	Johns Hopkins Medicine **Pathology Point of Care Testing Manual** **POCT GENERAL**	*Policy Number*	PGEN007
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I. PURPOSE

This procedure provides instructions on how to handle, perform, and document results of proficiency testing (PT) samples.

II. FREQUENCY

The number of proficiency testing samples received and the number of shipments received per year will vary by analyte and whether the Clinical Laboratory Improvement Act of 1988 (CLIA'88) requires proficiency testing for an analyte; i.e., a "regulated" analyte. In general, the number of samples and shipments received are as follows:

- "Regulated" Non-waived Analytes: 5 samples per shipment
  3 shipments per year
- "Non-regulated" Non-waived Analytes: 1-3 samples per shipment
  2-3 shipments per year
- Waived Analytes 1-3 samples per shipment
  2-3 shipments per year

The state of Maryland requires participation in a proficiency testing program for all analytes.

III. PROCEDURE: RECEIPT OF SAMPLES

Step	Action
1	Proficiency testing samples are shipped from the supplying agent on pre-determined ship dates.
2	Proficiency testing survey kits are generally received within 2 days of shipment in the Dept. of Pathology CQI Office. Contact the Dept. of Pathology CQI Office if survey kit is not received within 2 days.
3	The CQI Office notifies the participating site via e-mail and/or telephone that the survey has arrived and is available for pick-up. **NOTE:** The survey should be picked up the same day of notification. The CQI Office has limited refrigerated storage.
4	Inspect survey kit for damaged/broken or leaking sample containers and for the correct number of samples. *Do not use any damaged material for testing.* **NOTE:** Notify the Dept. of Pathology CQI Office immediately of any damaged testing materials or incorrect number of samples.
5	Note due date for survey submission and plan work accordingly. Store survey kit according to kit instructions until testing can be performed
6	Prepare worksheets by making a copy of the survey's results sheet. If survey is from CAP, blank result forms can be obtained and printed from their website.
7	Record the date of receipt of survey kit on the worksheet or kit instruction sheet.

IV. PROCEDURE : ANALYZING SAMPLES

STEP	ACTION
1	Locate and read instructions before testing.
2	Analyze proficiency testing samples as soon as possible. **NOTE:** Results must be submitted to the proficiency testing provider within 10 days of receipt (this may vary with the provider used).
3	In general, allow samples to come to room temperature before testing
4	Verify that quality control was performed according to standard operating procedures. If not, perform QC.
5	Reconstitute samples exactly as specified in the kit instructions. **NOTE:** Reconstitute and test specimens in numerical order. It may be helpful to prepare and run one sample at a time

6	• Test/analyze PT samples with your regular patient workload following standard operating procedures. • PT testing should be performed by staff who routinely perform the testing. • Rotate the performance of proficiency testing surveys among staff. • Follow survey kit instructions as well. **NOTE:** Notify the Dept. of Pathology's CQI Office or POCT Office immediately if samples break or if any unforeseen handling issues occur during testing. *Do not test compromised samples.*
7	Test samples the same number of times that you routinely test patient samples.
8	Record results on your worksheet.
9	On your worksheet, record the following information: • Date survey was performed. • ID of Instrument used for testing, • Lot number and expiration date of cuvettes/kit used, • Lot number/expiration date of QC material used, and • Your quality control results and acceptable limits, or provide a copy of your QC logsheet.
10	The individual testing the samples must sign the attestation statement section of the results sheet to attest to the routine integration of the samples into the patient workload using routne methods
11	The medical director is also required to sign the attestation statement section of the results sheet to attest to the routine integration of the samples into the patient workload using routine methods.
12	Completed worksheets are to be returned to the POCT Office; or the results can be entered electronically via the Proficiency Testing Organization's website.
13	See Appendix A for specific instructions on how to electronically submit CAP proficiency testing results.
14	Retain a copy of the results submitted electronically, all worksheets and all kit- supplied papers
15	**DO NOT:** a. Engage in interlaboratory communications pertaining to proficiency testing results until after the due date to report results to the PT Provider. This includes situations where the POCT Coordinators assist operators from a different CLIA number in entering proficiency test data online. b. Refer PT samples or portions of samples to another Lab for analysis.This includes situations where POC operators work in more than one site and have the opportunity to perform PT testing on more than one PT kit. c. Test PT samples more frequently than you routinely test patient samples.
16	Electronic submission of proficiency testing results is the preferred mode. However, if unable to do so, please fax the results and retain the fax transmission detail report.

V. PROCEDURE: PT SURVEY SUMMARY REPORT

Step	Action
1	Record the date of receipt on the PT Survey Summary Report.
2	The medical director is required to review and sign the report.
3	Satisfactory/acceptable performance on the survey is generally a score of 80% or better (this may vary by analyte).
4	All unacceptable performances /PT failures must be investigated and corrective actions taken to prevent reoccurrence. All steps taken must be documented and included in the review by the medical director.
5	Any PT challenges that were submitted and not graded or were not submitted are scored as 0% and must be investigated to determine the cause of the failure. Results that were not graded are compared to the results on the Summary Report. This investigation and comparison are signed by the director and filed with along with the Summary Report. Any unacceptable results are investigated in the same manner as described above.
6	The signed PT Survey Summary Report, remedial action documentation for each analyte outside acceptable limits, and the proficiency testing worksheets are kept for a minimum of 2 years.

VI. REFERENCES

2005-2006 Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing QC Standards 1.20 through 1.60.

CLIA'88 Federal Laboratory Regulations, Subpart H: Sections 493.801 through 493.959.

"Using e-LAB Solutions." January 28, 2009.

< http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=eLAB_page >

VII. SIGNATURES

Reviewed by Laboratory Director:

William Clarke Ph.D.

On:10/25/10

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Original signed document on file.

William Clarke, PhD

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Date: 2012.09.17 16:01:44 -04'00'