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Clinical Laboratory Proficiency Testing Handling and Processing	Origination: 10/2010 Version: 6.0

Policy Statement	<p>The Laboratory is accredited by the College of American Pathologists (CAP). The College of American Pathologists is a private accreditation organization with deemed status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare and Medicaid Services (CMS). The Laboratory has established a Proficiency Testing (PT) Program to meet CAP criteria.</p> <p>The Clinical Laboratory is committed to ensuring that all PT events are handled in the same manner as patient samples whenever possible.</p>
Purpose	This procedure has been established to provide direction on receiving, ordering and resulting PT surveys.
Scope	This program applies to the Clinical Laboratory management.
Responsibility	<p>Lab Management: The Lead Technologists are responsible for implementation of procedures and have pathologist-delegated authority to sign the attestation form. The Lead Technologists are also responsible for documenting evaluation report review, self-evaluation of non-graded events and completion of the CAP PT Exception Summary Response form (ERF).</p> <p>Quality Coordinator: Quality Coordinator or designee will receive and distribute all surveys for the Clinical Lab.</p> <p>Lab Associates: Associates are to process or assay the PT material within the normal workflow, utilizing standard quality control protocols and defined repeat criteria. PT material is to be handled and/or tested following standard operating procedures; special attention must be paid to the handling, processing and result reporting instructions that accompany the PT material.</p>

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Receipt of Survey	<ol style="list-style-type: none"> 1. Quality Coordinator will receive all surveys for the Clinical Lab. 2. Quality Coordinator will label outside of each survey box with date received, due date and the event program code. 3. Quality Coordinator will ensure the integrity of the material and contact the agency if any issues are determined. 4. Quality Coordinator will send an Outlook appointment to supervisory associates of the specific testing areas to notify them of receipt. Appointment will contain received date, specimen requirements, stability requirements, due date and then be delivered to the appropriate Lab section. 5. If surveys are shared by department, the order of delivery will be as follows: <ol style="list-style-type: none"> a. Blood Bank/Core Lab b. Microbiology/Core Lab
Specimen Handling	Specimens should be handled according to PT program instructions. Refer to: LADM 9005 R Proficiency Testing Program section titled PT Sample Processing Notes. Ensure all PT materials are stored according to PT guidelines.
PT Order Entry	<ol style="list-style-type: none"> 1. Sign in to Laboratory Information System (Meditech) <ol style="list-style-type: none"> a. All Clinical Laboratory locations will log-in using "LIVE". b. Blood Bank will log-in using "TEST". 2. Applications - LABORATORY *LIVE* 3. Facility – ST. AGNES HOSPITAL 4. Laboratory Information System – LABORATORY 5. Laboratory – SPECIMEN DESKTOP 6. Select "Enter/Edit Req." on right hand side bar 7. Enter the following information in the given fields. <ul style="list-style-type: none"> • Patient: SURVEY(year), (Abbreviation of survey organization)_(specimen #/ID on vial)

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	<p>Example: SURVEY2010, CAP CHM-11</p> <ul style="list-style-type: none"> • Enter a New Account • Facility – LAB CENSUS • Registration Screen – REFS • Age – 99 • Sex – U • Financial Class – U • Client – LAB • Attending – NONE. • Select SAVE • ADM Priority – OTHER (OTH) • Location – LABML • Select SAVE • Admission Form – N • Plate – N • Select OK • Req number – NEW • Coll Date – T (today) • Coll Time – N (now) • Priority – R (routine) • Received – Y (yes) • Recv Date – T (today) • Recv Time – N (now) • Recv by – Ordering Tech’s name will appear • Label Device – Select proper printer for label(s) • Order all applicable tests for survey • Select SAVE
Point of Care	<p>Glucose and Hemoglobin Meters</p> <ol style="list-style-type: none"> 1. Sign in to Laboratory Information System (Meditech) 2. Applications - LABORATORY *LIVE* 3. Facility – ST. AGNES HOSPITAL 4. Laboratory Information System – LABORATORY 5. Laboratory – SPECIMEN DESKTOP 6. Select “Enter/Edit Req.” on right hand side bar

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	<p>7. Enter the following information in the given fields.</p> <ul style="list-style-type: none"> • Patient: SURVEY(year), (Abbreviation of survey organization)_(specimen #/ID on vial) Example: SURVEY2010,CAP CHM-11 • Enter a New Account • Facility – LAB CENSUS • Registration Screen – REFS • Age – 99 • Sex – U • Financial Class – U • Client – LAB • Attending – NONE. • Select SAVE • ADM Priority – OTHER (OTH) • Location – LABML • Select SAVE • Admission Form – N • Plate – N • Select OK • Document Account Number <p>8. Print Patient Label</p> <ul style="list-style-type: none"> • Applications - LABORATORY *LIVE* • Facility – LAB CENSUS • Laboratory Information System – REPORTS • PRINT PATIENT LABEL • Enter Account Number and select OK • Print Label
Criteria for Pathologist Review	Pathologist review should be limited to specimens that meet the criteria for Pathology review.
Alternative PT Testing	For laboratory tests that do not have commercial PT material, the lab section will establish an alternative form of assessment in conjunction with the Medical Director.
Review of Results for Clerical Errors, Method Codes, Units of	1. The attestation form must be signed by all testing personnel. All testing personnel working will sign

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Measure and Result Reporting	<p>the attestation form in the testing areas with autoverification including benches with multiple associates assigned.</p> <ol style="list-style-type: none"> 2. The attestation form must also include the signed name of the Lab Director or designee. 3. All survey results are to be entered online or faxed into the PT provider prior to the due date. 4. Survey results must be reviewed by a second technologist before submission for clerical errors including method code selection, and units of measurement. 5. For faxed responses, check the fax transmittal receipt for successful transmission and retain the transmittal page with the survey documents. 6. For online entry of responses, print a hard copy of entered results, have the second individual compare the entered results against the result form or Meditech report. 7. All survey documents and Meditech result printouts are to be placed in the appropriate survey binder. <p>Refer to LADM 9005 R Proficiency Testing Program section titled Result Submission for specific information.</p>
Retention of PT Material	PT material is retained, at a minimum, until results are returned and reviewed.
Survey Evaluation Review	<p>Proficiency Testing Survey evaluations should be reviewed and follow-up completed within 30 calendar days of availability on the CAP website by the Medical Director/Designee.</p> <p>During review, the Medical Director/Designee may find that some results may not have been formally evaluated due to:</p> <ul style="list-style-type: none"> • Lack of participant consensus • Insufficient data (<10 responses for a given method) • Perceived compatibility issues

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	<ul style="list-style-type: none"> • Zero grade due to late or no participation by Lab section • Designated ungraded challenge • An Error Code as identified in the table of Appendix A, Proficiency Testing Results Exception Reason Codes. The Lead Technologist/designee will follow up to error code as required in the table of Appendix A. <p>When there is no formal grade or failure on the evaluation form, the Medical/Designee must:</p> <ul style="list-style-type: none"> • Compare the Lab's results with the data provided in the Participant Summary. • If the submitted result and the majority percentage response agree, document the intended response and comment on the agreement on the survey evaluation, date and sign evaluation form. • If the submitted result and the majority percentage response do not agree, document the intended response and comment on the agreement on the evaluation. Further investigation is required and a PT Exception Investigation Checklist must be completed.
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Appendix A

Proficiency Testing Results Exception Reason Codes and Action Required		
Code	Exception Reason Code Description	Action Required
11	Unable to analyze.	Document why the specimens were not analyzed (eg, instrument not functioning or reagents not available). Perform and document alternative assessment (ie, 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 using the data presented in the Participant Summary and compared its results to a similar method, all method, or all participant statistics if provided. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
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 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 and evaluation criteria 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.

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27,31	Lack of participant or referee consensus.	Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the Participant Summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested.
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 (ie, 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 and evaluation criteria supplied in the Participant Summary. If PT specimens were not analyzed, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
41	Results for this kit were received past the evaluation cut-off date.	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 and evaluation criteria supplied in the Participant Summary. If PT specimens were not analyzed, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.

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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.
45	Antimicrobial agent is likely ineffective for this organism or site of infection.	Document that the laboratory performed a self-evaluation of written protocols and practices for routine reporting of antimicrobial susceptibility reports to patient medical records. Document that routine reporting of this result to clinicians for patient care is compliant with specific recommendations of relevant Medical Staff and Committees (eg, infectious Diseases, Pharmacy and Therapeutics, Infection Control). Response to the CAP is not required.
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.

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