

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.

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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

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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

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

Lab Director/Technical Supervisor/Consultant/Designee

Anita Q. Control	<i>Anita Q. Control</i>	09/02/2025
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