluation and the corrective action will be reviewed and signed by the pathologist and supervisor, and all proficiency survey results and records will be maintained within the individual laboratory department.

10. For all PT challenges that were intended to be graded but were not, each department must have documentation of how the PT results were assessed. The "Actions Laboratories Should Take when a PT Result is not Graded" (Addendum A) lists some of the error codes and the action required. The information was taken from a March 2010 Participant Summary.

Procedure Notes

All tests for which there is no external proficiency program will have one patient sample split twice a year with tests run by two technologists and the results compared.
(In January and July)

There will be no inter-laboratory communication about proficiency testing samples before submission of data to the proficiency-testing provider. Proficiency testing specimens cannot be referred to another laboratory.

The Centers for Medicare and Medicaid Services (CMS) has directed the CAP and all CMS approved Proficiency Testing (PT) providers to change primary and secondary instrument reporting. PT specimens cannot be run on multiple analyzers at the same time. One instrument should be designated as the primary instrument. If multiple instruments are used for testing, proficiency test samples can be rotated among the other instruments, but all samples for one analyte within a shipment must be tested with the same instrument. If CAP PT is not reported for a secondary instrument, biannual correlation studies must be performed. Refer to PT kit instructions for specific reporting information.

References:

1. College of American Pathologists, Secondary Instrument Reporting, 2/12/2014.
2. College of American Pathologists, All Common Checklist, 4/21/2014.

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Approved By:	Medical Director: Thomas Gould, M.D.	12/23/14 Date

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Adopted or Date initiated: 05/1993

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Reviewed:

Date	Lab Manager/Designee	Date	Lab Manager/Designee

Revision History			
Version	Summary of Changes	Author	Date
13	Notes – paragraph 3 concerning primary and secondary analyzers	glik	12/23/14

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Addendum A:

Actions Laboratories Should Take when a PT Result is Not Graded

The College uses Exception Reason Codes for the proficiency testing (PT) analyte that has not been graded. The Exception Reason Code is located on the evaluation report in brackets to the right of the result. Identify all of the analytes with an Exception Reason Code and investigate the acceptability of performance with the same rigor as if it were an unacceptable performance. The actions accredited laboratories should take include but are not limited to:

Codes	*Exception Reason Code Description*	*Action Required*
11	Unable to analyze.	Document why the specimens were not analyzed (e.g., instrument not functioning or reagents not available). Perform and document alternative assessment (i.e., split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
20	No appropriate target/response; cannot be graded.	Document that the laboratory performed a self-evaluation and compared its results to the modal (most common) method, or "all method" data or "all instrument" data from the statistics supplied in the Participant Summary.
21	Specimen problem.	Document that the laboratory has reviewed the proper statistics supplied in the Participant Summary. Perform and document alternative assessment for the period that commercial PT was not tested to the same level and extent that would have been tested. Credit is not awarded in these cases.
22	Result is outside the method/ instrument reportable range.	Document the comparison of results to the proper statistics and peer group information supplied in the Participant Summary. Verify detection limits.
24	Incorrect response due to failure to provide a valid response code.	Document the laboratory's self-evaluation against the proper statistics supplied in the Participant Summary. Perform and document the corrective action of any unacceptable results. Document corrective action to prevent future failures.
25	Inappropriate use of antimicrobial.	Document the investigation of the result as if they were unacceptable and review the proper reference documents to gain knowledge of the reason your response is not appropriate.
26	Educational challenge.	Response to the CAP is not required. Laboratory should document its review.
27,31	Lack of participant or referee consensus.	Document that the laboratory performed a self-evaluation and compared its results to the modal (most common) statistics supplied in the Participant Summary.
28	Response qualified with a greater than or less than sign; unable to quantitate.	Document that the laboratory performed a self-evaluation and compared its results to the proper statistics supplied in the Participant Summary. Verify detection limits.
30	Scientific Committee decision.	Document that the laboratory has reviewed the proper statistics supplied in the Participant Summary.
33	Specimen determined to be unsatisfactory after contacting the CAP.	Document that the laboratory has contacted the CAP and no replacements specimens were available. Perform and document alternative assessment (i.e., split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
40	Results for this kit were not received.	Document why results were not received, corrective action to prevent recurrence and the laboratory's self-evaluation of the results by comparing results to the proper statistics supplied in the Participant Summary.
41	Results for this kit were received past the evaluation cut-off date.	
42	No credit assigned due to absence of response.	The Participant Summary indicates which tests are graded (see evaluation criteria) and which tests are Not Evaluated/Educational. Updates to grading will also be noted. If a test is educational, the laboratory is not penalized for leaving a result(s) blank. The code 42 that appears on the evaluation is not a penalty. However, if a test is graded (regulated and non-regulated analytes) and your laboratory performs that test, results cannot be left blank. The laboratory is required to submit results for all challenges within that test or use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the Kit Instructions and/or the Result Form. Document corrective actions to prevent future failures.
44	This drug is not included in our test menu. Use of this code counts as a correct response.	Verify that the drug is not tested on patient samples and document to ensure proper future reporting.
77	Improper use of the exception code for this mailing.	Document the identification of the correct code to use for future mailings.
91	There was an insufficient number of contributing challenges to establish a composite grade.	Document the investigation of the result as if it were an unacceptable result. Perform and document the corrective action if required.
35, 43, 88, 92	Various codes.	No action required.