WSLH Proficiency Testing
WISCONSIN STATE LABORATORY OF HYGIENE
UNIVERSITY OF WISCONSIN–MADISON

Follow-Up and Troubleshooting Table

This information is not intended to replace any existing protocol used by your facility, but to offer points for consideration. While this table is meant to broadly cover PT issues and possible solutions, this document should not be considered comprehensive.

All post event actions must be approved by your Laboratory Director/Technical Supervisor/Consultant. Any summary of actions must be documented, signed, dated, and filed with the proficiency testing records for the event.

Needs Follow-Up	Suspected Cause	Trouble-Shooting Action	Corrective Action
Exception Code entered instead of a result (100%)	Laboratory was not able to perform testing or submit results by the due date. An exception code and comment were submitted in lieu of results.	✓ Once able, perform testing on your PT samples and self-evaluate your result performance vs. expected results found in the Statistics Report. Save with your PT records. Any Comment submitted with Exception Code can be viewed on your Data Submission Report. Save DSR with your self-evaluation.	➢ Documentation of your exception code, reason for use (in lieu of results) and any self-evaluation will be required for audits or inspections. ➢ Save all documentation for your PT records.
Not scored, insufficient peer group (100%)	PT Provider was unable to score submitted results. • Small peer size (<10 labs submitting results) • Lab's instrument/method data is significantly different than other instrument/method data and could not be combined with any other composite scoring group.	✓ Evaluate your lab's reported results in comparison with the expected results/range on the Evaluation Report. ✓ Review peer data submitted with your Event Statistics to compare your results with other labs.	➢ Document your performance and save with your PT records. ➢ Consider changes to your testing method/instrument if aged, outdated, or obsolete. ➢ Perform split sample comparisons with another lab that uses the same test method using patient samples. If possible, choose samples that are similar in concentration to the PT samples under review. This is another tool to assess accuracy of patient results.
Non-consensus – Self-assessment needed (100%)	Results submitted by all labs in the scoring group showed large variability and could not agree on a result to meet PT grading requirements.	✓ Evaluate your lab's reported results in comparison with the expected results/range on the Evaluation Report. ✓ Review peer data submitted with your Event Statistics to compare your results with other labs. ✓ Retest the PT samples if necessary. Retested results may still not match expected results.	➢ Review the Event Notes for a summary of any potential PT scoring issues. ➢ Save your self-evaluation with your PT records.

WSLH Proficiency Testing
WISCONSIN STATE LABORATORY OF HYGIENE
UNIVERSITY OF WISCONSIN–MADISON

Follow-Up and Troubleshooting Table cont.

Needs Follow-Up	Suspected Cause	Trouble-Shooting Action	Corrective Action
No Results Received (0%)	Results were not submitted before the due date.	✓ Perform testing on your PT samples and self-evaluate your result performance vs. expected results found in the Statistics Report. Follow up on any failures and document. Save with your PT records.	➢ Review your Data Submission Report (DSR) for any blank/missing results before the due date has passed – missing results display with dashes. ➢ Add PT ship dates and due dates to laboratory calendar. ➢ Set reminders to test PT samples and enter results before the due date.
One or more failures	Clerical Error • Transcription/Transposition • Decimal Error • Incorrect units • Calculation error • Incomplete data • Incorrect instrument/method/reagent • Reported under wrong analyte • Incorrect use of <,> symbols	✓ Check that original printouts match the results on your evaluation report. ✓ Check for PT results that could have been switched when entering results. ✓ Check units of measure and calculations are correct. ✓ Check that all samples were reported with a result or an exception code on your Data Submission Report. ✓ Check that instrument/method/reagent is correct on your Evaluation Report and that it is evaluated against correct peer group. ✓ Greater than > and less than < symbols should only be used when the result is above or below the instrument's reportable range.	➢ Review PT reporting process and perform a careful review of PT results prior to submission including review of the Data Submission Report. ➢ Review PT Central setup is correct BEFORE entering results. Contact PT with changes to instruments/methods/ analytes/units/decimals. Certain instrument changes may require a program change.
Continues on next page	Specimen Mix-up • Wrong samples used	✓ Check the sample ID carefully and rerun the sample.	➢ Review sample identification processes and that the correct test is being performed.

WSLH Proficiency Testing
WISCONSIN STATE LABORATORY OF HYGIENE
UNIVERSITY OF WISCONSIN–MADISON

Follow-Up and Troubleshooting Table cont.

Needs Follow-Up	Suspected Cause	Trouble-Shooting Action	Corrective Action
One or more failures	Specimen Handling • Samples stored improperly • Delivery problem • Dilution/pipetting error • Time delay/testing sequence not followed • Improperly mixed • Misinterpretation of instructions	✓ Check that samples were received at correct temperature, on time, and stored properly. ✓ Check that pipetting and measurement devices are dispensing correctly – when were they last calibrated/are they damaged. ✓ Avoid delays/interruptions during sample testing. ✓ Verify that test procedures are up to date and are being followed. ✓ Review PT sample instructions to ensure they were followed. PT samples may require different procedure than patient samples.	➢ Train staff on proper routing, storage (according to coversheet instructions) and handling of specimens. ➢ Have master lab calendar of expected arrival of PT samples. Contact PT provider for tracking information if samples do not arrive on time. ➢ Develop a policy for re-training, continuing education, and competency assessment. ➢ Read PT sample instructions prior to testing.
	Reagents • Reagent lot change • Kit/reagent recall • Improper storage of standard/reagent/kit • Near expiration or out-of-date standard/reagent/kit being used	✓ Check if the reagent lot changed before PT samples were tested. ✓ Review the last lot to lot comparison to determine if the new lot caused significant bias in results. ✓ Check the QC, QA and Preventative Maintenance (PM) Records the day that PT was run to be sure daily maintenance was performed, kits/reagents were not expired and the QC was in range. ✓ Contact the reagent/kit vendor to see if other labs have reported any problems.	➢ Ensure process for testing new reagent lots uses patient samples (instead of QC or calibrators) and has appropriate acceptance criteria that will detect lot to lot changes beyond defined acceptable limits. ➢ Review lab processes for handling of reagents – both storage and expiration date management.
	Instrument technical problem	✓ Check to see if there is an action log indicating problems prior to or immediately after running PT samples. ✓ Check the QC, QA and Preventative Maintenance (PM) Records the day that PT was run to be sure daily maintenance was performed, kits/reagents were not expired and the QC was in range.	➢ Determine if maintenance fixed problems identified by reviewing QC and PT results. ➢ Contact manufacturer for troubleshooting assistance.

WSLH Proficiency Testing
WISCONSIN STATE LABORATORY OF HYGIENE
UNIVERSITY OF WISCONSIN–MADISON

Follow-Up and Troubleshooting Table cont.

Needs Follow-Up	Suspected Cause	Trouble-Shooting Action	Corrective Action
For Quantitative Analytes: One or more PT failures that show positive or negative bias for a specific analyte (i.e. all results are above or below the mean)	Calibration Issue	✓ Check SDI values for the analyte. Are SDI values all negative or all positive, +/-2? Or are the majority of the values outside +/-1.5? ✓ Check calibration records and determine if recalibration is required. ✓ Check for a change in mean QC values between lots or shipments of reagents/kits. ✓ If participating in a multi-site QC comparison program, check whether your QC means differ from other users of the same lot of QC material. ✓ Check all is current and acceptable with QC, calibrations, and preventative maintenance.	➢ Ensure calibration is performed and acceptable after changing lots or shipments of reagents/kits. ➢ Verify calibrator values are correctly entered into the instrument. ➢ Consider establishing an in-house procedure for validation of manufacturer-provided calibrator values. ➢ If calibration drifts or loss of precision is observed over the life of the reagent, consider more frequent calibration, smaller lots/shipments of reagent, or storing the reagent off instrument for a low volume test. ➢ If recalibration is necessary for corrective action, rerun any remaining stable PT samples and evaluate against acceptable results. ➢ Work with your instrument manufacturer if necessary.
	Reportable Range Issue	✓ Check if previous failure or systemic bias was observed in PT surveys for high or low samples. If the same instrument/reagent had previous problems at high or low values, check to see that the reportable range has been properly determined.	➢ If the reportable range is improperly determined, use reference materials to re-establish the range. If necessary, contact manufacturer for help with troubleshooting instrument/reagent problems.

WSLH Proficiency Testing
WISCONSIN STATE LABORATORY OF HYGIENE
UNIVERSITY OF WISCONSIN–MADISON

Follow-Up and Troubleshooting Table cont.

Needs Follow-Up	Suspected Cause	Trouble-Shooting Action	Corrective Action
Sample Issue	Specimen Integrity • Excessive hemolysis (whole blood samples) • Excessive precipitate/turbidity/bacterial contamination • Matrix Effect (not compatible with method)	✓ Check that samples were in good condition before testing. ✓ Check that you have the correct PT module for your analyzer.	➢ Create a process to note and record the condition of the samples upon their arrival. ➢ Contact PT provider regarding sample issues. ➢ Request replacements if needed. Sample replacement is subject to availability.
Random Error (e.g. a single sample fails for one analyte only) ***All other causes have been explored.***	Your results show random fluctuations.	✓ The assumption of random error can only be made when all other potential sources of error have been ruled out. ✓ May be resolved by retesting the PT sample.	➢ Document as random error or normal statistical variation.

Contact WSLH PT for further questions, guidance, or more robust statistical tools.

Email: ptservice@slh.wisc.edu

Phone: 800-462-5261