



This Troubleshooting Guide is a one-stop all-inclusive tool to help you perform troubleshooting and self-assessment when follow-up is required after a proficiency testing event.

### First - Where Do I Start?

[Troubleshooting Flowchart](#) (Page 2): *This flowchart outlines the steps you follow after you receive your Proficiency Evaluation Report. You can follow the color-coded Pass, Not Scored, or Fail paths to matching colored headers in the Follow-Up and Troubleshooting Table or take advantage of the hyperlinks to quickly get to your desired topic.*

### Next - How Do I Know What to Do?

[Follow-Up and Troubleshooting Table](#) (Pages 3-7): The table can assist you in follow-up, including troubleshooting actions that you could take, and corrective actions you may implement.

### Finally - How Do I Document This?

[PT Failure Corrective Action Worksheet](#) (Pages 8-10): This is a check-list style worksheet with Yes/No questions to help you identify the possible cause of failure and document your follow-up.

[Post Event Follow-Up Report with Instructions](#) (Pages 11-13): This fillable form allows you to succinctly document your troubleshooting/self-assessment actions and corrective actions.

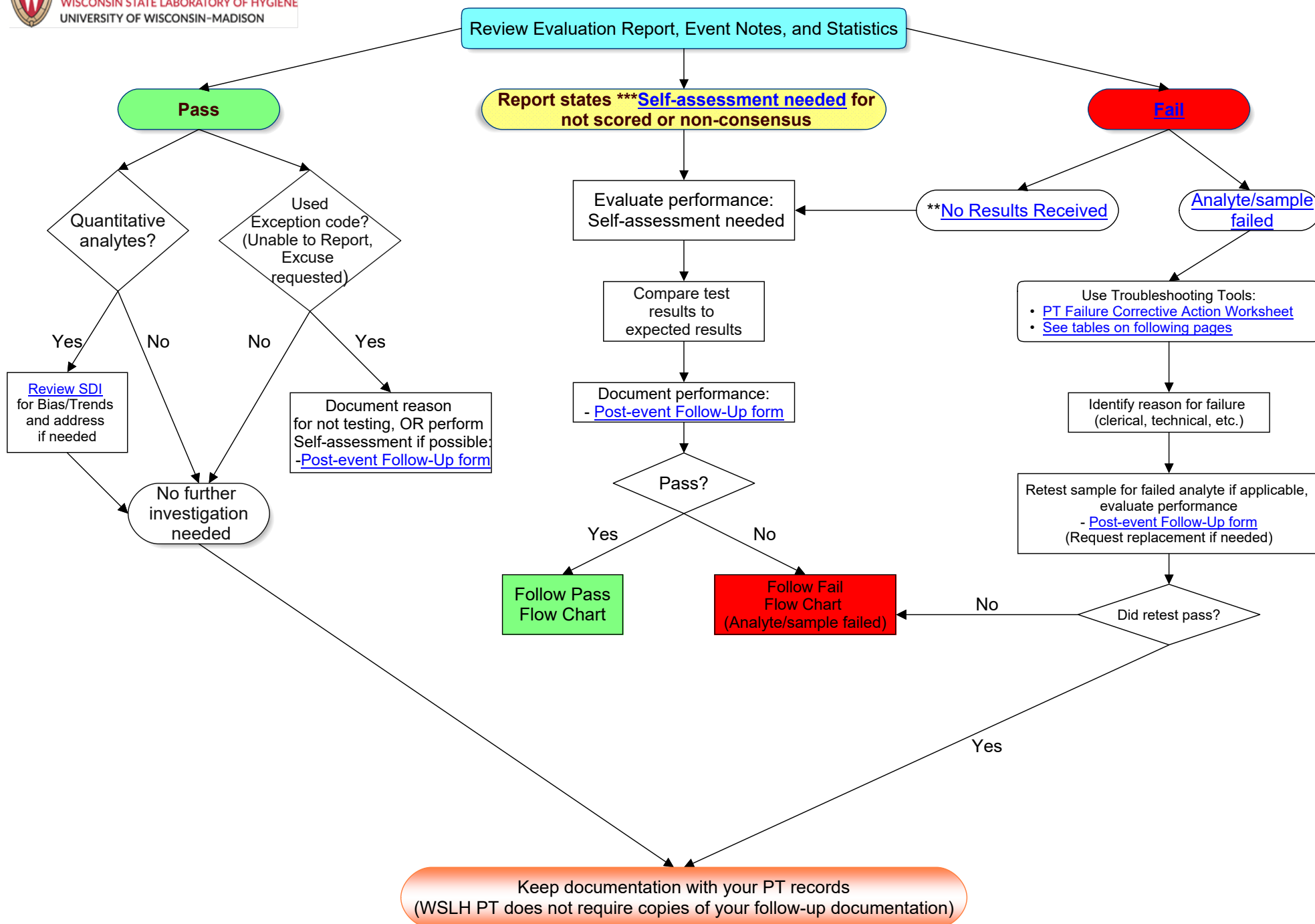
[Example of Post Event Follow-Up Report with Documentation](#) (Pages 14-17): The example provided shows what a failure could look like on your Proficiency Evaluation Report, how you can document it, and what supporting documentation might look like. This example is to help guide you and should not take the place of your situation and in-house process for follow-up.

### What else should I know?

[References Directory](#) (Page 18): This page details how you can navigate to other helpful documents such as Event Notes, Event Statistics, WSLH PT Handbook, and your Data Submission Report. *It also has important information regarding Documentation Retention Requirements and statements about following up with your accrediting agency.*

## Proficiency Testing Report Follow-up Flow Chart

\*Order of steps may vary with situation



\*\* No Results Received: If your facility isn't currently performing testing, document reason and save with your PT records. Notify WSLH and your accreditation agency about any permanent test menu changes.

## 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.	<ul style="list-style-type: none"> <li>✓ 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.</li> <li>✓ Any Comment submitted with Exception Code can be viewed on your Data Submission Report. Save DSR with your self-evaluation.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Documentation of your exception code, reason for use (in lieu of results) and any self-evaluation will be required for audits or inspections.</li> <li>➤ Save all documentation for your PT records.</li> </ul>
Not scored, insufficient peer group (100%)	PT Provider was unable to score submitted results. <ul style="list-style-type: none"> <li>• Small peer size (&lt;10 labs submitting results)</li> <li>• Lab's instrument/method data is significantly different than other instrument/method data and could not be combined with any other composite scoring group.</li> </ul>	<ul style="list-style-type: none"> <li>✓ Evaluate your lab's reported results in comparison with the expected results/range on the Evaluation Report.</li> <li>✓ Review peer data submitted with your Event Statistics to compare your results with other labs.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Document your performance and save with your PT records.</li> <li>➤ Consider changes to your testing method/instrument if aged, outdated, or obsolete.</li> <li>➤ 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.</li> </ul>
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.	<ul style="list-style-type: none"> <li>✓ Evaluate your lab's reported results in comparison with the expected results/range on the Evaluation Report.</li> <li>✓ Review peer data submitted with your Event Statistics to compare your results with other labs.</li> <li>✓ Retest the PT samples if necessary. Retested results may still not match expected results.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Review the Event Notes for a summary of any potential PT scoring issues.</li> <li>➤ Save your self-evaluation with your PT records.</li> </ul>

## Follow-Up and Troubleshooting Table

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  Continues on next page	Clerical Error <ul style="list-style-type: none"> <li>• Transcription/Transposition</li> <li>• Decimal Error</li> <li>• Incorrect units</li> <li>• Calculation error</li> <li>• Incomplete data</li> <li>• Incorrect instrument/method/reagent</li> <li>• Reported under wrong analyte</li> <li>• Incorrect use of &lt;, &gt; symbols</li> </ul>	✓ 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.
	Specimen Mix-up <ul style="list-style-type: none"> <li>• Wrong samples used</li> </ul>	✓ Check the sample ID carefully and rerun the sample.	➤ Review sample identification processes and that the correct test is being performed.

## Follow-Up and Troubleshooting Table

Needs Follow-Up	Suspected Cause	Trouble-Shooting Action	Corrective Action
One or more failures	Specimen Handling <ul style="list-style-type: none"> <li>Samples stored improperly</li> <li>Delivery problem</li> <li>Dilution/pipetting error</li> <li>Time delay/testing sequence not followed</li> <li>Improperly mixed</li> <li>Misinterpretation of instructions</li> </ul>	<ul style="list-style-type: none"> <li>✓ Check that samples were received at correct temperature, on time, and stored properly.</li> <li>✓ Check that pipetting and measurement devices are dispensing correctly – when were they last calibrated/are they damaged.</li> <li>✓ Avoid delays/interruptions during sample testing.</li> <li>✓ Verify that test procedures are up to date and are being followed.</li> <li>✓ Review PT sample instructions to ensure they were followed. PT samples may require different procedure than patient samples.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Train staff on proper routing, storage (according to coversheet instructions) and handling of specimens.</li> <li>➤ Have master lab calendar of expected arrival of PT samples. Contact PT provider for tracking information if samples do not arrive on time.</li> <li>➤ Develop a policy for re-training, continuing education, and competency assessment.</li> <li>➤ Read PT sample instructions prior to testing.</li> </ul>
	Reagents <ul style="list-style-type: none"> <li>Reagent lot change</li> <li>Kit/reagent recall</li> <li>Improper storage of standard/reagent/kit</li> <li>Near expiration or out-of-date standard/reagent/kit being used</li> </ul>	<ul style="list-style-type: none"> <li>✓ Check if the reagent lot changed before PT samples were tested.</li> <li>✓ Review the last lot to lot comparison to determine if the new lot caused significant bias in results.</li> <li>✓ 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.</li> <li>✓ Contact the reagent/kit vendor to see if other labs have reported any problems.</li> </ul>	<ul style="list-style-type: none"> <li>➤ 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.</li> <li>➤ Review lab processes for handling of reagents – both storage and expiration date management.</li> </ul>
	Instrument technical problem	<ul style="list-style-type: none"> <li>✓ Check to see if there is an action log indicating problems prior to or immediately after running PT samples.</li> <li>✓ 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.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Determine if maintenance fixed problems identified by reviewing QC and PT results.</li> <li>➤ Contact manufacturer for troubleshooting assistance.</li> </ul>

## Follow-Up and Troubleshooting Table

Needs Follow-Up	Suspected Cause	Trouble-Shooting Action	Corrective Action
<b>For Quantitative Analytes:</b>  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	<ul style="list-style-type: none"> <li>✓ 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?</li> <li>✓ Check calibration records and determine if recalibration is required.</li> <li>✓ Check for a change in mean QC values between lots or shipments of reagents/kits.</li> <li>✓ 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.</li> <li>✓ Check all is current and acceptable with QC, calibrations, and preventative maintenance.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Ensure calibration is performed and acceptable after changing lots or shipments of reagents/kits.</li> <li>➤ Verify calibrator values are correctly entered into the instrument.</li> <li>➤ Consider establishing an in-house procedure for validation of manufacturer-provided calibrator values.</li> <li>➤ 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.</li> <li>➤ If recalibration is necessary for corrective action, rerun any remaining stable PT samples and evaluate against acceptable results.</li> <li>➤ Work with your instrument manufacturer if necessary.</li> </ul>
	Reportable Range Issue	<ul style="list-style-type: none"> <li>✓ 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.</li> </ul>	<ul style="list-style-type: none"> <li>➤ 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.</li> </ul>

**WSLH PT does not require copies of your follow-up documentation.**

## Follow-Up and Troubleshooting Table

Needs Follow-Up	Suspected Cause	Trouble-Shooting Action	Corrective Action
Sample Issue	Specimen Integrity <ul style="list-style-type: none"> <li>Excessive hemolysis (whole blood samples)</li> <li>Excessive precipitate/turbidity/bacterial contamination</li> <li>Matrix Effect (not compatible with method)</li> </ul>	<ul style="list-style-type: none"> <li>✓ Check that samples were in good condition before testing.</li> <li>✓ Check that you have the correct PT module for your analyzer.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Create a process to note and record the condition of the samples upon their arrival.</li> <li>➤ Contact PT provider regarding sample issues.</li> <li>➤ Request replacements if needed. Sample replacement is subject to availability.</li> </ul>
Random Error (e.g. a single sample fails for one analyte only)  ***All other causes have been explored.***	Your results show random fluctuations.	<ul style="list-style-type: none"> <li>✓ The assumption of random error can only be made when all other potential sources of error have been ruled out.</li> <li>✓ May be resolved by retesting the PT sample.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Document as random error or normal statistical variation.</li> </ul>

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

Email: [ptservice@slh.wisc.edu](mailto:ptservice@slh.wisc.edu)

Phone: 800-462-5261

**WSLH PT does not require copies of your follow-up documentation.**

Year: _____	Date Samples Received: _____
Event Name: _____	Date Samples Tested: _____
Sample ID(s): _____	Date Results Submitted: _____
Analyte(s): _____	Date Results Due to PT provider: _____
Personnel Who Performed the Testing: _____	

**Sample Storage and Handling:**

- Yes ☐ No ☐ Were the samples received on time and in an acceptable condition?
- Yes ☐ No ☐ Were the samples stored according to the instructions?
- Yes ☐ No ☐ Were the samples hemolyzed (if whole blood)?
- Yes ☐ No ☐ Did the samples contain excessive precipitate, turbidity, or bacterial contamination?
- Yes ☐ No ☐ Were the samples at the proper temperature before analysis (per instructions)?
- Yes ☐ No ☐ Were the samples properly mixed?
- Yes ☐ No ☐ Were the samples tested according to the instructions?
- Yes ☐ No ☐ Was there a time delay before or during analysis?

Notes:

**Clerical Errors:**

- Yes ☐ No ☐ Were results submitted by the due date?
- Yes ☐ No ☐ Were the correct samples used and/or reported (sample mix-up)?
- Yes ☐ No ☐ Were the results reported under the correct analyte?
- Yes ☐ No ☐ Were the results reported with the correct instrument/kit?
- Yes ☐ No ☐ Was the correct method principle and reagent selected (if applicable)?
- Yes ☐ No ☐ Was there a dilution/calculation error?
- Yes ☐ No ☐ Were the results reported in the designated units?
- Yes ☐ No ☐ Were all the samples reported with a result or exception code (not left blank) for each listed analyte?
- Yes ☐ No ☐ Do the results on your evaluation report match the results from the instrument printout and/or worksheet?

Notes:

**Quality Control (QC):**

- Yes ☐ No ☐ Were the QC results within range on the date the PT samples were tested?
- Yes ☐ No ☐ Were there any shifts or trends in the QC values the week before, on the day, or after the PT samples were tested?

Notes:



**Reagent/Kit:**

- Yes ☐ No ☐ Was the reagent/kit stored and handled properly?
- Yes ☐ No ☐ Was the reagents/kit expired or was the open vial stability exceeded?
- Yes ☐ No ☐ Was there a reagent lot change (did QC shift after the lot change)?
- Yes ☐ No ☐ Have there been any changes in reagent/kit manufacturer or formulation (are you looking at the most current package insert)?
- Yes ☐ No ☐ If applicable, have you contacted the reagent/kit manufacturer for further assistance?

Notes:

**Calibration:**

- Yes ☐ No ☐ Were there any problems with the most recent calibration?  
How often is the calibration required?  
When was the date of the last calibration?  
When was the last calibration verification/linearity performed?
- Yes ☐ No ☐ Did the calibrator lot change?
- Yes ☐ No ☐ Do the calibrator values on the package insert match those in the instrument?
- The SDI (Standard Deviation Index) value on the evaluation report is a measurement of how close your result is to the mean result. Check the SDI value on your evaluation report.
- Yes ☐ No ☐ Are the SDI values all negative or all positive,  $\pm 2$ ?
- Yes ☐ No ☐ Are more than half of your results  $\pm 1.5$ ?

If yes, check the calibration records and determine if it is time to recalibrate.

Notes:

**Instrument:**

Check if the maintenance is up to date.

- Yes ☐ No ☐ Daily Maintenance?
- Yes ☐ No ☐ Weekly maintenance?
- Yes ☐ No ☐ Monthly maintenance?
- Yes ☐ No ☐ Quarterly maintenance?
- Yes ☐ No ☐ Yearly maintenance?
- Yes ☐ No ☐ Has there been any recent maintenance on the analyzer?
- Yes ☐ No ☐ Were any instrument problems noted before, on the day, or after the samples were tested?
- Yes ☐ No ☐ Are the pipetting/measurement devices dispensing correctly?  
When was the last calibration check performed on the pipettes/measuring devices?
- Yes ☐ No ☐ If applicable, have you contacted the instrument manufacturer for further assistance?

Notes:

**Culture:**

- Yes ☐ No ☐ Was the media stored according to the manufacturer's instructions?
- Yes ☐ No ☐ Was the media expired?
- Yes ☐ No ☐ Was the appropriate QC performed on the media?
- Yes ☐ No ☐ Was the appropriate media setup for the sample source?
- Yes ☐ No ☐ Was the incubator temperature/gas/humidity within acceptable limits?
- Yes ☐ No ☐ If applicable, have you contacted your kit manufacturer for assistance?

Notes:

**Training/Competency:**

Determine if the PT failure indicates problems with technical competency or personnel performing the testing.

Yes ☐ No ☐ Is the training & competency file up to date for the personnel who performed the testing?

Yes ☐ No ☐ Does the personnel need to be trained/retrained in areas of the lab (preanalytical, analytical, postanalytical)?

If yes, which area(s)?

Notes:

**Summary of Findings:**

Summarize the source of the PT failure (Clerical, Technical etc.). If applicable, rerun the PT sample. If the sample stability is expired/compromised, contact WSLH PT for a replacement sample.

Notes:

Were patient results affected? Yes / No Explain the course of action:

For example, splitting patient specimens with another lab that offers the same tests may assist to determine if the PT failure is related to the PT specimens or indicates a problem with patient test results.

Notes:

**Corrective Action(s):**

Determine a corrective action plan to prevent the source of the failure from occurring in the future.

Notes:

Person Performing the Investigation: \_\_\_\_\_

Date: \_\_\_\_\_

Lab Director/Designee: \_\_\_\_\_

Date: \_\_\_\_\_

The corrective action worksheet is a tool to assist laboratories with troubleshooting PT failures. Completion of this worksheet does not guarantee future successful performances. It is the laboratory's responsibility to effectively troubleshoot and resolve all PT failures. Completed corrective action worksheets should not be submitted to WSLH PT. Keep all documentation as part of your event record as you may be required to provide documentation to an inspector or agency. If you should have any questions, contact WSLH PT at (800) 462-5261.



## Instructions

This form can be used when follow-up is required on a Proficiency Testing Evaluation Report. This can include failures, not scored, non-consensus, self-assessment, use of an exception code, SDI bias or trends, etc.

*Note: This document and its process are not intended to replace any existing protocol used by your facility or to replace any guidance or instructions given by an accrediting agency.*

**Documentation Retention Requirements:** PT records and related documents (follow-up reports, calibration, daily QC, maintenance, etc.) must be retained for two years unless longer retention is required for specific analytes (such as Blood Bank for 5 years).

- **Facility Name:** If your facility is part of a large system, include a unique identifier such as city, WSLH PT Lab ID, or CLIA ID.
- **Year, Event Name, and Event Number:** This information is located on the top right of the Proficiency Testing Evaluation Report. On the fillable form, choose year, event name and event number from the drop-down menus.
- **Module/Analyte/Sample:** List your module number, analyte, and sample ids that require follow-up.
- **Instrument/Method:** Include a unique identifier for the instrument if necessary, such as a serial number. Kit name and lot number can be documented here.
- **Reason for Follow-Up:** This is displayed under “Status” or “Comments” on your Proficiency Testing Evaluation Report (such as Fail, Non-consensus, Not scored, etc.) On the fillable form, choose the reason for follow-up from the drop-down menu. The “Additional Comments” box can be used to document the reason for the use of an exception code or choice of “Other” and also provides additional space to list analytes/sample IDs that need follow-up.
- **Identified Cause:** The cause of the deficiency must be determined in order to implement corrective actions. For assistance in identifying potential causes and troubleshooting actions, see the [WSLH Troubleshooting Guide](#).
- **Troubleshooting or Self-Assessment Actions Performed:** Document the steps taken to identify the root cause of the issue. Include with this report any documents that pertain to this such as retesting results, recalibration documentation, maintenance logs, service call logs, peer data and data calculator spreadsheets, split patient sample comparison data, etc.
- **Corrective Action:** Identify actions your facility can implement to prevent similar issues in the future. Include with this report any documents that pertain to this such as retraining documents, forms, updated SOPs, meeting minutes, etc.
- **Person Completing Report:** This lets any accrediting agencies know who to contact for any follow-up questions or concerns.
- **Lab Director/Technical Supervisor/Consultant/Designee:** All post event actions must be approved, signed and dated by the appropriate personnel.

**WSLH PT does not require copies of your follow-up documentation.**



## Post Event Follow-Up Report

Facility Name

PT Event

Year

Event Name

Event Number

Module/Analyte/Sample

Instrument/Method

Reason for Follow-Up

As stated in the evaluation report

Additional Comments

Identified Cause

Troubleshooting or Self-Assessment Actions Performed

Include any necessary documentation including retesting results, recalibration, service call log, etc.

Continued on page 2



### Troubleshooting or Self-Assessment Actions Performed continued from page 1

### Corrective Action

Include any necessary documentation such as forms, retraining documents, etc.

### Person Completing Report

Printed Name	Signature	Date

### Lab Director/Technical Supervisor/Consultant/Designee

Printed Name	Signature	Date

## Example: Fail – Invalid response

### Identified Cause: Incorrect use of greater than (>) symbol in resulting

The Proficiency Testing Evaluation below shows several data points have failed with an explanation of “Invalid response.” Each result has either a greater than (>) or less than (<) in front of it. The results vary across the instrument’s measurement range.

#### Example Report

Analyte	Reported Method	Sample	Result	Mean	SD	SDI	Range	Scoring Group	Status	Comments
Module: 1080, Blood Lead - 5 samples										
Subspecialty: Toxicology										
Blood lead ug/dL										
Analyte Score: 20%										
LeadCare II Analyzer (Waived)										
		PB-6	<3.3	---	---	---	0.0 - 3.3	PG-LeadCare II Analyzer (Waived)	Pass	
		PB-7	>4.3	4.9	0.69	-0.87	2.9 - 6.9	PG-LeadCare II Analyzer (Waived)	Fail	Invalid response
		PB-8	>10.9	13.0	1.07	-1.96	11.0 - 15.0	PG-LeadCare II Analyzer (Waived)	Fail	Invalid response
		PB-9	>59.4	57.0	4.61	0.52	51.3 - 62.7	PG-LeadCare II Analyzer (Waived)	Fail	Invalid response
		PB-10	>39.4	41.5	3.08	-0.68	37.4 - 45.6	PG-LeadCare II Analyzer (Waived)	Fail	Invalid response

The great than and less than signs are only to be used when results are either higher or lower than the highest and lowest values of the reportable range. In this case, the LeadCare II Analyzer has a reportable range of 3.3 to 65.0 ug/dL. All results between those two values should not have a < or > in front of them and those that do are considered invalid. The result <3.3 ug/dL is appropriate and therefore passes.

#### Troubleshooting Action:

Compare the results to the acceptable range given on the Proficiency Testing Evaluation, dismissing the use of the greater than signs. Those results within the range would have passed.

Additional troubleshooting for those results outside of the range needs to occur. One result still falls outside of the acceptable range once the inappropriate sign is removed.

#### Example Report

Analyte	Reported Method	Sample	Result	Mean	SD	SDI	Range	Scoring Group	Status	Comments
Module: 1080, Blood Lead - 5 samples										
Subspecialty: Toxicology										
Blood lead ug/dL										
Analyte Score: 20%										
LeadCare II Analyzer (Waived)										
		PB-6	<3.3	---	---	---	0.0 - 3.3	PG-LeadCare II Analyzer (Waived)	Pass	
		PB-7	>4.3	4.9	0.69	-0.87	2.9 - 6.9	PG-LeadCare II Analyzer (Waived)	Fail	Invalid response
		PB-8	>10.9	13.0	1.07	-1.96	11.0 - 15.0	PG-LeadCare II Analyzer (Waived)	Fail	Invalid response
		PB-9	>59.4	57.0	4.61	0.52	51.3 - 62.7	PG-LeadCare II Analyzer (Waived)	Fail	Invalid response
		PB-10	>39.4	41.5	3.08	-0.68	37.4 - 45.6	PG-LeadCare II Analyzer (Waived)	Fail	Invalid response

Retesting the sample after mixing well would be an appropriate next step for troubleshooting.

#### Corrective Action:

Analysts need to relearn the instrument’s reportable range and the proper use of the greater than and less than signs. Rereading both of the facility’s SOP and WSLH Supplemental Instructions would be appropriate. Documentation should include a signed attestation statement that the instructions were read and understood.

Results of retesting samples need to also be included in your documentation.

See the following Post Evaluation Follow-Up Report as an example on how to document these failures.



### Facility Name

WSLH Clinic - Madison

### PT Event

Year	2025	Event Name	Chem/Endo/Tx	Event Number	2
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### Module/Analyte/Sample

1080 Blood Lead

### Instrument/Method

LeadCare II Analyzer

### Reason for Follow-Up

As stated in the evaluation report

### Fail - Invalid response

Additional Comments	Failed PB-7, PB-8, PB-9, PB-10
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### Identified Cause

Clerical Error - Misused greater than symbols in data entry, resulting in failures.

Specimen Handling - Sample PB-8 was not well mixed before testing.

### Troubleshooting or Self-Assessment Actions Performed

Include any necessary documentation including retesting results, recalibration, service call log, etc.

Once the misused sign was removed, each result was compared to the range provided on the Proficiency Testing Evaluation. PB-7, PB-9, and PB-10 each fell within their respective ranges and therefore would have passed had there been no clerical error.

PB-8 fell outside of its respective range by 0.1 ug/dL. The stored sample was well mixed before retesting. The retested result is 11.7 ug/dL. This result is within the respective range for PB-8 provided on the report.

Continued on page 2



### Troubleshooting or Self-Assessment Actions Performed continued from page 1

-Intentionally Blank-

### Corrective Action

Include any necessary documentation such as forms, retraining documents, etc.

On 8/20/2025, the technical supervisor had a brief informal meeting with the staff that use the LeadCare II Analyzer about the proficiency testing failures. Staff were instructed that they must reread both the facility's "Blood Lead" SOP and the WSLH Blood Lead Supplemental Instructions that come with the PT samples, both of which explain the reportable range and use of greater than and less than signs in reporting. Staff were required to sign and date an attestation page that they read and understood both documents.

The analyst that originally tested PB-8 then retested the sample after mixing well. The result was within the acceptable range and documented by the analyst.

Included at the end of this report is a copy of the completed attestation page (Figure 1) and the retested PB-8 results (Figure 2).

### Person Completing Report

<b>Ima Tester</b>	<i>Ima Tester</i>	<b>08/28/2025</b>
Printed Name	Signature	Date

### Lab Director/Technical Supervisor/Consultant/Designee

<b>Anita Q. Control</b>	<i>Anita Q. Control</i>	<b>09/02/2025</b>
Printed Name	Signature	Date





I attest that I have read and understand both the WSLH Clinic SOP "Blood Lead" and the WSLH PT Blood Lead Supplemental Instructions. I understand the instrument's reportable range and the correct use of greater than and less than signs in reporting.

Signature	Date
<i>Ima Tester</i>	<i>8/22/2025</i>
<i>Perry Pipettes</i>	<i>8/25/2025</i>
<i>Jane Doe</i>	<i>8/26/2025</i>

Figure 1



## Blood Lead Recording Worksheet

Instrument: LeadCare II

Date	Sensor lot #	QC Performed (Y/N)	Patient ID	Result (ug/dL)	Tech Initials
<i>8/25/25</i>	<i>1924M</i>	<i>Yes</i>	<i>WSLH PT PB-8</i>	<i>11.7</i>	<i>p.p.</i>

Figure 2

All names, signatures, and logos shown are fictitious and are used for illustrative purposes only.



## References Directory:

Access the following by logging into PT Central with your login/password at: [www.pt-central.com/wslhpt](http://www.pt-central.com/wslhpt).

- Event Notes (scoring information): PT Central/Reports/Year & Event, Apply/Event Notes
- Event Statistics (correct responses/ranges): PT Central/Reports/Year & Event, Apply/Event Statistics Report
- PT Handbook (Helpful information, Definitions, Scoring and Evaluation tips): PT Central/Help and Resources/Handbook
- Data Submission Report (proof of online submission, displays exception code/comment entered): PT Central/Reports/Year & Event, Apply/Data Submission Report

**Your State and/or Accrediting agency may require further follow-up for failures or not-scored situations.**

**Multiple failures for the same analyte or multiple analytes across 2 or more events may require a remedial event. Check with your accreditation agency for details on remedial requirements.**

**PT records and related documents (Calibration, Daily QC, maintenance, etc.) must be retained for two years (Immunohematology is required for 5 years).**