PROFICIENCY TESTING AND RESULT MANAGEMENT

☒ St. Joseph Medical Center, Tacoma, WA	☒ St. Anthony Hospital Gig Harbor, WA	☐ Harrison Medical Center, Bremerton, WA
☒ St. Francis Hospital, Federal Way, WA	☒ St. Elizabeth Hospital Enumclaw, WA	☐ Harrison Medical Center, Silverdale, WA
☒ St. Clare Hospital Lakewood, WA	☐ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide instructions for the management of Proficiency Testing (PT) specimens to ensure specimens are properly distributed, analyzed, reported, reviewed, and corrective action is documented.

RELATED DOCUMENTS

R-F-AD0603	External Proficiency Testing Response Template
R-F-AD0815	Proficiency Testing Survey Tracking Form
R-F-AD0213	Competency Performance Improvement Plan
R-F-AD0610	Retention Policy
R-PO-AD0510	Medical Director Designee Policy

INSTRUCTIONS

Handling

1. PT samples arrive at the laboratory.
2. Document received date on the shipping container or designated container, and the Survey Result form. Person receiving the kit initials the kit.
3. Give PT samples to the MT Coordinator, Department Manager or designee.
4. Check package contents for damage. If damaged, contact the proficiency testing provider for replacement samples.
5. Place samples in refrigerator/freezer/RT per instructions; leave a message for the PT sample coordinator or Manager.
6. PT Coordinator or Manager initiates the Proficiency Testing Survey Tracking Form.

PT sample assignment

1. The PT samples are rotated to all shifts, based on staff availability and rotation, to allow completion of testing within the allotted time frame.
2. PT surveys for some specialty areas, such as blood bank and microbiology, are assigned to the staff that routinely performs the testing.
3. Surveys should be assigned and analyzed ASAP to ensure sample integrity.

4. Register samples in LIS using a date of birth, and time of birth for neonate samples, to assure valid checking (AMR) limits are applied**. NOTE**: this must be entered in REQ Entry in order for valid checking limits (AMR) to be applied and evaluated to the sample correctly.

5.

Site	SAH	SEH	SCH	SFH	SJMC Core Lab	Transfusion Svc (Safetrace)
Submitter	CAP, SAH	CAP, SEH	CAP, SCH	CAP, SFH	CAP, SJMC	NA
Patient Type	Non-human	Non-human	Non-human	Non-human	Non-Human	NA
Name-Survey Mnemonic (example)	NB-A	NB-A	NB-A	NB-A	NB-A	J-A
Patient Name (example)	CAP A, ANB-01	CAP E, ANB-01	CAP C, ANB-01	CAP F, ANB-01	CAP J, ANB-01	SJMC CAP, J01 YYYY
Authorizing Provider	Folz, Brian	Burkhardt, Linda	Burkhardt, Linda	Burkhardt, Linda	Keylock, Joren	Keylock, Joren

6. All specimens are ordered in LIS and treated like patient samples, with the exception of linearity/calibration verification surveys where replicate testing is required.

7. Point of Care proficiency testing results are managed in RALS and will not be ordered in the LIS.

8. Staff performing testing or entering/reviewing data for proficiency testing are prohibited from utilizing any inquiry functions in the EMR for any other PT sample registrations other than their own facility for any purpose.

PT ANALYSIS

1. Treat all PT samples in the same manner as patient samples.

2. Referral of proficiency testing samples to another laboratory is not permitted for any analysis whether normally performed on site or not.

3. Do not discuss results or interpretation of proficiency testing results with any other laboratory as such communication is not permitted until after the deadline date for submission of data to proficiency testing provider.

4. Analysis of PT on a second instrument is not permitted before the result submission cutoff date.

RESULTING PT IN LIS

1. Print a hard copy of results from the instrument that testing is performed on when possible.

2. PT sample results are entered into LIS manually or via an interface.

3. Compare instrument printout or the manually entered result worksheet to the LIS results on the result entry screen, prior to verification.

4. Compare all data with printed report. Review results as you would a patient, and repeat testing only if indicated and/or appropriate for a patient.

PT RESULT FORM

1. The results will be entered onto the PT Survey Result Form after comparison with instrument printouts.

2. Med Tech Coordinator, Supervisor, or Manager will review the results, method codes, and instrumentation codes to ensure proper completion of the PT Survey Result Form.

3. Attestation Statements require the signature of testing personnel and Laboratory Director or designee per Medical Director Designee Policy.

4. Enter directly into PT provider's website or fax the completed Survey Result Form and save the receipt of fax confirmation and all worksheets.

RETENTION OF PT SPECIMENS

1. Upon completion of PT survey, PT samples are bagged and stored at an appropriate temperature that will allow for future use.

2. Specimens are retained until results are evaluated. PT samples may be retained to be used for research or educational purposes at the discretion of the manager.

RESULT EVALUATION AND SIGNATURES

1. Upon receiving the PT survey results, all results must be reviewed and any discrepancies must be investigated and corrective actions taken per CHI-FH Lab policy.

2. All evaluations are reviewed and signed by the MTC, Lead Tech, Charge Tech, or the Cardiopulmonary Manager. Completed surveys are reviewed and signed by the section manager or regulatory-compliance manager.

INVESTIGATING EXCEPTIONS AND CORRECTIVE ACTION

1. Investigate discrepancies by reviewing testing documentation for PT and QC, equipment logs, repeat of PT sample testing on retained samples, or consultation with staff.

2. Morphology discrepancies should be reviewed with a pathologist when appropriate or when deemed necessary by the manager.

3. If retraining is indicated, refer to Competency Performance Improvement Plan.

4. Utilize the External Proficiency Testing Response Template to document the investigation and subsequent corrective actions for all exceptions. The laboratory medical director or designee must review and sign this document.

5. PT results must be evaluated for evidence of bias. If the average SDI is more than +/- 1.5, this may indicate systematic error. If the spread of the SDI is greater than 4 this may indicate random error. The spread is calculated by adding the absolute value of the largest positive bias and the largest negative bias for an analyte. (example: there is a positive bias of 2.8 and a negative bias of 1.3, so 2.8 +1.3 = 4.1). These types of bias may indicate systematic or random error, corrective action must be initiated and documented using the External Proficiency Testing Response Template.

6. In the event that PT challenges are not graded because lack of consensus, or because results were submitted after the cut-off date, results not submitted at all, or results were not entered correctly (typographical errors) results will be compared to the proper peer group statistics by evaluating the proficiency testing provider Participant Summary, whenever possible, and action documented.

7. If the Participant Summary cannot be used to evaluate the report, compare results with the other CHI-FH laboratories to determine acceptability.

EXCEPTION REVIEW ONLY

1. Results for exceptions [26] Education, [27, 31] lack of consensus results, [30] Scientific Committee, or [28] unable to quantitate will be reviewed and supportive documentation attached when indicated.

2. No External Proficiency Testing Response Template is required.

EXCEPTION INVESTIGATION

1. All other exception codes are investigated. The investigation is documented on the External Proficiency Testing Response Template.

2. All graded and non-graded exceptions are reviewed and documented for performance in accordance with the document from CAP titled "*Actions Laboratories Should Take when a PT result is Not Graded"* when an Exception Reason Code description is generated on the PT summary.

3. Results of proficiency testing challenges intended to be graded but for which no grade was received are reviewed, investigated and corrective action documented in the same manner as graded challenges. For example, when results are not submitted or incorrect method code is entered on the result form.

4. Results of investigation are filed with the proficiency testing Participant Summary report.

5. When summary results are available for the next challenge for the analyte requiring corrective action, the actions taken are evaluated for success.

6. If corrective action was successful, the manager and Medical Director sign the External Proficiency Testing Response Template, and "No further action required" is noted on the form.

7. If actions were not successful, initiate further investigation as indicated.

Reason Code	Code Description	External PT Response Template Required	Documentation

11	Unable to analyze	Yes	Document why the specimens were not analyzed(e.g. instrument not functioning or reagent issues). Perform and document alternative assessment (e.g. split samples) for the period that commercial PT was not tested to the same extent that would have been tested (e.g. 5 samples/analyte)
22	Result is outside the method/instrument reportable range	No	Document the less than or greater than and/or verify detection limits on evaluation form.
26	Education challenge	No	Review the results and if indicated attached supportive document.
27,31	Lack of participant of referee consensus	No	Review the results with the participant summary report lists the participant response along with the percentage reporting that response.
28	Response qualified with a “greater than” or “less than” sign, or unable to quantitate.	No	Review results and the instrument AMR ranges.
30	Scientific committee decision	No	Review results
40	Results for this kit are not received	Yes	Attached supportive document.
41	Results for this kit were received past the due date	Yes	Attached supportive document.
42	No credit assigned due to absence of response	Yes	Attached SOP for the missing analyte or provide supportive document.
Unacceptable	Unacceptable result	Yes	Possible cause, incorrect or incomplete method/instrument data, Clerical error, Decimal point placement and specimen handling error. Review and document the possible cause.

RETENTION OF PAPERWORK

1. Retain all copies of PT summary performance results, instrument printouts, and calculations, and tracking forms. Instrument results and documentation submitted are filed together by survey type and retained in accordance with the Retention Policy.

CATHOLIC HEALTH INITIATIVES GUIDANCE ON PROFICIENCY TESTING

- The laboratory must not send proficiency testing samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory.
- Any laboratory that CMS determines inappropriately referred its proficiency testing samples to another laboratory for analysis may have its certification revoked for at least one year.
- Any laboratory that receives proficiency testing samples from another laboratory for testing must notify the Laboratory Regulatory Compliance Manager, CHI Compliance, and CMS of the receipt of those samples.
- PT challenges are only to be analyzed and reported on behalf of the CLIA licensed laboratory for which they were obtained. Laboratories may not share PT specimens with other licensed CLIA laboratories. Purchased PT samples are tied directly to the CLIA number of the purchasing laboratory and to share that specimen with another laboratory and to report the result of the second laboratory will be in interpreted as specimen referral which carries steep penalties.