AQR: Proficiency Test Result Inconsistencies

Sources of inconsistencies

Inconsistencies between the test manufacturer's target results and the analyst's results may occur for several reasons, including:

- test defects
  - the test was poorly designed
  - the test sample was improperly manufactured or had deteriorated
- procedural limits
  - the target results fell outside of laboratory procedure capabilities or parameters
- analyst error
  - the analyst did not understand the instructions
  - the analyst utilized inadequate or improper analytical procedures
  - the analyst erred in interpreting the analytical data resulting in inaccurate or inappropriate conclusions
- system error
  - technical problems were not recognized during the review process
  - available written procedures were inadequate or faulty

A single test may contain multiple sources of error.

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Addressing test defects

A test that is poorly designed, improperly made, or contains items subject to rapid degradation may result in the analyst being unable to obtain the anticipated results.

A test may be declared defective by the external provider or the Quality Manager. The Quality Manager will consult with the unit supervisor, the DNA Technical Lead, or the appropriate peer group before making this determination. The Quality Manager will provide a written justification for declaring a test to be defective. External provider statements and internal justifications become part of the test file.

If a test is declared defective, it will be cancelled and a new test will be issued.

Exception: If a test is judged only partly defective, the Quality Manager may decide, in consultation with the unit supervisor, that the acceptable portion of the test is sufficient for testing purposes and no new test will be issued.

Addressing procedural limits

Manufacturer target results may fall outside of the analytical capabilities or the testing parameters of the laboratory's routine procedures resulting in partial answers or false negatives.

In these situations, the Quality Manager may accept a written explanation from the testing analyst, another qualified analyst, the discipline peer group, or the unit supervisor and no additional corrective action will be required. The written explanation becomes part of the test file.

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Addressing analyst and system errors

Inconsistencies from expected results may occur because of

- a lack of understanding, insufficient training, or poor judgment on the part of the analyst, leading to analytical or reporting errors
- technical problems not identified during the review process or inadequate or faulty procedures resulting in false or misleading data and reporting errors
- a combination of both factors

If an inconsistency occurs that cannot be attributed to a defective test or conflict with procedural limits, the Quality Manager will inform the Laboratory Director, the unit supervisor, and the DNA Technical Lead of the situation.

The Quality Manager will consult with the supervisor, the DNA Technical Lead, the Laboratory Director, and/or the testing analyst as required, to determine the cause and appropriate corrective action for the error.

The Director may suspend analyst or discipline casework, as appropriate, pending completion of corrective action. If the proficiency is related to DNA, the DNA Technical Lead has the authority to suspend a DNA analyst from casework pending the completion of the corrective action.

Depending upon the nature and extent of an identified *analyst error*, corrective actions may include, but are not limited to, one or more of the following:

- counseling the analyst
- requesting the analyst to re-evaluate test data or reanalyze test items
- retraining the analyst in specified areas
  – training plans must be documented and attached to the test file
- issuing a new test
  – a new test is required after retraining

Depending upon the nature and extent of an identified *system error*, corrective actions may include, but are not limited to, one or more of the following:

- counseling or retraining the technical reviewer
- modifying existing or writing new technical procedures
- issuing a new test

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Classes of inconsistencies

Classes of inconsistencies, denoting the seriousness of a given analyst or system error and its effect on the Quality System of the laboratory, have been established by ASCLD/LAB.

The classes are as follows:

Class	Description
I	The inconsistency raises immediate concern regarding the quality of the laboratory's work product.
II	The inconsistency is due to a problem which may affect the quality of the work, but is not serious enough to cause immediate concern for the over-all quality of the laboratory's work product.
III	The inconsistency is unlikely to recur, is not systemic, and does not significantly affect the fundamental reliability of the laboratory's work product.

NOTE: Some ASCLD/LAB approved external tests are reviewed by an ASCLD/LAB Proficiency Review Committee (see *PRC review*). The committee will assign its own class level to an identified inconsistency. If this level does not agree with the laboratory-assigned level, or if the laboratory did not initially identify an inconsistency, the laboratory will apply the committee's assignment.

Assigning class levels for unreported proficiency tests

After consulting with the Quality Manager and the unit supervisor, the Laboratory Director will assign a class level to all inconsistencies resulting from analyst or system error. The Director will provide a written justification for the assignment of a Class I inconsistency. This justification will be attached to the test result report.

The class level will be noted on the test result report.

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Dispute resolution

There may be times when agreement as to the form or extent of corrective action cannot be reached.

Disputes that cannot be settled are brought by the Quality Manager to the Laboratory Director for resolution.

Corrective action requests

Corrective actions resulting from analyst or system errors will be documented on a *Corrective Action Request* form. This form contains information on the nature of the inconsistency and the recommended corrective action.

Corrective actions are given a maximum 90-day due date from the date it was initiated.

Once the corrective action has been successfully completed, the Laboratory Director will sign the completion line of the form and attach it to the test file. See *DPC: Corrective Action* for more information on how the form is filled out.

Note on disciplinary action

Analyst errors resulting in inconsistencies will not result in disciplinary action on the initial attempt to complete a proficiency test.

It is anticipated that consultation, re-training or additional testing will resolve most problems.

If analyst or system error results in an inconsistency in a second proficiency test, the matter will be submitted to the Laboratory Director for review and recommendation.

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PRC review

ASCLD/LAB has established a Proficiency Review Committee (PRC) for each technical discipline to review test results submitted by accredited laboratories to approved external test providers.

Permission for approved providers to release test results to ASCLD/LAB is given by the Quality Manager or Laboratory Director. The laboratory should approve the release of results for at least one test from each discipline each year.

If the PRC determines that an apparent inconsistency is present in the reported test results, the committee will request a response from the laboratory addressing the issue.

The laboratory has the choice of either acknowledging the inconsistency and providing a plan of corrective action, or challenging the PRC's evaluation by providing an explanation in support of the results. A challenge may also include a request for re-analysis by a referee laboratory.

If the PRC supports the challenge, the issue is closed.

If the PRC does not support the challenge or if the laboratory acknowledges the inconsistency, the PRC will assign an apparent class to the inconsistency (see *Classes of inconsistencies* and *Assigning class levels for unreported proficiency tests,* above), approve a plan of corrective action, and close the inquiry when satisfied with the corrective action results.

Non-responsiveness to a PRC inquiry, or very serious or repeated inconsistencies, may result in sanctions for the laboratory from the ASCLD/LAB Board.